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Presidential Documents

Title 3—

The President

Memorandum of July 26, 2024

Deferred Enforced Departure for Certain Lebanese Nationals

Memorandum for the Secretary of State [and] the Secretary of Homeland Security

Humanitarian conditions in southern Lebanon have significantly deteriorated due to tensions between Hezbollah and Israel. While I remain focused on de-escalating the situation and improving humanitarian conditions, many civilians remain in danger; therefore, I am directing the deferral of removal of certain Lebanese nationals who are present in the United States.

Pursuant to my constitutional authority to conduct the foreign relations of the United States, I have determined that it is in the foreign policy interest of the United States to defer for 18 months the removal of any Lebanese national subject to the conditions and exceptions provided below.

Accordingly, I hereby direct the Secretary of Homeland Security to take appropriate measures to defer for 18 months the removal of any Lebanese national who is present in the United States on the date of this memorandum, except for those:

(1) who have voluntarily returned to Lebanon after the date of this memorandum;

(2) who have not continuously resided in the United States since the date of this memorandum;

(3) who are inadmissible under section 212(a)(3) of the Immigration and Nationality Act (INA) (8 U.S.C. 1182(a)(3)) or deportable under section 237(a)(4) of the INA (8 U.S.C. 1227(a)(4));

(4) who have been convicted of any felony or two or more misdemeanors committed in the United States, or who meet any of the criteria set forth in section 208(b)(2)(A) of the INA (8 U.S.C. 1158(b)(2)(A));

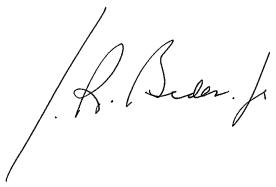
(5) who are subject to extradition;

(6) whose presence in the United States the Secretary of Homeland Security has determined is not in the interest of the United States or presents a danger to public safety; or

(7) whose presence in the United States the Secretary of State has reasonable grounds to believe would have potentially serious adverse foreign policy consequences for the United States.

I further direct the Secretary of Homeland Security to take appropriate measures to authorize employment for noncitizens whose removal has been deferred, as provided by this memorandum, for the duration of such deferral, and to consider suspending regulatory requirements with respect to F–1 nonimmigrant students who are Lebanese nationals as the Secretary of Homeland Security determines to be appropriate.

The Secretary of Homeland Security is authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, July 26, 2024

[FR Doc. 2024–17006
Filed 7–30–24; 8:45 am]
Billing code 4410–10–P

Rules and Regulations

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

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

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 10005]

RIN 1545–BQ67

Plan-Specific Substitute Mortality Tables for Determining Present Value

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document sets forth final regulations that update the requirements that a plan sponsor of a single-employer defined benefit plan must meet to obtain IRS approval to use mortality tables specific to the plan in calculating present value for minimum funding purposes (as a substitute for the generally applicable mortality tables). These regulations affect participants in, and beneficiaries of, certain retirement plans and employers maintaining those plans.

DATES:

Effective date: These regulations are effective July 31, 2024.

Applicability date: These regulations apply for plan years beginning on or after January 1, 2025.

FOR FURTHER INFORMATION CONTACT: Arslan Malik or Linda S.F. Marshall, Office of Associate Chief Counsel (Employee Benefits, Exempt Organizations, and Employment Taxes) at (202) 317–6700 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Section 412 of the Internal Revenue Code (Code) prescribes minimum funding requirements for defined benefit pension plans. Section 430 specifies the minimum funding requirements that apply generally to defined benefit plans that are single-employer plans (that is, not multiemployer plans).[1] For a plan subject to section 430, section 430(a) defines the minimum required contribution for a plan year by reference to the plan's funding target for the plan year. Under section 430(d)(1), a plan's funding target for a plan year generally is the present value of all benefits accrued or earned under the plan as of the first day of that plan year.

Section 430(h)(3) provides rules regarding the mortality tables to be used under section 430. Under section 430(h)(3)(A), except as provided in section 430(h)(3)(C) or (D), the Secretary is to prescribe by regulation mortality tables to be used in determining any present value or making any computation under section 430. Section 430(h)(3)(C) prescribes rules for a plan sponsor's use of substitute mortality tables reflecting the specific mortality experience of a plan's population instead of using the generally applicable mortality tables. Under section 430(h)(3)(C), the plan sponsor may request the Secretary's approval to use plan-specific substitute mortality tables that meet requirements specified in section 430(h)(3)(C)(iii). If the Secretary determines that the proposed tables meet the statutory standards and approves the request, the substitute mortality tables are used to determine present values and make computations under section 430 during the period of consecutive plan years (not to exceed 10) specified in the request.

Under section 430(h)(3)(C)(iii), a substitute mortality table may be used for a plan only if: (1) the plan has a sufficient number of plan participants and has been maintained for a sufficient period of time to have credible mortality information necessary to create a substitute mortality table; and (2) the table reflects the actual mortality experience of the plan's participants and projected trends in general mortality experience. Except as provided by the Secretary, a plan sponsor may not use substitute mortality tables for any plan unless substitute mortality tables are established and used for each plan maintained by the plan sponsor or a member of its controlled group.

Final regulations (TD 9826) under section 430(h)(3) were published in the **Federal Register** on October 5, 2017 (82 FR 46388). The final regulations issued in 2017 include rules regarding generally applicable mortality tables under section 430(h)(3)(A), which are set forth in § 1.430(h)(3)–1, as well as rules regarding substitute mortality tables under section 430(h)(3)(C), which are set forth in § 1.430(h)(3)–2. Section 1.430(h)(3)–2(d)(2) provides that substitute mortality tables must be based on the plan's mortality experience during an experience study period that consists of 2, 3, 4, or 5 consecutive 12-month periods. In conjunction with the 2017 issuance of § 1.430(h)(3)–2, the Department of the Treasury (Treasury Department) and the IRS issued Rev. Proc. 2017–55, 2017–43 IRB 373, which sets forth the procedure by which a plan sponsor of a defined benefit plan may request and obtain approval for the use of plan-specific substitute mortality tables.

Beginning in 2020 and extending into the first part of 2023, for many defined benefit pension plans, the mortality experience of the plan participants was significantly higher than expected due to the COVID–19 pandemic. The Treasury Department and the IRS are concerned that, if a plan sponsor applied for approval of plan-specific substitute mortality tables using an experience study period that reflects the actual mortality experience for the plan's population during those years, then unless there is a change in the rules that are used for generating those tables, the resulting plan-specific substitute mortality tables would overstate the expected future mortality for the plan's population. This is because § 1.430(h)(3)–2(d)(4)(i) provides that substitute mortality tables are constructed using a mortality ratio calculated for the plan's population, which is determined by dividing the amounts-weighted number of actual deaths for plan participants during the experience study period by the amounts-weighted number of expected

[1] Section 302 of the Employee Retirement Income Security Act of 1974, Public Law 93–406, 88 Stat. 829 (1974), as amended (ERISA), sets forth funding rules that are parallel to those in section 412 of the Code, and section 303 of ERISA sets forth additional funding rules for defined benefit plans (other than multiemployer plans) that are parallel to those in section 430 of the Code. Pursuant to section 101 of Reorganization Plan No. 4 of 1978, 5 U.S.C. App., as amended, the Secretary of the Treasury has interpretive jurisdiction over the subject matter addressed in these regulations for purposes of ERISA, as well as the Code. Thus, these regulations issued under section 430 of the Code also apply for purposes of section 303 of ERISA.

deaths for those participants under the generally applicable mortality tables. In the absence of any changes to the rules and procedures for generating plan-specific substitute mortality tables, a mortality ratio developed using an experience study period that includes the period in which the COVID–19 pandemic occurred (COVID–19 pandemic period) will likely be unusually high, as the numerator of the mortality ratio will reflect the actual number of deaths for the plan population during this period, while the denominator of that ratio will be based on the expected number of deaths from the generally applicable mortality tables (which reflect only a small fraction of the significant short-term increase in mortality rates that occurred during the COVID–19 pandemic period). The Treasury Department and the IRS are concerned that if a substitute mortality table constructed using that mortality ratio is used for a plan's actuarial valuation, then the plan's liabilities will be understated.

To address this concern, proposed regulations that provide rules regarding the use of mortality experience data for the COVID–19 pandemic period in the construction of substitute mortality tables were published in the **Federal Register** on October 20, 2023 (88 FR 72409) (the proposed regulations). On the same date that the proposed regulations were issued, the Treasury Department and the IRS issued final regulations amending § 1.430(h)(3)–1 to update the generally applicable mortality tables under section 430(h)(3)(A) (88 FR 72357) (2023 final mortality regulations).

Under § 1.430(h)(3)–2(c)(6)(ii)(E), approval to use a previously approved substitute mortality table terminates in conjunction with the replacement of the generally applicable mortality tables under section 430(h)(3)(A) and § 1.430(h)(3)–1 as of the date specified in guidance published in the Internal Revenue Bulletin. The preamble to the 2023 final mortality regulations indicated that the Treasury Department and the IRS will not require that the use of any previously approved plan-specific substitute mortality tables be terminated in conjunction with the replacement of the generally applicable mortality tables until amendments to the substitute mortality regulations are finalized and an updated revenue procedure that reflects those final regulations is issued.

Four comments on the proposed regulations were received. No commenters requested to speak at a public hearing. The Treasury Department and IRS considered the comments that were received and are finalizing the proposed regulations with certain revisions, as explained in the following summary of comments and explanation of revisions. In addition, the Treasury Department and IRS are issuing Rev. Proc. 2024–32, 2024–34 IRB ____, which updates the procedures set forth in Rev. Proc. 2017–55 to reflect the amendments to § 1.430(h)(3)–2 made by this Treasury decision.

Summary of Comments and Explanation of Revisions

These regulations provide rules regarding the use of mortality experience data for the COVID–19 pandemic period that supplement the methodology for developing substitute mortality tables provided in § 1.430(h)(3)–2. These rules have the same structure as the rules that were included in the proposed regulations (under which the expected probability of death must be adjusted to reflect the generally higher mortality that occurred during the COVID–19 pandemic period) but eliminate the adjustment for 2023 and provide for a different adjustment for 2022.

To develop a mortality ratio that is more accurately predictive of future mortality experience for a plan population, these regulations provide that the expected deaths for the plan population used in determining the denominator in the mortality ratio are calculated by adjusting the mortality rates in the generally applicable mortality tables. Specifically, the regulations provide that, for each 12-month period that is included in the experience study period and that begins after 2019 and before 2023, the expected mortality rate for an individual is determined by multiplying the expected mortality rate for that individual from the standard mortality tables by an adjustment factor.

The proposed regulations provided for an adjustment factor for each 12-month period that is included in the experience study period and that began after 2019 and before 2024. The proposed adjustment factor for each of those years approximated the ratio (as reported by the National Center for Health Statistics, which is part of the Centers for Disease Control and Prevention) of (1) the actual number of deaths for the general population for the year to (2) the expected number of deaths for the general population for that year.[2] Under the proposed regulations, the adjustment factor for a 12-month period beginning in 2020 or 2021 was 1.15, for a 12-month period beginning in 2022 was 1.10, and for a 12-month period beginning in 2023 was 1.05.

The Treasury Department and IRS received four comments regarding the adjustment factors set forth in the proposed regulations. The four commenters stated that a single adjustment factor for each year inadequately captured the age, gender, and regional variances in excess mortality during the COVID–19 pandemic. In addition, three commenters suggested that the adjustment factor for 2023 be eliminated (because preliminary data from 2023 showed a decline in excess mortality such that no adjustment may be needed for 2023), and that the adjustment factor for 2022 be reduced. After considering these comments and the most recent mortality data available, the Treasury Department and IRS are eliminating the adjustment for 2023 and reducing the adjustment for 2022. However, the Treasury Department and IRS concluded that providing adjustment factors based on age would be inconsistent with the overall model for developing substitute mortality tables, and that providing separate adjustment factors based on gender or geography would add a degree of complexity that would outweigh any potential increase in precision that these adjustment factors may provide.

The four commenters also suggested that, as an alternative to applying the adjustment factors, plan sponsors be permitted to construct substitute mortality tables without taking into account any mortality experience from the COVID–19 pandemic period. The Treasury Department and IRS have considered this approach but rejected it because providing for such an approach would mean that the mortality experience used to construct the substitute mortality table could be so out of date that it would be less reliable in predicting future mortality for the plan population. For example, if a plan sponsor was applying for approval of a substitute mortality table in 2024 using calendar year mortality experience without taking into account mortality experience for 2020, 2021, and 2022, the most recent mortality experience would be from 2019, which is more than 4 years prior to the application for approval.

Under a transition rule in the proposed regulations, substitute mortality tables that were previously approved for use for a plan year beginning in 2025 would be treated as satisfying the rules for developing

[2] *See* Excess Deaths Associated with Covid–19 at *https://www.cdc.gov/nchs/nvss/vsrr/covid19/excess_deaths.htm.*

substitute mortality tables that apply for that plan year. This transition rule, which is included in these regulations, addresses plans with previously approved substitute mortality tables that were based on a mortality experience study that included data from the COVID–19 pandemic period (and therefore do not satisfy the requirements specified in these regulations).

One commenter requested clarification as to the extent to which other previously approved substitute mortality tables may continue to be used for the remainder of their approval period even if that approval period extends beyond 2025. The Treasury Department and IRS considered this comment and decided to continue to allow the use of previously approved substitute mortality tables that were developed based on an experience study that did not include data from the COVID–19 pandemic period for the original duration of the approval, provided that there has not been a significant change in plan coverage, as described in the first sentence of § 1.430(h)(3)–2(c)(6)(iii)(A).[3] Thus, if the experience study for a substitute mortality table that has been approved for use for a plan year beginning in 2025 includes mortality data from 2020, 2021, or 2022 (or the number of individuals covered by the substitute mortality table is less than 80 percent or more than 120 percent of the average number of individuals in that population over the years covered by the experience study), then the substitute mortality table may be used for a plan year beginning in 2025 (but may not be used for later years).

These regulations also include a transition rule that applies to requests for approval to use substitute mortality tables for a plan year beginning in 2025. Under that rule, a request for approval to use substitute mortality tables for that plan year will be considered timely if it is submitted on or before October 31, 2024, provided that the plan sponsor agrees to a 90-day extension under § 1.430(h)(3)–2(b)(2)(iv) of the 180-day review period under § 1.430(h)(3)–2(b)(2)(iii).

Applicability Date

These regulations apply for plan years beginning on or after January 1, 2025.

[3] The termination of the use of previously approved substitute mortality tables is described in section 12 of Rev. Proc. 2024–32. Under that revenue procedure, if there has been a significant change in plan coverage, a previously approved substitute mortality table cannot be used for a plan year that begins on or after January 1, 2026, even if the plan actuary certifies that the table continues to be accurately predictive of future mortality of the plan population.

Statement of Availability of IRS Documents

IRS Revenue Rulings, Revenue Procedures, and Notices cited in this document are published in the Internal Revenue Bulletin (or Cumulative Bulletin) and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *www.irs.gov.*

Special Analyses

I. Regulatory Planning and Review

Pursuant to the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the IRS are not subject to the requirements of section 6 of Executive Order 12866, as amended. Therefore, a regulatory impact assessment is not required.

II. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that this rule will not have a significant economic impact on a substantial number of small entities. Small employers generally cannot use plan-specific substitute mortality tables because their defined benefit pension plans do not have credible mortality experience (which is defined as a minimum number of deaths during the experience study period) as is required to use substitute mortality tables. Therefore, a regulatory flexibility analysis under the Regulatory Flexibility Act is not required.

Pursuant to section 7805(f), the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business, and no comments were received.

III. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a State, local, or Tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. These regulations do not include any rule that include any Federal mandate that may result in expenditures by State, local, or Tribal governments, or by the private sector in excess of that threshold.

IV. Executive Order 13132: Federalism

Executive Order 13132 (Federalism) prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on State and local governments, and is not required by statute, or preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. These regulations do not include rules that have federalism implications, impose substantial direct compliance costs on State and local governments, or preempt State law within the meaning of the Executive order.

V. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

Drafting Information

The principal authors of these regulations are Arslan Malik and Linda S.F. Marshall of the Office of Associate Chief Counsel (Employee Benefits, Exempt Organizations, and Employment Taxes). However, other personnel from Treasury and the IRS participated in the development of these regulations.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, the Treasury Department and the IRS amend 26 CFR part 1 as follows:

PART 1—INCOME TAXES

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

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

■ **Par. 2.** Section 1.430(h)(3)–2 is amended by:

■ a. In paragraph (a), removing the language ''§ 601.601(d)(2)(ii)(b)'' and adding the language ''§ 601.601(d)(2)'' in its place;

■ b. In paragraph (d)(2)(ii)(B), removing the language ''January 1, 2019 year is'' and adding the language ''January 1, 2019 is'' in its place;

■ c. Revising paragraphs (d)(4)(iii) and (g).

The revisions read as follows:

§ 1.430(h)(3)–2 Plan-specific substitute mortality tables used to determine present value.

* * * * *

(d) * * *

(4) * * *

(iii) *Standard mortality table*—(A) *Projection of base table.* Except as otherwise provided in this paragraph (d)(4)(iii), the standard mortality table for a year is the mortality table determined by applying cumulative mortality improvement factors determined under § 1.430(h)(3)–1(b)(2)(ii) to the base mortality table under § 1.430(h)(3)–1(d) for the period beginning with the base year for that mortality table and ending in the base year for the base substitute mortality table determined under paragraph (c)(3)(ii) of this section. For purposes of the preceding sentence, the cumulative mortality improvement factors are determined using the mortality improvement rates described in § 1.430(h)(3)–1(b)(1)(iii) that apply for the calendar year during which the plan sponsor submits the request for approval to use substitute mortality tables.

(B) *Adjustments to standard mortality table for 2020, 2021, and 2022.* If a 12-month period in the experience study period begins after December 31, 2019, and before January 1, 2023, the probability of death for an individual under paragraph (d)(4)(ii)(A)(*2*)(*i*) of this section is determined as the mortality rate for the individual's age (at the beginning of the year) and gender from the standard mortality table determined under paragraph (d)(4)(iii)(A) of this section multiplied by the adjustment factor in Table 1 for the calendar year that includes the first day of the 12-month period. For example, for an experience study period that begins April 1, 2019, and ends March 31, 2023, the probability of death for the year beginning April 1, 2022, for a male annuitant who is age 65 as of that date is the probability of death from the base mortality table (0.01087), multiplied by the cumulative mortality improvement factor for the period from 2012 to 2021 (1.02292) and by the adjustment factor for the 2022 calendar year of 1.075, resulting in a probability of death of 0.01195.

TABLE 1 TO PARAGRAPH (d)(4)(iii)(B)

Calendar year	*Adjustment factor*
2020	1.15
2021	1.15
2022	1.075

(C) *Selection of base table.* If the population consists solely of annuitants, the annuitant base mortality table set forth in § 1.430(h)(3)–1(d) must be used for purposes of paragraph (d)(4)(iii)(A) of this section. If the population consists solely of nonannuitants, the nonannuitant base mortality table set forth in § 1.430(h)(3)–1(d) must be used for that purpose. If the population includes both annuitants and nonannuitants, a combination of the annuitant and nonannuitant base tables set forth in § 1.430(h)(3)–1(d) must be used for that purpose. The combined table is constructed using the weighting factors for small plans that are set forth in § 1.430(h)(3)–1(d). The weighting factors are applied to develop the combined table using the following equation:

Combined mortality rate = [nonannuitant rate * (1 − weighting factor)] + [annuitant rate * weighting factor].

* * * * *

(g) *Applicability date*—(1) *General rule.* This section applies for plan years beginning on or after January 1, 2025. Except as provided in paragraph (g)(2) or (3) of this section, the substitute mortality table used for a plan for such a plan year must comply with the rules of paragraphs (a) through (f) of this section.

(2) *Transition rule for previously approved substitute mortality tables.* If a plan sponsor has received approval from the Commissioner to use substitute mortality tables for a plan year beginning in 2025, then the plan's base substitute mortality tables that were approved are treated as satisfying the requirements of paragraph (d) or (e) of this section, as applicable, for that plan year.

(3) *Transition rule for requests for approval to use substitute mortality tables.* A written request described in paragraph (b)(1)(i) of this section to use substitute mortality tables for a plan year that begins during 2025 does not fail to satisfy the timing requirement of paragraph (b)(1)(ii) of this section if it is submitted no later than October 31, 2024, provided that the plan sponsor agrees to a 90-day extension of the 180-day review period in accordance with paragraph (b)(2)(iv) of this section.

Douglas W. O'Donnell,

Deputy Commissioner.

Approved: July 8, 2024

Aviva R. Aron-Dine,

Acting Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2024–16520 Filed 7–30–24; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0023]

RIN 1625–AA11

Safety Zone; Sea Otter Point, Port of Valdez, AK

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is amending the regulation titled Safety Zone; City of Valdez July 4th Fireworks, Port Valdez; Valdez, AK. The City of Valdez has changed the annual firework displays from July 4th to December 31st each year. It is therefore necessary to amend the CFR to reflect the correct date of the fireworks display.

DATES: rule is effective August 30, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2024–0023 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email LT Abigail Ferrara, Marine Safety Unit Valdez, US Coast Guard. Telephone 907–835–7209, email *Abigail.C.Ferrara@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Prince William Sound
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard began issuing temporary final rules establishing safety zones during the Valdez July 4th fireworks display beginning in 2014. The Coast Guard received no comments or concerns from the public when the temporary safety zones were in place. Due to the repeating nature of the event, on February 28, 2017, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Safety Zone; City of Valdez July 4th Fireworks, Port Valdez; Valdez, AK (82 FR 12076). There we stated why we issued the NPRM and invited comments on our

proposed regulatory action related to this fireworks display. Since then, the City of Valdez has changed the firework display from July 4th to December 31st. The Coast Guard again began issuing temporary final rules annually for the new date. Again, due to the repeating nature of the event, we are issuing this final rule to change the date and time to reflect the correct event details.

On May 21, 2024, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Safety Zone; Sea Otter Point, Port of Valdez, AK (89 FR 44945). There we stated why we issued the NPRM and invited comments on our proposed regulatory action related to this fireworks display. During the comment period that ended June 21, 2024, we received one comment.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Prince William Sound (COTP) has determined that it is necessary to amend the CFR to reflect the correct date of the fireworks display.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received one comment on our NPRM published May 21, 2024. The comment supported this change, stating that fireworks do not occur in Valdez on July 4th because the sky does not get dark. The commenter claimed to be the City of Valdez events coordinator who has managed the December 31st fireworks for seven years. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

The COTP is amending the current safety zone found in 33 CFR 165.1713 to reflect the correct date of the City of Valdez's annual fireworks display. The date will change from July 4th to December 31st. The regulatory text we are amending appears at the end of this document.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on extremely limited vessel traffic in the winter months, as well as the size, location, time of day, and duration of the safety zone. Furthermore, vessels may request authorization to transit through the safety zone with the permission of the COTP, Prince William Sound, Alaska. The Coast Guard will still issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

Also, this rule does not have Tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a

significant effect on the human environment. This rule involves changing the date and shortening the duration of an existing safety zone, which prohibits traffic within 200 yards of a firework display. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Revise § 165.1713 as follows:

§ 165.1713 Safety Zone; City of Valdez Annual Fireworks Display within the Captain of the Port, Prince William Sound Zone, Port Valdez; Valdez, AK.

(a) *Regulated area.* The following area is a safety zone: All waters of Port Valdez, from surface to bottom, within a 200-yard radius from a position of 61°07′22″ N and 146°21′13″ W. These coordinates are based on the 1984 World Geodetic System (WGS 84). This includes the entrance to the Valdez small boat harbor.

(b) *Definitions.* As used in this section, *designated representative* means any Coast Guard commissioned, warrant or petty officer of the U.S. Coast Guard and a Federal, State, and local officer designated by or assisting the Captain of the Port Prince William Sound (COTP) in the enforcement of the safety zone. The term ''official patrol vessel'' may consist of any Coast Guard, Coast Guard Auxiliary, State, or local law enforcement vessels assigned or approved by the COTP Prince William Sound.

(c) *Regulations.* (1) The general safety zone regulations contained in subpart C of this part, as well as the following regulations, apply.

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or the designated representative during periods of enforcement.

(3) All persons and vessels shall comply with the instructions of the COTP or the designated representative. Upon being hailed by a designated representative by siren, radio, flashing light, or other means, the operator of the vessel shall proceed as directed.

(4) Anyone desiring to enter or operate within the regulated area may request permission from the COTP via VHF Channel 16 or (907) 835–7205 (Prince William Sound Vessel Traffic Center) to request permission to do so.

(5) The COTP may be aided by other Federal, State, borough, and local law enforcement officials in the enforcement of this section.

(d) *Enforcement period.* This section will be enforced from 7:30 p.m. until 9 p.m. on December 31st of each year, or during the same time frame on specified weather delay dates January 1st through January 5th each year.

Dated: July 24, 2024.

S.K. Rousseau,

Commander, U.S. Coast Guard, Captain of the Port Prince William Sound.

[FR Doc. 2024–16821 Filed 7–30–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2024–0649]

Regulated Navigation Area; Lake Washington, Seattle, WA

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

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a regulated navigation area on Lake Washington, Seattle Washington immediately before and after Seafair events from 8 a.m. through 8 p.m. each day from August 1, 2024, through August 4, 2024. This action is being taken to provide for the safety of life on navigable waterways throughout the duration of this 4-day event. The location of this regulated navigation area on portions of Lake Washington, Seattle, Washington is specified in the regulation. During the enforcement periods all vessels and persons transiting the regulated navigation area must proceed at a speed which creates minimum wake, 7 miles per hour or less, unless a higher minimum speed is necessary to maintain bare steerageway.

DATES: The regulation in 33 CFR 165.1341 will be enforced immediately before and after Seafair events from 8 a.m. through 8 p.m. each day from August 1, 2024, through August 4, 2024.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Lieutenant Commander John Robertson, U.S. Coast Guard, Sector Puget Sound, Waterways Management Division; by telephone 206–217–6051, or email *SectorPugetSoundWWM@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the regulated navigation area in 33 CFR 165.1341 immediately before and after Seafair events from 8 a.m. through 8 p.m. each day from August 1, 2024, through August 4, 2024. This action is being taken to provide for the safety of life on navigable waterways during this 4-day event. Seafair will be having several events sporadically throughout the day. Before and after these events, the Coast Guard will be enforcing the regulated navigation area in order to protect the public from the potential hazards of excessive vessel traffic associated with these events. The regulation, § 165.1341(a), specifies the location of the regulated navigation area encompassing portions of Lake Washington, Seattle, Washington. During the enforcement periods, as reflected in § 165.1341(c), all vessels and persons transiting the regulated navigation area must proceed at a speed which creates minimum wake, 7 miles per hour or less, unless a higher minimum speed is necessary to maintain bare steerageway.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of the enforcement period via marine information broadcast and Local Notice to Mariners.

Dated: July 24, 2024.

Mark A. McDonnell,

Captain, U.S. Coast Guard, Captain of the Port, Sector Puget Sound.

[FR Doc. 2024–16820 Filed 7–30–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0626]

RIN 1625–AA00

Safety Zone; Sunsation Powerboats Fireworks, Lake St. Clair; New Baltimore, MI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters on Lake St. Clair, New Baltimore, MI. The safety zone is necessary and intended to protect personnel, vessels, and the marine environment from potential hazards associated with fireworks displays created by Sunsation Powerboats Inc. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Detroit, or his designated representative.

DATES: This rule is effective from 9:30 p.m. through 10:30 p.m. on August 1, 2024, and in the case of inclement weather from 10 p.m. through 10:30 p.m. on August 2, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2024–0626 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Tracy Girard, Waterways Department, Sector Detroit, Coast Guard; telephone (313) 568–9564, email *Tracy.M.Girard@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the event sponsor notified the Coast Guard with insufficient time to publish an NPRM and immediate action is necessary to protect personnel, vessels, and the marine environment on Lake St. Clair. It is impracticable and contrary to the public interest to publish a NPRM because we must establish this safety zone by August 1, 2024.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. For the same reasons discussed in the preceding paragraph, delaying the effective date of this rule would be impracticable because immediate action is needed to respond to the potential safety hazards associated with a fireworks display.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Detroit (COTP) has determined that potential hazards associated with fireworks displays will be a safety concern for anyone within a 200-yard radius of the launch site. The likely combination of recreational vessels, darkness punctuated by bright flashes of light, and fireworks debris falling into the water presents risks of collisions which could result in serious injuries or fatalities. This rule is necessary to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone during the fireworks display.

IV. Discussion of the Rule

This rule establishes a safety zone from 9:30 p.m. through 10:30 p.m. on August 1, 2024. In the case of inclement weather on August 1, 2024, this safety zone will be enforced from 10 p.m. through 10:30 p.m. on August 2, 2024. The safety zone will encompass all U.S. navigable waters of Lake St. Clair within a 200-yard radius of the fireworks launch site located 42°39′55.69″ N, 082°45′23.58″ W, in New Baltimore, MI. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters during the fireworks display. Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Detroit or his designated representative. The Captain of the Port Detroit or his designated representative may be contacted via VHF Channel 16.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the size, location, and duration of the safety zone. Vessel traffic will be able to safely transit around this safety zone which would impact a small, designated area of Lake St. Clair one hours during the evening when vessel traffic is normally low. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM Marine Channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

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

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

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business,

organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting only 1 hour that will prohibit entry within 200-yard radius of where the fireworks display will be conducted. It is categorically excluded from further review under paragraph L[60] of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—Regulated Navigation Areas and Limited Access Areas

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

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

■ 2. Add § 165.T09–0626 to read as follows:

§ 165.T09–0626 Safety Zone; Sunsation Fireworks display, Lake St. Clair; Chesterfield, MI.

(a) *Location.* The following area is a temporary safety zone: all U.S. navigable waters of Lake St. Clair within a within a 200-yard radius of the fireworks launch site located at position 42°39′55.69″ N, 082°45′23.58″ W. All geographic coordinates are North American Datum of 1983 (NAD 83).

(b) *Enforcement period.* This regulation will be enforced from 9:30 p.m. through 10:30 p.m. on August 1, 2024. In the case of inclement weather on August 1, 2024, this safety zone will be enforced from 10 p.m. through 10:30 p.m. on August 2, 2024. The Captain of the Port Detroit, or a designated representative may suspend enforcement of the safety zone at any time.

(c) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Detroit (COTP) in the enforcement of the safety zone.

(d) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Detroit or his designated representative.

(2) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port Detroit or his designated representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Detroit or his designated representative. The COTP Detroit or his designated representative may be contacted via VHF Channel 16.

Dated: July 24, 2024.

Richard P. Armstrong,

Captain, U.S. Coast Guard, Captain of the Port Sector Detroit.

[FR Doc. 2024–16819 Filed 7–30–24; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2023–0308; FRL–12049–01–OCSPP]

Pendimethalin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pendimethalin in or on fig and fig, dried. BASF Corporation has requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 31, 2024. Objections and requests for hearings must be received on or before September 30, 2024 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2023–0308, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room, and for the OPP Docket is (202) 566–1744. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2023–0308, in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before September 30, 2024. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2023–0308, by one of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.

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

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/where-send-comments-epa-dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of December 19, 2023 (88 FR 87733) (FRL–10579–11), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2F9038) by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide pendimethalin, including its metabolites and degradates, in or on the raw agricultural commodities fig at 0.1 parts per million (ppm) and fig, dried at 3.0 ppm. That document referenced a summary of the petition prepared by BASF, the registrant, which is available in the docket at *https://www.regulations.gov.*

The December 19, 2023, notice of filing supersedes a notice of filing published in the **Federal Register** of July 26, 2023 (88 FR 48179) (FRL–10579–06), which was based on an earlier version of the same petition (2F9038) requesting tolerances for tropical and subtropical fruit, medium to large fruit, edible peel subgroup 23B at 0.1 ppm and fig, dried fruit at 3.0 ppm; and an inadvertent tolerance for cilantro, fresh leaves at 0.1 ppm. Following that July 2023 publication, BASF amended its petition to request tolerances only for fig and fig, dried, as noticed in the December 2023 publication.

No comments were received in response to the December 19, 2023, and the July 26, 2023, notices of filing.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA has modified the level at which one of the tolerances is being established. The reason for this change is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will

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

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

In an effort to streamline its publications in the **Federal Register**, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings for the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

In the **Federal Register** of February 16, 2018 (83 FR 6975) (FRL–9973–03) and October 25, 2019 (84 FR 57336) (FRL–10000–06), EPA published tolerance rulemakings for pendimethalin in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to pendimethalin and established tolerances for residues of that chemical. EPA is incorporating previously published sections from these rulemakings as described further in this rulemaking, as they remain unchanged.

Toxicological profile. For a discussion of the Toxicological Profile of pendimethalin, see Unit III.A. of the October 25, 2019, rulemaking.

Toxicological points of departure/Levels of concern. For a summary of the Toxicological Points of Departure/Levels of Concern for pendimethalin used for human health risk assessment, please reference Unit III.B. of the February 16, 2018, rulemaking.

Exposure assessment. Much of the exposure assessment for pendimethalin remains unchanged from the discussion in Unit III.C. of the October 25, 2019, rulemaking, except as described below.

Dietary exposure from food and feed uses. EPA's dietary exposure assessments have been updated to include the additional exposure from the proposed new uses on fresh and dried fig. The acute and chronic dietary (food and drinking water) exposure assessments in support of the proposed fresh and dried fig uses were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID) Version 4.02. This software uses 2005–2010 food consumption data from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The unrefined acute and chronic dietary exposure assessments assumed 100 percent crop treated (PCT), tolerance-level residues for all crops, and maximum anticipated residues to address all residues of concern in ruminant commodities.

Drinking water and non-occupational exposures. The drinking water numbers have not changed as a result of the proposed fresh and dried fig uses. For a detailed summary of the drinking water analysis for pendimethalin used for the human health risk assessment, please reference Unit III.C.2. of the October 25, 2019, rulemaking.

There are no residential exposures expected from the currently proposed uses; however, pendimethalin is currently registered for residential usage on gardens, golf course turf, lawns, and ornamentals. The highest anticipated short-term aggregate exposure scenarios for children and adults did not present risks of concern (*i.e.,* margins of exposure (MOEs) are > the level of concern (LOC) of 30). Intermediate-term exposures to pendimethalin are not likely because of the intermittent nature of applications by homeowners (*e.g.,* garden sprays). Long-term aggregate exposure is not anticipated for residential uses.

Cumulative exposure. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity The Agency has utilized this framework for pendimethalin and determined that although pendimethalin shares some chemical and/or toxicological characteristics (*e.g.,* chemical structure or apical endpoint) with other pesticides, the toxicological database does not support a testable hypothesis for a common mechanism of action. No further data are required to determine that no common mechanism of toxicity exists for pendimethalin, and other pesticides and no further cumulative evaluation is necessary for pendimethalin.

Safety factor for infants and children. EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor from 10X to 1X. See Unit III.D. of the October 25, 2019, rulemaking for a discussion of the Agency's rationale for that determination.

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

The results of the acute dietary analysis for food and drinking water at the 95th percentile of exposure shows that the acute dietary risk estimates are below the Agency's level of concern (<100% of the aPAD) for all population subgroups and were estimated at <1% of the aPAD for the U.S. general population and 2.1% of the aPAD for the most highly exposed population subgroup (infants <1 years old). The results of the chronic dietary analysis for food and drinking water indicate that the chronic dietary risk estimates are below the Agency's level of concern (<100% of the cPAD) for all population subgroups and were estimated at <1% of the cPAD for the U.S. general population and 2.3% of the cPAD for the most highly exposed population subgroup (children 1 to 2 years old).

Acute aggregate exposure is anticipated to occur from dietary exposure in food and drinking water only. There are no risks of concern for acute dietary exposure and thus no risks of concern for acute aggregate exposure. Short-term aggregate risk assessment was performed since there is potential

for post-application exposure from the existing uses in residential settings. The highest anticipated short-term aggregate exposure scenarios for children and adults did not present risks of concern (*i.e.,* MOEs are >LOC of 30). Intermediate-term exposures to pendimethalin are not likely because of the intermittent nature of applications by homeowners (*e.g.,* garden sprays). Long-term aggregate exposure is not anticipated for residential uses. Therefore, chronic aggregate risk estimates for pendimethalin include food and drinking water only, and are equivalent to the chronic dietary risk estimates, and are below HED's LOC. Pendimethalin is classified as a ''possible human carcinogen.'' However, the chronic dietary risk assessment is considered to be protective of any cancer effects; therefore, a separate quantitative cancer dietary risk assessment is not required. The chronic reference dose (cRfD)/cPAD is considered to be protective of all chronic toxicity, including carcinogenicity, that could result from exposure to pendimethalin. Since there are no chronic aggregate risks of concern, there are no cancer aggregate risks of concern.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to pendimethalin residues. More detailed information on the subject action to establish tolerances in or on fig commodities can be found in the document titled ''Pendimethalin—Human Health Risk Assessment to Support the Proposed New Use on Fig.'' available at *https://www.regulations.gov* in docket ID number EPA–HQ–OPP–2023–0308.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate analytical enforcement methodology, gas chromatography with electron capture detection (GC/ECD), is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established any MRLs for pendimethalin for the crops covered by this action.

C. Revisions to Petitioned-For Tolerances

EPA is establishing the tolerance for fig, dried at 3 ppm rather than 3.0 ppm to be consistent with Organisation for Economic Cooperation and Development (OECD) rounding class practices.

V. Conclusion

Therefore, tolerances are established for residues of pendimethalin in or on the raw agricultural commodities fig at 0.1 parts per million (ppm) and fig, dried at 3 ppm.

VI. Statutory and Executive Order Reviews

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

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

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

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: July 19, 2024.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

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

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

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

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

■ 2. In § 180.361, amend paragraph (a)(1) by designating the table as ''Table 1 to Paragraph (a)(1)'' and adding to newly designated table 1, in alphabetical order, the entries ''Fig'' and ''Fig, dried'' to read as follows:

§ 180.361 Pendimethalin; tolerances for residues.

(a) * * *

(1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
* * * * *	
Fig	0.1
Fig, dried	3
* * * * *	

* * * * *

[FR Doc. 2024–16544 Filed 7–30–24; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 24–112; RM–11981; DA 24–720; FR ID 235234]

Television Broadcasting Services Jacksonville, Florida

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Video Division, Media Bureau (Bureau), has before it a Notice of Proposed Rulemaking issued in response to a Petition for Rulemaking filed by Multimedia Holdings Corporation (Petitioner or Multimedia), the licensee of WTLV (Station or WTLV), channel 13, Jacksonville, Florida (Jacksonville). The Petitioner has requested the substitution of UHF channel 33 for VHF channel 13 in the Table of TV Allotments. TEGNA Inc., on behalf of its wholly owned subsidiary, Multimedia, filed comments in support of the Petition, as required by the Commission's rules (rules), reaffirming Multimedia's commitment to apply for channel 33 and, if authorized, to promptly implement the facilities modifications necessary for the Station to operate on channel 33.

DATES: Effective July 31, 2024.

FOR FURTHER INFORMATION CONTACT: Joyce Bernstein, Media Bureau, at (202) 418–1647 or *Joyce.Bernstein@fcc.gov*, or Mark Colombo, Media Bureau, at (202) 418–7611 or *Mark.Colombo@fcc.gov*.

SUPPLEMENTARY INFORMATION: The proposed rule was published at 89 FR 31125 on April 24, 2024. The Petitioner filed comments in support of the petition reaffirming its commitment to apply for channel 33. No other comments were filed.

The Bureau believes the public interest would be served by substituting channel 33 for channel 13 at Jacksonville. According to the Petitioner, the Station has received persistent reception complaints from viewers, many of whom state that they can receive signals from other local stations on UHF channels, but not WTLV on VHF channel 13. The Petitioner states that the Commission has recognized that VHF channels have certain characteristics that pose challenges for their use in providing digital television service, including propagation characteristics that allow undesired signals and noise to be receivable at relatively far distances, and that although VHF reception issues are not universal, ''environmental noise blockages affecting [VHF] signal strength and reception exist'' and ''[vary] widely from service area to service area. Additionally, the Petitioner notes that the Commission has observed the large variability in the performance of indoor antennas available to consumers, with most antennas receiving ''fairly well at UHF and . . . not so well to very poor at high-VHF.'' WTLV is an NBC network affiliate and while an analysis provided by the Petitioner indicates that the Station's move to channel 33 will result in 274,303 persons no longer being located within the Station's noise limited service contour (NLSC), all but 16,737 persons in the predicted loss area are within the NLSC of three other NBC affiliated TV stations. Further, when the Commission's *TVStudy* software is run for the Station's licensed and proposed facility with the ''Study Area Mode'' set to ''unrestricted'' to predict coverage outside the proposed channel 33 NLSC, all viewers in the remaining predicted loss area would continue to receive over-the-air NBC network programming from WTLV on channel 33. Thus, once service provided by other NBC stations and the terrain-limited coverage predictions are taken into account, we find that the proposed channel 33 facility will result in no loss of NBC service to existing viewers within the Station's current NLSC.

We also find that the proposal complies with all relevant technical requirements for amendment of the Table of TV Allotments, including the interference protection requirements of § 73.622(a) of the rules, and further demonstrates that the proposed channel 33 facility will provide full principal community coverage to Jacksonville as required by § 73.618 of the rules. In fact, this channel substitution from VHF to UHF will help improve service to existing viewers, including those in the Station's principal community of license, by eliminating reception issues related to the Station's current operation on a high-VHF channel. As proposed, channel 33 can be substituted for channel 13 at Jacksonville in compliance with the principal community coverage requirements of § 73.618(a) of the rules, at coordinates 30–16′–25″ N. and 81–33′–12″ W. In addition, we find that this channel change meets the technical requirements set forth in § 73.622(a) of the rules.

This is a synopsis of the Commission's *Report and Order,* MB Docket No. 24–112; RM–11981; DA 24–720, adopted July 24, 2024, and released July 24, 2024. The full text of this document is available for download at *https://www.fcc.gov/edocs.* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

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

The Commission will send a copy of the *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the

Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73 Television.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

Final Rule

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

PART 73—RADIO BROADCAST SERVICES

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

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

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

§ 73.622 Digital television table of allotments.

* * * * *

(j) * * *

Community	Channel No.
* * * * *	
Florida	
* * * * *	
Jacksonville ...	* 9, 14, 18, 19, 20, * 21, 33.
* * * * *	

* * * * *

[FR Doc. 2024–16870 Filed 7–30–24; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 240514–0137; RTID 0648–XE075]

Fisheries Off West Coast States; Modification of the West Coast Salmon Fisheries; Inseason Actions #1 Through #3

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

ACTION: Inseason modification of 2024–2025 management measures.

SUMMARY: NMFS announces three inseason actions for the 2024–2025 ocean salmon fishing season. These inseason actions modify the commercial salmon troll fisheries in the area from the U.S./Canada border to the Oregon/California border.

DATES: The effective dates for these inseason actions are set out in this document under the heading ''Inseason Actions'' and the actions remain in effect until the dates identified or until superseded.

FOR FURTHER INFORMATION CONTACT: Anna Heeter, 425–606–1814, *Anna.Heeter@noaa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The annual management measures for the 2024 and early 2025 ocean salmon fisheries (89 FR 44553, May 21, 2024) govern the commercial and recreational fisheries in the area from the U.S./Canada border to the U.S./Mexico border, effective from 0001 hours Pacific Daylight Time (PDT), May 16, 2024, until the effective date of the 2025 management measures, as published in the **Federal Register**. NMFS is authorized to implement inseason management actions to modify fishing seasons and quotas as necessary to provide fishing opportunity while meeting management objectives for the affected species (50 CFR 660.409). Inseason actions in the salmon fishery may be taken directly by NMFS (50 CFR 660.409(a)—Fixed inseason management provisions) or upon consultation with the Chairman of the Pacific Fishery Management Council (Council), and the appropriate State Directors (50 CFR 660.409(b)—Flexible inseason management provisions).

Management of the salmon fisheries is divided into two geographic areas: north of Cape Falcon (NOF) (U.S./Canada border to Cape Falcon, OR), and south of Cape Falcon (SOF) (Cape Falcon, OR, to the U.S./Mexico border). The action described in this document affects the NOF commercial salmon troll fisheries and SOF recreational fisheries, as set out under the heading ''Inseason Actions'' below.

Consultation with the Council Chairperson on these inseason actions occurred on May 16, 2024, and on June 18, 2024. These consultations included representatives from NMFS, Washington Department of Fish and Wildlife, Oregon Department of Fish and Wildlife, and California Department of Fish and Wildlife. Representatives from the Salmon Advisory Subpanel and Salmon Technical Team were also present. A Council representative was present on May 16, 2024, and June 18, 2024.

These inseason actions were announced on NMFS' telephone hotline and U.S. Coast Guard radio broadcast on the date of the consultations (50 CFR 660.411(a)(2)).

Inseason Actions

Inseason Action #1

Description of the action: Inseason action #1 modifies the NOF ocean salmon troll commercial fishery from the U.S./Canada border to Cape Falcon, OR.

Effective dates: Inseason action #1 takes effect for the following areas and dates, and remains in effect until superseded.

- Effective 12:30 p.m. Thursday, May 16, 2024, for the ocean salmon troll commercial fishery, the landing and possession limit for the entire area between Cape Falcon and the U.S./Canada border is increased from 150 Chinook salmon per vessel per landing week (Thursday through Wednesday) to 225 Chinook salmon per vessel per landing week (Thursday through Wednesday).
- Effective 12:30 p.m. Thursday, May 16, 2024, for the ocean salmon troll commercial fishery, the landing and possession limit in the area between the U.S./Canada border and the Queets River is increased from 60 Chinook salmon per vessel per landing week (Thursday–Wednesday) to 70 Chinook salmon per vessel per landing week (Thursday through Wednesday).
- Effective 12:30 p.m. Thursday, May 16, 2024, for the ocean salmon troll commercial fishery, the landing and possession limit in the area between the Queets River and Leadbetter Point is increased from 150 Chinook salmon per vessel per landing week (Thursday through Wednesday) to 225 Chinook salmon per vessel per landing week (Thursday through Wednesday).
- Effective 12:30 p.m. Thursday, May 16, 2024, for the ocean salmon troll commercial fishery, the landing and possession limit in the area between Leadbetter Point and Cape Falcon is increased from 60 Chinook salmon per vessel per landing week (Thursday through Wednesday) to 80 Chinook salmon per vessel per landing week (Thursday through Wednesday).

Reason and authorization for the action: Due to lower than anticipated catch rates, this action will result in increased fishing interest and allow greater access to the quota for the area without exceeding it.

The NMFS West Coast Regional Administrator (RA) considered the 2024

abundance forecasts for Chinook salmon stocks, the timing of the actions relative to the length of the season, and determined that this inseason action is necessary to meet management and conservations goals for the 2024–2025 management measures. This inseason action modified quotas and/or fishing seasons under 50 CFR 660.409(b)(1)(i).

Inseason Action #2

Description of the action: Inseason action #2 modifies the SOF recreational ocean salmon fishery in the Klamath Management Zone (KMZ) between Humbug Mountain and the Oregon/California border. All salmon harvested in the recreational ocean salmon fishery between Humbug Mountain and the Oregon/California border through October 31, 2024, must be landed north of the Oregon/California border.

Effective dates: Inseason action #2 takes effect at 12:30 p.m. on Thursday, May 16, 2024, and remains in effect through October 31, 2024.

Reason and authorization for the action: The closure of commercial and recreational ocean salmon fisheries in California in 2024 presented a scenario in the KMZ between Humbug Mountain and Latitude 40°10′ N (California KMZ) where recreational fishing opportunity is open on the Oregon side of the KMZ but not on the California side of the KMZ, in order to protect California Chinook salmon and coho salmon. An enforcement concern was subsequently identified, in that the original 2024–2025 rules do not expressly prohibit landing salmon in the closed area. Allowing California vessels to land salmon in California would hinder enforcement efforts, as it might not be possible to determine whether landed fish were caught legally in Oregon or caught unlawfully within the closed area, thereby undermining the original intent of the closure. This inseason action clarifies that salmon may not be caught or landed within the closed area. With full closures in California there are not sufficient monitoring programs in place to adequately sample and estimate salmon landings brought into California from Oregon which could compromise managers ability to assess fishing impacts against conservation objectives. This inseason action would clarify that landing of salmon in California is prohibited to address the enforcement and monitoring concerns discussed above.

The RA considered port access issues and the need to monitor landings to assess fishing impacts, and determined that this inseason action was necessary to meet management and conservation objectives. These inseason action clarifies landing boundaries under 50 CFR 660.409(b)(1)(v).

Inseason Action #3

Description of the action: Inseason action #3 modifies the NOF commercial ocean salmon fishery. The area between the U.S./Canada border and Cape Falcon is closed.

Effective dates: Inseason action #3 takes effect at 11:59 p.m. on Wednesday, June 19, 2024, and remains in effect through June 30, 2024, at 11:59 p.m.

Reason and authorization for the action: Inseason action #3 is necessary to avoid exceeding the NOF quota for Chinook salmon. The RA considered the 2024 abundance forecasts for Chinook salmon stocks, the catch rates and anticipated effort relative to the remaining quota, and determined that this inseason action is necessary to meet management and conservations goals for the 2024–2025 management measures. This inseason action modifies fishing seasons under 50 CFR 660.409(b)(1)(i).

All other restrictions and regulations remain in effect as announced for the 2024 ocean salmon fisheries (89 FR 44553, May 21, 2024).

The states and tribes manage the fisheries in state waters adjacent to the areas of the U.S. exclusive economic zone (3–200 nautical miles; 5.6–370.4 kilometers) off the coasts of the States of Washington, Oregon, and California consistent with these Federal actions. As provided by the inseason notice procedures at 50 CFR 660.411, actual notice of the described regulatory actions was given, prior to the time the actions became effective, by telephone hotline numbers 206–526–6667 and 800–662–9825, and by U.S. Coast Guard Notice to Mariners broadcasts on Channel 16 VHF–FM and 2182 kHz.

Classification

NMFS issues these actions pursuant to section 305(d) of the Magnuson-Stevens Fishery Conservation and Management Act (MSA). These actions are authorized by 50 CFR 660.409, which was issued pursuant to section 304(b) of the MSA, and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(3)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest. Prior notice and opportunity for public comment on this action was impracticable because NMFS had insufficient time to provide for prior notice and the opportunity for public comment between the time Chinook and coho salmon abundance, catch, and effort information were developed and fisheries impacts were calculated, and the time the fishery modifications had to be implemented in order to ensure that fisheries are managed based on the best scientific information available and consistent with the conservation objectives. As previously noted, actual notice of the regulatory action was provided to fishers through telephone hotlines and radio notifications. These actions comply with the requirements of the annual management measures for ocean salmon fisheries (88 FR 30235, May 11, 2023), the Pacific Salmon Fishery Management Plan (FMP), and regulations implementing the FMP under 50 CFR 660.409 and 660.411.

There is good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effective date, as a delay in effectiveness of this action would allow fishing at levels inconsistent with the goals of the FMP and the current management measures.

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

Dated: July 26, 2024.

Lindsay Fullenkamp,

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

[FR Doc. 2024–16866 Filed 7–30–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

[Docket No. 240725–0204]

RIN 0648–BM76

Pacific Island Fisheries; Annual Catch Limit and Accountability Measure for the Commonwealth of the Northern Mariana Islands Bottomfish in 2024–2025

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

ACTION: Final rule.

SUMMARY: This final rule implements an annual catch limit (ACL) and annual catch target (ACT) for bottomfish in the Commonwealth of the Northern Mariana Islands (CNMI) for fishing years 2024 and 2025. This rule does not revise, add, or remove the most recent current accountability measure (AM) in NOAA's regulations. Under that AM, NMFS will reduce the ACL and ACT in the following fishing year by the amount of the overage if the average catch from the most recent 3 years exceeds the ACL.

This final rule supports the long-term sustainability of the CNMI bottomfish fishery.

DATES: This rule is effective August 30, 2024.

ADDRESSES: Background information on the bottomfish fishery in the Commonwealth of the Northern Mariana Islands is found in the Fishery Ecosystem Plan for the Mariana Archipelago (FEP) available from the Western Pacific Regional Fishery Management Council, 1164 Bishop St., Suite 1400, Honolulu, HI 96813, telephone 808–522–8220, fax 808–522–8226, or *https://www.wpcouncil.org.* Copies of supporting documents for this action are available at *https://www.regulations.gov/docket/NOAA-NMFS-2024-0002,* or from Sarah Malloy, Acting Regional Administrator, NMFS Pacific Islands Regional Office (PIRO), 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818.

FOR FURTHER INFORMATION CONTACT: Keith Kamikawa, NMFS Pacific Islands Regional Office, Sustainable Fisheries, 808–725–5177.

SUPPLEMENTARY INFORMATION: NMFS and the Western Pacific Regional Fishery Management Council (Council) manage the bottomfish fishery in the U.S. Exclusive Economic Zone (*i.e.,* Federal waters, generally 3–200 nautical miles (nmi) (345 kilometers (km)) around the CNMI under the Fishery Ecosystem Plan for the Mariana Archipelago (FEP), as authorized by the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Consistent with the process in the FEP, the Council and NMFS must specify ACLs, ACTs, and AMs for each stock and stock complex of each management unit species (MUS), as recommended by the Council, and must consider the best available scientific, commercial, and other information about the fishery. If a fishery exceeds an ACL, regulations require the Council to act (*e.g.,* enactment of an AM reducing the ACL for the subsequent fishing year by the amount of the overage). ACTs can be used as an additional management measure to help ensure catch does not exceed the ACL.

NMFS is implementing for the CNMI bottomfish fishery an ACL of 82,000 pounds (lb) (37,195 kilograms (kg)) and an ACT of 75,000 lb (34,019 kg) (Table 1). The fishing year begins on January 1 and ends on December 31, and catch from both territorial waters (generally from the shoreline to 3 nmi, (5.6 km offshore)) and Federal waters will be counted towards the ACL and ACT.

TABLE 1—ANNUAL CATCH LIMITS AND ANNUAL CATCH TARGETS FOR THE CNMI BOTTOMFISH COMPLEX

	2024	2025
ACL (lb)	82,000	82,000
ACT (lb)	75,000	75,000

The rule will not change the current AM for the CNMI bottomfish fishery: if the average catch of the three most recent years exceeds the specified ACL in a fishing year, NMFS will reduce the ACL and the ACT for the subsequent year by the amount of the overage in a separate rulemaking. If the average catch from the most recent 3-year period exceeds the ACT, but is below the ACL, NMFS will not apply a post-season correction.

This rule is consistent with recommendations made by the Council at its 195th meeting in June 2023. Additional background information on this action is in the preamble to the proposed rule (89 FR 45623, May 23, 2024).

Comments and Responses

On May 23, 2024, NMFS published a proposed rule and request for public comments (89 FR 45623). The comment period ended on June 24, 2024. NMFS received one public comment about offshore wind and the North Atlantic right whale, which is not related to the proposed rule or any other relevant topic. Therefore, NMFS made no changes to the final rule based on the public comment received.

Changes From the Proposed Rule

This final rule contains no changes from the proposed rule.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the FEP, other provisions of the Magnuson-Stevens Act, and other applicable law.

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

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

This final rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 50 CFR Part 665

Fisheries, Fishing, Commonwealth of the Northern Mariana Islands, Bottomfish management unit species, Annual catch limit, Accountability measure, Pacific Islands, Western Pacific.

Dated: July 25, 2024.

Kimberly Damon-Randall,

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

For the reasons set out in the preamble, NMFS amends 50 CFR part 665 as follows:

PART 665—FISHERIES IN THE WESTERN PACIFIC

■ 1. The authority citation for 50 CFR part 665 continues to read as follows:

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

■ 2. In § 665.408, revise paragraph (a) to read as follows:

§ 665.408 CNMI Annual Catch Limits (ACL) and Annual Catch Targets (ACT).

(a) In accordance with § 665.4, the ACL and ACT for Mariana bottomfish MUS in the CNMI Management Subarea for each fishing year are as follows:

TABLE 1 TO PARAGRAPH (a)

	2024	2025
ACL (lb)	82,000	82,000
ACT (lb)	75,000	75,000

* * * * *

[FR Doc. 2024–16822 Filed 7–30–24; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 89, No. 147
Wednesday, July 31, 2024

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

CONSUMER FINANCIAL PROTECTION BUREAU

12 CFR Part 1026

[Docket No. CFPB–2024–0032]

Truth in Lending (Regulation Z); Consumer Credit Offered to Borrowers in Advance of Expected Receipt of Compensation for Work

AGENCY: Consumer Financial Protection Bureau.

ACTION: Notice of proposed interpretive rule; request for comment.

SUMMARY: The Consumer Financial Protection Bureau (CFPB) is charged with promoting competition and innovation in consumer financial products and services. After careful study of emerging offerings in the paycheck advance marketplace, including those marketed as ''earned wage advances'' and ''earned wage access,'' the CFPB is proposing this interpretive rule to help market participants determine when certain existing requirements under Federal law are triggered. The proposed interpretive rule would also address certain costs that are in substantial connection with extensions of such credit, such as expedited delivery fees and costs marketed as ''tips.''

DATES: Comments must be received by August 30, 2024.

ADDRESSES: You may submit comments, identified by Docket No. CFPB–2024–0032, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: 2024-Paycheck-Advance-Interpretive-Rule@cfpb.gov.* Include Docket No. CFPB–2024–0032 in the subject line of the message.
- *Mail/Hand Delivery/Courier:* Comment Intake—2024 Paycheck Advance Interpretive Rule, c/o Legal Division Docket Manager, Consumer Financial Protection Bureau, 1700 G Street NW, Washington, DC 20552. Because paper mail in the Washington, DC area and at the CFPB is subject to delay, commenters are encouraged to submit comments electronically.

Instructions: The CFPB encourages the early submission of comments. All submissions must include the document title and docket number. In general, all comments received will be posted without change to *https://www.regulations.gov.* All submissions, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Proprietary information or sensitive personal information, such as account numbers or Social Security numbers, or names of other individuals, should not be included. Submissions will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT: George Karithanom, Regulatory Implementation & Guidance Program Analyst, Office of Regulations, at 202–435–7700 or at: *https://reginquiries.consumerfinance.gov/.* If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

One major source of demand for consumer credit is derived from the mismatch of when American workers receive compensation for their labor and when they incur expenses. While there have long been sources of credit for consumers to pay expenses in advance of receiving their compensation, there are a number of new offerings that seek to provide additional choices for consumers.

Instead of being paid daily or upfront, American workers generally provide services before employers pay for those services some time later—typically on a biweekly or semi-monthly wage cycle.[1] Employers have a strong incentive to delay payment, since these delays reduce working capital needs. Nearly three-quarters of non-farm payroll employees remain paid biweekly or even less frequently, and the remainder are generally paid their wages weekly. To address liquidity challenges, many consumers therefore turn to third-party credit products, such as payday loans, personal installment loans, and credit cards. In recent years, American consumers have significantly expanded their use of products sometimes marketed as ''earned wage access'' or ''earned wage advance.'' [2] As these paycheck advance products generally have features that make them subject to the CFPB's jurisdiction, the CFPB has sought to understand these and other products, particularly those offered online, by engaging in ongoing monitoring of the market, including, for example, collecting and analyzing data, engaging with stakeholders (*e.g.,* market participants, consumer groups, and States), tracking and studying market developments, and conducting market research, among other things.

While many of these products have similarities to payday loans, there are important distinctions. The CFPB has found that there are two emerging models of earned wage products: employer-partnered and direct-to-consumer.

For ''employer-partnered'' products, providers contract with employers to offer funds in amounts not exceeding accrued wages. Those funds are recovered via one or more payroll deductions, lowering the consumer's paychecks accordingly, with other recourse options generally unavailable to the third-party provider. In contrast, ''direct-to-consumer'' products provide funds to employees in amounts that they estimate to be below accrued wages; funds are then recovered via automated withdrawal from the consumer's bank account,[3] and generally without limit to the provider's ability to seek further recourse as necessary.[4]

Some of the significant differences between these two types of earned wage products, however, are starting to erode.

[1] While the terms ''employer'' and ''employee'' are used throughout, the proposed interpretive rule would apply more broadly to situations where consumers receive payment for work performed.

[2] A CFPB report describes rapid recent growth in one part of this developing market. *See* CFPB, *Developments in the Paycheck Advance Market,* at 3 (July 2024) (hereinafter *2024 Paycheck Advance Report*).

[3] This includes, without limitation, *e.g.,* prepaid and payroll card accounts.

[4] As described, direct-to-consumer products lie outside the scope of the ''wage advance'' (12 CFR 1041.3(d)(7)) and ''no cost advance'' (12 CFR 1041.3(d)(8)) exclusions from the CFPB's 2017 Payday Rule. Employer-partnered products, however, may be (but are not necessarily) within the scope of one exclusion or both, with their revenue model particularly relevant to that determination. *See* 12 CFR 1041.3(d)(7)(ii)(A), (d)(8).

For example, some direct-to-consumer providers are now connecting directly to payroll records and recouping funds from payroll deductions, and ongoing State legal developments may cause them to limit their recourse options as well.[5]

Before the CFPB's market monitoring of these products intensified, the CFPB issued an advisory opinion in November 2020,[6] that described how one particular type of earned wage product does not involve the offering or extension of ''credit'' as that term is defined in Regulation Z (12 CFR part 1026) and the Truth in Lending Act (TILA).[7] The opinion explained that an earned wage product is not TILA or Regulation Z credit if it meets *all* of several identified conditions, including: providing the consumer with no more than the amount of accrued wages earned; provision by a third party fully integrated with the employer; no consumer payment, voluntary or otherwise, beyond recovery of paid amounts via a payroll deduction from the next paycheck, and no other recourse or collection activity of any kind; and no underwriting or credit reporting.

The 2020 advisory opinion was silent about whether earned wage products that do not meet all of these conditions are credit under TILA and Regulation Z.[8] The opinion did not address what counts under TILA and Regulation Z as a finance charge with respect to any such product that is credit. As the CFPB has acknowledged, the 2020 advisory opinion appears to have caused significant regulatory uncertainty.[9]

The CFPB is taking a number of steps to spur greater competition in markets for consumer financial products, including to address the credit needs of households who incur costs due to a mismatch in the timing of their income and expenses. In addition, some market participants and investors seek to better understand the applicability of existing federal law in these emerging business models. To provide greater clarity, the CFPB is proposing to replace the 2020 advisory opinion with a new interpretive rule. In light of the uncertainty caused by the 2020 advisory opinion as noted above and the fact that the CFPB is proposing to overturn and replace that opinion, the CFPB is opting to publish this proposed interpretive rule to solicit public comment. The proposed interpretive rule is informed by the CFPB's extensive study of this market, including data collection, continuous monitoring, investigation, coordination with states, and engagement with market participants. The CFPB is seeking comment on any aspect of this this proposed interpretive rule. The CFPB intends to publish a final interpretive rule after considering comments received.

II. Proposed Interpretive Rule

The text of the proposed interpretive rule is as follows.

A. Coverage

1. Earned Wage Products

This interpretive rule applies to products that involve both: (1) the provision of funds to the consumer in an amount that is based, by estimate or otherwise, on the wages that the consumer has accrued in a given pay cycle; and (2) repayment to the third-party provider via some automatic means, like a scheduled payroll deduction or a preauthorized account debit,[10] at or after the end of the pay cycle. Many payday loans would also meet this definition where the lender or State law restricts the amount of the loan based on accrued wages.[11]

2. Other Products and Other Laws

This interpretive rule only addresses the application of certain Regulation Z and TILA provisions; it does not address the application of any other laws that concern ''credit.'' Because the rule explains the applicability of Regulation Z, the rule may be useful to designers and creators of other financial products, including those relying on ''tips'' and other related payment mechanisms.

B. Legal Analysis

1. The Truth in Lending Act and Regulation Z Cover Products Where There Is an Obligation to Repay Debt

Section 1026.2(a)(14) of Regulation Z defines ''credit'' as ''the right to defer payment of debt or to incur debt and defer its payment.'' [12] TILA defines ''credit'' virtually identically as ''the right granted by a creditor to a debtor to defer payment of debt or to incur debt

[5] *See 2024 Paycheck Advance Report, supra* note 2, at 4 n.7. Several recently enacted State laws prohibit providers of earned wage products, including direct-to-consumer products, from compelling consumer repayment of earned wage amounts and fees through various means, such as lawsuits or third-party debt collection. *See, e.g.,* 24 Mo. Rev. Stat. sec. 361.749(5)(6); Wis. Stat. sec. 203.04(2)(f); *cf.* Montana Op. Att'y Gen., Vol. 59, Op. 2 (Dec. 22, 2023) (finding earned wage products do not meet the state law definitions of ''consumer loan'' or ''deferred deposit loan'' when they are ''fully non-recourse,'' among other criteria).

[6] CFPB, *Truth in Lending (Regulation Z); Earned Wage Access Programs* (Nov. 2020), *https://files.consumerfinance.gov/f/documents/cfpb_advisory-opinion_earned-wage-access_2020-11.pdf* (hereinafter *2020 Advisory Opinion*).

[7] Regulation Z defines credit at § 1026.2(a)(14).

[8] The opinion stated that it had no application to such products. *See 2020 Advisory Opinion, supra* note 6, at 3–7.

[9] *See, e.g.,* Nat'l Consumer L. Ctr., Ctr. for Responsible Lending, *Concern About Prior Leadership's Finding that Certain Earned Wage Access Products Are Not ''Credit'' Under TILA,* Nat'l Consumer L. Ctr., Ctr. for Responsible Lending, at 36–37 (Oct. 12, 2021), *https://www.responsiblelending.org/sites/default/files/nodes/files/research-publication/crl-nclc-ewa-letter-to-cfpb-oct2021.pdf* (noting ''chaos'' and ''further questions'' caused by advisory opinions); U.S. Gov't Accountability Off., *GAO–23–105536, Financial Technology: Products Have Benefits and Risks to Underserved Consumers, and Regulatory Clarity is Needed,* at 36–37 (Mar. 2023), *https://www.gao.gov/assets/gao-23-105536.pdf* (citing industry requests for clarification). The CFPB has acknowledged the need for clarification in this area. *See, e.g.,* Letter from CFPB Director Rohit Chopra (Feb. 13, 2023) in U.S. Gov't Accountability Off., *supra,* at 51; Letter from CFPB Acting General Counsel to N.J. Citizen Action, *et al.,* at 2 (Jan. 18, 2022).

Problematically, the 2020 advisory opinion has been widely cited in support of legal conclusions that it did not reach. For example, it has erroneously been cited for the general propositions that no-fee earned wage products are not credit, *see, e.g.,* Ariz. Op. Att'y Gen. No. I22–005 (Dec. 16, 2022), *https://www.azag.gov/sites/default/files/2022-12/I22-005.pdf,* and that employer-partnered earned wage products are also not credit, *see, e.g.,* ZayZoon, Comment Letter on Cal. Dep't of Fin. Prot. & Innovation re: Notice of Proposed Rulemaking [PRO 01–21], at 4 (May 17, 2023), *https://dfpi.ca.gov/wp-content/uploads/sites/337/2023/08/46-PRO-01-21-ZayZoon-US-Inc.-5.17.23_Redacted.pdf;* Innovative Payments Ass'n, Comment Letter on Cal. Dep't of Fin. Prot. & Innovation re: Notice of Proposed Rulemaking [PRO 01–21], at 4 (May 11, 2023), *https://dfpi.ca.gov/wp-content/uploads/sites/337/2023/08/10-PRO-01-21-Innovative-Payments-Association-5.11.23_Redacted.pdf.* Some regulatory uncertainty may have resulted from the near-contemporaneous issuance of a ''Sandbox Approval Order'' that gave one provider a temporary safe harbor from liability under TILA and Regulation Z with respect to a specific product that did not satisfy all the conditions that the 2020 advisory opinion identified as taking such a product outside the reach of TILA and Regulation Z. *See* CFPB, *Payactiv Approval Order,* at 5 (Dec. 30, 2020), *https://files.consumerfinance.gov/f/documents/cfpb_payactiv_approval-order_2020-12.pdf.* The 2020 advisory opinion applied only to products that had all of a number of characteristics, including that they were free to consumers. In contrast, the approval order encompassed earned wage transactions in connection with which the consumer incurred fees. *See id.* The approval order was issued under a CFPB policy that is no longer in effect. *See generally* CFPB, *Statement on Competition and Innovation* (Sept. 30, 2022), *https://files.consumerfinance.gov/f/documents/cfpb_statement-on-competition-innovation_2022-09.pdf.* However, that approval order was never of general interpretative applicability, *see Payactiv Approval Order, supra,* at 4 n.15, and was terminated even before its temporary status expired, CFPB, *CFPB Rescinds Special Regulatory Treatment for Payactiv* (June 30, 2022), *https://www.consumerfinance.gov/about-us/newsroom/cfpb-rescinds-special-regulatory-treatment-for-payactiv/.*

[10] This includes repayment via ACH, check, or any other preauthorized repayment.

[11] This interpretive rule does not apply to an employer's actual payment of wages. Note that while the terms ''employer'' and ''employee'' are used throughout, this interpretive rule applies more broadly to situations where consumers receive payment for work performed.

[12] 12 CFR 1026.2(a)(14).

and defer its payment.'' [13] As described further below, earned wage products are consumer credit for purposes of TILA and Regulation Z.

TILA and Regulation Z do not define ''debt.'' Used infrequently in the statute and the regulation, ''debt'' for the most part only appears in the definition of ''credit.'' The term ''debt'' in ordinary usage means simply ''something owed,'' without any obvious limitation.[14] Legal dictionaries, including those dating to the enactment of TILA,[15] similarly describe debt as a ''sum of money due by certain and express agreement'' or ''a financial liability or obligation owed by one person, the debtor, to another, the creditor.'' [16] If Congress had intended to substantially narrow the types of transactions that could constitute ''debt,'' it could have done so by defining the term in TILA.[17] In light of this precedent, and the context in which the term ''debt'' appears in TILA, ''debt'' in TILA and Regulation Z includes any obligation by a consumer to pay another party.

This commonsense understanding of debt is reflected in State laws [18] defining the term, which also tend to use very broad language to describe debt to mean an obligation by the consumer to pay.[19] Bankruptcy law also uses a broad definition—''liability on a claim,'' where a ''claim'' is ''the right to payment, whether or not such right is reduced to judgment, liquidated, unliquidated, fixed, contingent, matured, unmatured, disputed, undisputed, legal, equitable, secured, or unsecured.'' [20]

The only enumerated consumer financial law identified in the Consumer Financial Protection Act [21] that defines ''debt,'' the Fair Debt Collection Practices Act (FDCPA), broadly states that debt encompasses ''any obligation or alleged obligation of a consumer to pay money arising out of a transaction in which the money, property, insurance, or services which are the subject of the transaction are primarily for personal, family, or household purposes, whether or not such obligation has been reduced to judgment.'' [22] The main limiting feature in the definition of ''debt'' in the FDCPA is that it is limited to transactions for personal, family, or household purposes, a limitation already imposed elsewhere in TILA.[23] The FDCPA definition, therefore, also supports a broad reading of ''debt'' under TILA and Regulation Z in this context, consistent with ordinary usage that includes all obligations to pay another.

In an earned wage transaction, the consumer incurs an obligation to pay money at a future date. For some earned wage products, the specific amount of money that the consumer is obligated to pay at a future date has an element of contingency; for example, the obligation may be limited by whether funds available from the next payroll event (or events) are sufficient to cover the amount of earned wage funds the consumer received. But that is still an obligation to pay money at a future date. TILA has long been understood to cover contingent obligations.[24]

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[13] 15 U.S.C. 1602(f).

[14] *Debt,* Merriam-Webster, *https://www.merriam-webster.com/dictionary/debt* (last updated Jan. 30, 2024).

[15] *See New Prime Inc.* v. *Oliveira,* 586 U.S. 105, 113 (2019) (''It's a fundamental canon of statutory construction that words generally should be interpreted as taking their ordinary meaning at the time Congress enacted the statute.'') (cleaned up).

[16] *Debt,* Black's Law Dictionary (4th ed. 1968) (defining debt as ''[a] sum of money due by certain and express agreement; as by bond for a determinate sum, a bill or note, a special bargain, or a rent reserved on a lease, where the amount is fixed and specific, and does not depend upon any subsequent valuation to settle it.''); *Debt,* Wex, *https://www.law.cornell.edu/wex/debt* (last updated Sept. 2021).

[17] As the Court observed in *Whitman* v. *Am. Trucking Ass'ns,* ''Congress, we have held, does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes.'' 531 U.S. 457, 468 (2001).

[18] *See* 12 CFR 1026.2(b)(3) (providing interpretive guidance with respect to undefined terms). As the Board of Governors of the Federal Reserve System noted when it first proposed § 1026.2(b)(3), the provision and its fellow rules of construction ''are intended to assist in understanding the regulatory language.'' 45 FR 29702, 29705 (May 5, 1980).

[19] *See, e.g.,* Cal. Civ. Code sec. 1788.2(d) (''The term 'debt' means money, property, or the equivalent that is due or owing or alleged to be due or owing from a natural person to another person.''); Colo. Rev. Stat. Ann. sec. 5–16–103(8)(a) (''Debt' means any obligation or alleged obligation of a consumer to pay money arising out of a transaction, whether or not the obligation has been reduced to judgment.''); D.C. Code Ann. sec. 28–3814(b)(2) (''Consumer debt' means money or its equivalent, or a loan or advance of money, which is, or is alleged to be, more than 30 days past due and owing, unless a different period is agreed to by the consumer, as a result of a purchase, lease, or loan of goods, services, or real or personal property for personal, family, medical, or household purposes.''); Fla. Stat. Ann. sec. 559.55(6) (''Debt' or 'consumer debt' means any obligation or alleged obligation of a consumer to pay money arising out of a transaction in which the money, property, insurance, or services which are the subject of the transaction are primarily for personal, family, or household purposes, whether or not such obligation has been reduced to judgment.''); Haw. Rev. Stat. Ann. sec. 480D–2 (''Debt' means any obligation or alleged obligation of a person to pay money arising out of any transaction, whether or not the obligation has been reduced to judgment.''); Me. Rev. Stat. tit. 32, sec. 11002(5) (''Debt' means any obligation or alleged obligation of a consumer to pay money arising out of a transaction in which the money, property, insurance or services that are the subject of the transaction are primarily for personal, family or household purposes, whether or not the obligation has been reduced to judgment.''); N.H. Rev. Stat. Ann. sec. 358–C:1(VI) (''Debt' means any obligation or alleged obligation arising out of a consumer transaction.''); N.M. Stat. Ann. sec. 61–18A–2(F) (''[D]ebt' means an obligation or alleged obligation of a debtor to pay money arising out of a transaction in which the money, property, insurance or services that are the subject of the transaction are primarily for personal, family or household purposes, whether or not such obligation has been reduced to judgment.''); N.Y. Gen. Bus. Law sec. 600(6) (''Debt' means any obligation or alleged obligation of a consumer to pay money arising out of a transaction in which the money, property, insurance, or services which are the subject of the transaction are primarily for personal, family, or household purposes, whether or not such obligation has been reduced to judgment.''); N.D. Cent. Code Ann. sec. 13–05–01.1(6) (''Debt' means an obligation or alleged obligation to pay money arising out of a transaction, regardless of whether the obligation has been reduced to a judgment.''); Or. Rev. Stat. Ann. sec. 646.639(f) (''Debt' means an obligation or alleged obligation that arises out of a consumer transaction.''); 19 R.I. Gen. Laws Ann. sec. 19–14.9–3(4) (''Debt' means any obligation or alleged obligation of a consumer to pay money arising out of a transaction in which the money, property, insurance, or services that are the subject of the transaction are primarily for personal, family, or household purposes, whether or not the obligation has been reduced to judgment.''); Tex. Fin. Code Ann. sec. 392.001(2) (''Consumer debt' means an obligation, or an alleged obligation, primarily for personal, family, or household purposes and arising from a transaction or alleged transaction.''); Utah Code Ann. sec. 12–1–11(1)(b) (''Debt' means an obligation or alleged obligation to pay money arising out of a transaction for money, property, insurance, or services.''); Wash. Rev. Code Ann. sec. 6.01.060(2) (''Consumer debt' means any obligation or alleged obligation of a consumer to pay money arising out of a transaction in which the money, property, insurance, or services which are the subject of the transaction are primarily for personal, family, or household purposes.''); Wyo. Stat. Ann. sec. 33–11–101(a)(vii) (''Debt' means any obligation or alleged obligation of a consumer to pay money arising out of a transaction in which the money, property, insurance or services which are the subject of the transaction are primarily for personal, family or household purposes, whether or not the obligation has been reduced to judgment.'').

[20] 11 U.S.C. 101(5)(A), (12). Bankruptcy law defines ''consumer debt'' as ''debt incurred by an individual primarily for a personal, family, or household purpose.'' 11 U.S.C. 101(8).

[21] 12 U.S.C. 5481(12).

[22] 15 U.S.C. 1692a(5); *see also* 12 CFR 1006.2(h); *Pollice* v. *Nat'l Tax Funding,* 225 F.3d 379, 410 (3d Cir. 2000) (''Although [TILA] does not contain a definition of the term 'debt,' we believe the term as used in [TILA] should be construed as it is defined in the FDCPA.''). Like TILA, the Consumer Financial Protection Act and Equal Credit Opportunity Act, for example, use the term ''debt'' in their definitions of ''credit'' without defining it. *See* 12 U.S.C. 5481(7); 15 U.S.C. 1691a(d).

[23] 15 U.S.C. 1602(g), (i).

[24] *See, e.g., Madewell* v. *Marietta Dodge, Inc.,* 506 F. Supp. 286 (N.D. Ga. 1980) (retail installment contract for purchase of automobile subject to TILA even though contingent on seller's ability to arrange financing); *Bailey* v. *Comm'r of Internal Revenue,* 993 F.2d 288, 292 (2d Cir. 1993) (discussing ''[n]onrecourse debt''); 12 CFR 1026.33(a) (reverse mortgages—where repayment is contingent on future home value at the time of a termination event, such as the death of the borrower—subject to TILA as credit); *cf.* Small Business Lending Under the Equal Credit Opportunity Act (Regulation B), 88 FR 35150, 35163 (May 31, 2023) (explaining that merchant cash advances—under which a provider offers a merchant a lump sum in

Earned wage products provide consumers with ''the right to defer payment of debt or to incur debt and defer its payment'' because they incur a ''debt'' when they obtain money with an obligation to repay via an authorization to debit a bank account or using one or more payroll deductions.[25] It does not matter that the obligation to repay is sometimes satisfied via payroll deduction.[26] It is still an act of repayment. In contrast, when an employer pays wages, no later act of repayment is required, by deduction or otherwise.

This interpretive rule replaces the advisory opinion the CFPB issued in November 2020, which stated that some earned wage products are not ''credit'' because they would not constitute a ''debt.'' [27] A primary justification for this statement, based on a legal dictionary definition of ''debt'' requiring a ''liability,'' was that the narrow type of earned wage products covered by that opinion—which, among other characteristics, were administered through the employer and cost-free to the consumer—were ''effectively'' providing earned wages to consumers early and, therefore, were not debts. Per the analysis above, the 2020 advisory opinion—narrowly focused as it was on one unique type of product—did not consider the full scope of available precedent and definitions in common legal usage when reaching its narrow conclusion.[28] Many credit products are used to gain liquidity in advance of receipt of a paycheck and thus will have some *de facto* resemblance to early payment of wages, but that does not take them outside the definition of credit. Earned wage products, as distinct from an employer's actual payment of wages, are no exception.[29]

Moreover, because the 2020 advisory opinion only addressed one particular type of product, its analysis does not shed light on how TILA and Regulation Z apply to new offerings on the market. The 2020 advisory opinion found that the products it addressed ''functionally operate[ ] like an employer that pays its employees earlier than the scheduled payday,'' but earned wage products in which, for example, consumers make a payment in connection with receiving funds do *not* leave consumers in the same position that they would be if their employer just paid them earlier. While the 2020 advisory opinion emphasized the absence of fees or charges to support its conclusion that covered products were different in kind from the credit covered by TILA and Regulation Z, except on a small number of employer-specific products, the vast majority of earned wage transactions involve consumer payment.[30]

2. Finance Charge Disclosures Include Consumer Payments That Are Made Incident to the Extension of Credit and Imposed by the Creditor Directly or Indirectly on the Consumer

a. General

In general, the obligations of Regulation Z apply to any credit provider that regularly offers or extends consumer credit subject to a finance charge.[31] The finance charge is ''the cost of consumer credit as a dollar amount.'' [32] Unless specifically excluded by the regulation, this includes ''any charge payable directly or indirectly by the consumer and imposed directly or indirectly by the creditor as an incident to or a condition of the extension of credit.'' [33] If providers do not disclose finance charges properly, they violate Regulation Z.

Neither Regulation Z nor TILA further explains the meaning of ''incident to the extension of credit.'' The statute's history and context indicate that Congress intended this term to be interpreted expansively. When TILA was enacted in 1968, Black's Law Dictionary defined ''incident'' to mean ''anything which is usually connected with another, or connected for some purposes, though not inseparably.'' [34] The phrase ''incident to the extension of credit'' thus did not require that the degree of connection be significant. The Supreme Court, in a unanimous decision by Justice Thomas, noted in the context of TILA's finance charge

exchange for a specific portion of the merchant's proceeds from future sales of goods and services—are credit, notwithstanding that the repayment obligation may be contingent on the merchant's future sales); Consent Order, *In re Better Future Forward, Inc.,* Admin. Proceeding No. 2021–CFPB–005 (Sept. 7, 2021) (identifying as credit income share agreements, which ''finance postsecondary education'' whereby ''[i]n exchange for money up front, students agree that once their income exceeds an income threshold, they will make payments based on a percentage of their income until either: (i) they meet a payment cap or (ii) a period of years elapses.'').

[25] Earned wage products are offered or extended to consumers primarily for personal, family, or household purposes, so they also meet the Regulation Z definition of ''consumer credit.'' 12 CFR 1026.2(a)(12).

[26] It is not uncommon for credit providers to compel repayment of debt using wage garnishment automatically deducted from consumer paychecks. Payday lenders are sometimes repaid through court-ordered wage garnishment. *See* CFPB, *Ask CFPB: Can a Payday Lender Garnish My Bank Account or My Wages?* (last reviewed Sept. 23, 2022), *https://www.consumerfinance.gov/ask-cfpb/can-a-payday-lender-garnish-my-wages-en-1609/.* Consumers may pay some lenders directly by paycheck allotment. *Cf.* 12 CFR part 1026, supplement I, comment 2(a)(14)–2 (''Credit includes a transaction in which a cash advance is made to a consumer . . . in exchange for the consumer's authorization to debit the consumer's deposit account, and where the parties agree . . . that the consumer's deposit account will not be debited, until a designated future date.'').

[27] *See 2020 Advisory Opinion, supra* note 6.

[28] The 2020 advisory opinion stated that there would not be a ''liability.'' That word is not used in all dictionary definitions of the term ''debt,'' and regardless, the earned wage product did require repayment.

[29] The CFPB also noted that the 2020 advisory opinion would be consistent with 12 CFR part 1026, supplement I, comment 2(a)(14)–A31JY2.1.v. *See 2020 Advisory Opinion, supra* note 6, at 9. However, that comment was promulgated as an exclusion from the definition of ''credit'' after notice and comment, which suggests that the product would be subject to TILA and Regulation Z but for the exclusion. Products similar to products in the exclusion, but not covered by the exclusion, should therefore be presumed to be ''credit.''

In the 2020 advisory opinion, the CFPB also noted that its interpretation was consistent with certain statements in the CFPB's 2017 Payday Lending Rule. However, the Payday Rule did not make a determination as to whether earned wage products are credit, stating only that some product constructs ''may not be.'' The CFPB declined to perform the more detailed analysis necessary to come to a considered conclusion on the boundaries of TILA and Regulation Z at that time because that was not necessary for the rulemaking exercise. It is performing that analysis now, in this interpretive rule. Some earned wage products may not be covered by the Payday Rule because of its ''wage advance'' and ''no cost advance'' exclusions. *See* 12 CFR 1041.3(d)(7) and (8). However, these exclusions can only apply to earned wage products to the extent that such products are TILA and Regulation Z credit. As a result, the CFPB's earlier decision to exclude certain earned wage product constructs from the Payday Rule has no impact on the credit status of such products under TILA or Regulation Z.

[30] *See, e.g., 2024 Paycheck Advance Report, supra* note 2, at 11 (''Without employer subsidization, across both years in our [employer-partnered earned wage] sample, around 90% of workers paid at least one fee and approximately 82% of transactions incurred a fee.''); Cal. Dep't of Fin. Prot. & Innovation, *2021 Earned Wage Access Data Findings,* at 7 (2023), *https://dfpi.ca.gov/wp-content/uploads/sites/337/2023/03/2021-Earned-Wage-Access-Data-Findings-Cited-in-ISOR.pdf* (''In 2021, for the 5,827,120 transactions completed by tip-based companies, providers received tips 73% of the time.''). To the extent the interpretation underlying the 2020 Payactiv approval order articulated a different rationale regarding fees or charges for earned wage transactions, the CFPB no longer believes that interpretation is correct.

[31] *See* 12 CFR 1026.1(c)(1)(iii). Note that finance charges are not a necessary precondition for the obligations of Regulation Z to apply to a provider of Regulation Z credit. For example, the requirements of Regulation Z will apply where the provider regularly offers or extends consumer credit that is payable by a written agreement in more than four installments, even if the credit provided is not subject to finance charges. *See id.* As another example, certain Regulation Z requirements apply when the offering or extension of consumer credit involves a credit card, even if the credit is not subject to a finance charge. *See* 12 CFR 1026.1(c)(2). This interpretive rule does not state any view about grounds on which an earned wage provider of Regulation Z credit might be subject to Regulation Z obligations other than due to their provision of credit subject to a finance charge.

[32] 12 CFR 1026.4(a).

[33] *Id.*

[34] *Incident,* Black's Law Dictionary (4th ed. 1968).

provision that while ''the phrase 'incident to or in conjunction with' implies some necessary connection between the antecedent and its object . . . the phrase 'incident to' does not make clear whether a substantial (as opposed to a remote) connection is required.'' [35] Thus, while a substantial connection may not be the minimum degree of connection required under Regulation Z and TILA for a payment to be part of the consumer's cost of credit, as an interpretive matter, any payment exacted by the creditor that *is* substantially connected must be part of the finance charge.[36]

In addition, a payment may be ''imposed directly or indirectly by the creditor'' and hence part of the finance charge even if the credit can be obtained without making such payment. Regulation Z includes in the cost of credit payments imposed by the creditor that are ''conditions of'' the extension of credit and that are ''incident to'' it.[37] By the same token, a creditor can ''impose'' a cost on a consumer—in the sense of exacting it from them—''directly or indirectly'' even if that payment is not required for the extension of credit.[38] The non-exhaustive list of finance charges provided in Regulation Z includes consumer payments that, even when they are not a condition of the extension of credit, are nonetheless finance charges because the creditor exacts them in connection with the extension of credit.[39]

Two costs that consumers may incur in connection with particular extensions of earned wage credit are ''tips'' (and other similarly labeled payments, like ''gratuities'') and expedited funds delivery fees. When incurred, these payments are substantially connected to the extension of credit. Each happens because of the associated extension of credit, and the connection between each type of payment and that extension is close and clear. Thus, each is incident to the extension of credit. Expedited funds delivery fees are also ''imposed directly or indirectly by the creditor'' and so should be included as part of the ''cost of consumer credit as a dollar amount.'' Under certain circumstances, discussed further below, ''tips'' and similarly styled consumer payments may similarly be ''imposed directly or indirectly by the creditor'' such that they are a part of the finance charge.

b. Expedited Funds Delivery Fees

Speed of access to funds is an integral and defining aspect of earned wage products. They are designed to address—and marketed as addressing—the liquidity problem that arises between the accrual of wages and their actual payment. That problem necessarily occurs in a very short period,[40] so the value of this type of credit to the consumer includes the rapid availability of funds. Thus, when earned wage product providers offer two speeds for delivering funds (which they typically do), consumers predominantly opt for the faster.[41] That option typically involves direct imposition of an expedited delivery or ''instant funds'' fee that the creditor does not impose on the slower form of credit.

Availability of a slower speed does not control the cost of credit for the faster form of credit. Though consumers may not have to opt for faster funds, when they do so, the resulting speed is a feature of the credit extended, so the resulting fee is part of the cost of credit. As observed by the Board of Governors of the Federal Reserve System, ''even though a lender may not require a particular loan feature, the feature may become a term of the credit if it is included.'' [42] The speed with which earned wage credit provides liquidity to the consumer is an integral feature of such credit, which is why consumers tend to opt for faster delivery when it is available. Thus, when the consumer pays for that faster delivery, the associated fee is immediately and directly connected to the particular extension of credit. That substantial connection makes this ''a fee imposed as an incident to that particular extension of credit,'' and accordingly one that must be disclosed as part of the finance charge.[43]

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[35] *Household Credit Servs., Inc.* v. *Pfennig,* 541 U.S. 232, 240–41 (2004). In *Pfennig,* the Supreme Court held that an overlimit fee was not unambiguously imposed as an incident to the extension of credit because it could reasonably be seen as a penalty for violation of the credit agreement instead. *See id.* at 239–41. The Court recognized that ''regardless of how the fee is characterized,'' there was ''at least some connection'' between the fee and credit extension, but that was not enough to conclude that the fee was necessarily imposed as an ''incident to'' credit because the term ''does not make clear whether a substantial (as opposed to a remote) connection is required.'' *Id.* at 241.

[36] This interpretive rule does not seek to establish the degree of connection required beyond interpreting ''incident to'' to cover charges that are substantially connected to a particular extension of credit.

[37] TILA's definition of finance charge only references charges imposed ''as an incident to the extension of credit.'' 15 U.S.C. 1605(a). The Board's implementing regulation then interprets the statutory term ''incident to'' as encompassing—while not being limited to—payments that are conditions of the extension of credit. *See* 12 CFR 1026.4(a). This interpretation has been in uninterrupted effect since the Board first adopted TILA regulations on point.

[38] TILA's history and context indicate that Congress intended the word ''imposed'' to be interpreted broadly to encompass a variety of charges the creditor might seek to have a consumer pay in connection with the extension of credit. The finance charge definition uses parallel language: the charges are ''payable directly or indirectly by'' the consumer, and ''imposed directly or indirectly by'' the creditor. The structure of the provision thus uses ''imposed'' as a counterpoint to ''payable,'' so as to identify the party doing the charging as opposed to the party being charged. Similarly, the 1968 Black's Law Dictionary definition of ''impose''—''to levy or exact as by authority; to lay as a burden, tax, duty, or charge''—emphasizes the deployment of power by the party doing the imposing. *Impose,* Black's Law Dictionary (4th ed. 1968). As the Board previously noted, ''the term 'imposed' is understood broadly, to include any cost charged by the creditor (unless otherwise excluded).'' 60 FR 66179, 66180 (Dec. 21, 1995). *See also, e.g., Impose,* Merriam-Webster, *https://www.merriam-webster.com/dictionary/impose* (last updated Feb. 9, 2024) (defining ''impose'' with a range of meanings, from ''to establish or apply by authority'' to ''to establish or bring about *as if* by force'' to simply ''pass off'' (emphasis added)).

[39] *See* 12 CFR 1026.4(b); *see also* 61 FR 49237, 49239 (Sept. 19, 1996) (explaining that payments for services that the creditor does not require can still be finance charges when the payment is ''imposed as an incident to that particular extension of credit''); *cf. Incident,* Black's Law Dictionary (11th ed. 2019) (defining ''incident'' as ''[d]ependent upon, subordinate to, arising out of, or otherwise connected with (something else, usu. of greater importance)'').

[40] To obtain earned wage credit, consumers must first accrue wages within a given pay period. Repayment then occurs at or very shortly after the conclusion of that same pay period. As a result, the duration of any particular earned wage credit extension has to be very brief.

[41] *See 2024 Paycheck Advance Report, supra* note 2, at 11. For the sample of employer-partnered providers covered in the CFPB's 2024 Report, expedited delivery fees accounted for more than 96.6 percent of all consumer-paid fee revenue by dollar value. *See id.* Public data also indicates that earned wage advance providers relying on a tipping revenue model obtain more than 25 percent of the dollar value of consumer payments as expedited delivery fees. *See* Cal. Dep't of Fin. Prot. & Innovation, *supra* note 30, at 6 n.11, 7.

[42] 61 FR 49237, 49239 (Sept. 19, 1996). The expedite fee at issue here differs in kind from the two types of expedite fees previously considered by the Board of Governors of the Federal Reserve System in the context of credit cards accessing home equity lines of credit: a fee for expediting delivery of the physical card, and a fee for expediting a consumer's payment. *See* 12 CFR part 1026, supplement I, comments 6(a)(2)–2(ix) and (x). The Board determined that fees for those services did not need to be included in account opening disclosures as ''other charges'' or ''finance charges.'' *See* 68 FR 16185, 16186–87 (Apr. 3, 2003). Neither of those services—faster possession of a physical card or faster payments of amounts outstanding—are as closely and integrally connected to the extension of credit as faster funds access is to obtaining an earned wage product.

[43] *Cf.* 61 FR 49237, 49239 (Sept. 19, 1996) (noting with respect to debt cancellation fees that ''[a]lthough the same loan may be available without that feature, with respect to a loan that has been structured in this manner, the . . . fee is one that has been imposed as an incident to that particular extension of credit''). Before this clarification from the Board, the Eleventh and Seventh Circuits had held that charges for optional services should not be considered finance charges because the consumer assumed their payment voluntarily. *See Veale* v. *Citibank,* 85 F.3d 577, 579–81 (11th Cir. 1996); *McGee* v. *Kerr-Hickman,* 93 F.3d 380, 381–86 (7th Cir. 1996). The CFPB sees no textual basis

Regulation Z also covers expedited delivery fees as finance charges because such a fee is a ''condition'' of an extension of credit. As noted above, when an earned wage product provider offers a slower and faster loan, and the faster loan requires payment of an expedited delivery fee, the expedited delivery fee is a ''condition'' of the extension of that type of credit.

c. ''Tips'' and Similarly Labeled Payments

In connection with the extension of earned wage credit, some providers solicit consumers for what they variously describe as ''tips,'' ''gratuities,'' ''donations,'' ''voluntary contributions,'' or the like. The CFPB is aware of a wide range of practices used by credit providers to solicit these kinds of payments from consumers, including: default ''tip'' amounts that the consumer must remove each time to avoid being charged; suggesting particular ''tip'' amounts or percentages; suggesting or stating that ''tips'' serve to ensure the future supply of credit to the individual or other users; and including multiple prompts to ''tip'' throughout the process of receiving credit.

Whatever the exact practice used, when such ''tip'' payments are solicited and then paid in connection with the extension of credit, there is a clear and close connection between the ''tip'' and the associated extension of credit. In such circumstances, consumers pay the ''tip'' for the credit extended, and the credit is the direct and proximate cause of the ''tip.'' [44] That substantial connection between payment and associated extension of credit means that the payment is ''incident to . . . the extension of credit.'' [45] Indeed, as a practical matter, tips are a central source of revenue for the earned wage product providers that solicit them. For such providers, public data shows that consumers made ''tip'' payments in connection with about 73 percent of all such credit extensions, with such payments representing roughly the same share of consumer-side revenue for these providers.[46]

As explained above, a payment may be ''imposed directly or indirectly by the creditor'' and hence may be part of the finance charge even if the credit can be obtained without making the payment.[47] Under certain circumstances, ''tips'' and similarly styled consumer payments may be ''imposed directly or indirectly by the creditor'' such that they are part of the finance charge. A provider using its authority—real or implied—to exact a ''tip'' from a consumer in connection with an earned wage transaction has ''imposed'' the resulting consumer payment.[48] Relevant considerations when determining whether a ''tip'' or similar payment is imposed by the creditor as part of the finance charge include but are not limited to: soliciting a ''tip'' before or at the time of a credit extension (rather than some significant time after it); labeling the solicited payment with a term (such as ''tip'') that carries an expectation that the consumer will make such a payment in the normal course; setting default ''tip'' amounts or otherwise making it practically more difficult for the consumer to avoid leaving a ''tip''; suggesting ''tip'' amounts or percentages to the consumer; repeatedly soliciting ''tips,'' even in the course of a single transaction; and stating or otherwise implying, directly or indirectly, truthfully or otherwise, that ''tipping'' may impact subsequent access to or use of the product.[49]

III. Regulatory Matters

This is a proposed interpretive rule issued under the CFPB's authority to interpret TILA and Regulation Z, including under section 1022(b)(1) of the Consumer Financial Protection Act of 2010, which authorizes guidance as may be necessary or appropriate to enable the CFPB to administer and carry out the purposes and objectives of Federal consumer financial laws.[50] While not required under the Administrative Procedure Act (APA), the CFPB is soliciting comments on the proposal and may make revisions when it issues a final interpretive rule as appropriate in light of feedback received.

By operation of TILA section 130(f), no provision of TILA sections 130, 108(b), 108(c), 108(e), or section 112 imposing any liability would apply to any act done or omitted in good faith in conformity with the final interpretive rule, notwithstanding that after such act or omission has occurred, the final interpretive rule is amended, rescinded, or determined by judicial or other authority to be invalid for any reason.[51]

The CFPB has determined that this proposed interpretive rule, if finalized, would not impose any new or revise any existing recordkeeping, reporting, or disclosure requirements on covered entities or members of the public that would be collections of information requiring approval by the Office of Management and Budget under the Paperwork Reduction Act.[52]

Rohit Chopra,

Director, Consumer Financial Protection Bureau.

[FR Doc. 2024–16827 Filed 7–30–24; 8:45 am]

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in the regulation (or statute) to disagree with the Board's considered 1996 position on payment for voluntary services. As the Board discerned, it does not matter that it is possible to obtain credit without the relevant service if the service is a feature of the loan affecting the total price paid for the credit.

[44] Such payments are not tips or gratuities in any traditional sense. Consumers generally pay tips to individual workers in the service industry, not to firms (whether partnered with the employer or otherwise) for lending them money. Providers should exercise care in ensuring that the language they use here is not deceptive.

[45] *See supra* note 35.

[46] *See* Cal. Dep't of Fin. Prot. & Innovation, *supra* note 30, at 1, 7.

[47] As explained above, payments that are not required as a condition of the credit but are nonetheless incident to it can be ''imposed directly or indirectly by the creditor.'' Including only ''conditions of'' the extension of credit in the finance charge would improperly read ''incident to'' out of Regulation Z's definition of finance charge, and a creditor can ''impose'' a cost on a consumer even if the cost is not required for the extension of credit.

[48] A consumer's reasonable understanding that a provider expects a ''tip'' in connection with a transaction is evidence that the provider exacts it as if by authority. This kind of reasonable understanding does not depend on whether ''tipping'' impacts the supply of credit to the consumer now or in the future.

[49] The presence or absence of one or all of these considerations may not be determinative. The importance and relevance of these and other considerations will vary in the context of a particular product and how it is offered or provided to consumers.

[50] 12 U.S.C. 5512(b)(1).

[51] 15 U.S.C. 1640(f).

[52] 44 U.S.C. 3501–3521.

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

[CPSC Docket No. CPSC–2021–0015]

Banned Hazardous Substances: Aerosol Duster Products Containing More Than 18 mg in Any Combination of HFC–152a and/or HFC–134a

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The U.S. Consumer Product Safety Commission (Commission or CPSC) is proposing to declare that any aerosol duster products that contain more than 18 mg in any combination of HFC–152a and/or HFC–134a are banned hazardous substances under the Federal Hazardous Substances Act (FHSA). For the ten-year period from 2012 to 2021, CPSC is aware of more than 1,000 deaths, and estimates 21,700 treated injuries involving the inhalation of aerosol duster products. The proposed

rule addresses deaths and injuries associated with the propellants HFC–152a and HFC–134a used in aerosol duster products. The Commission is providing an opportunity for interested parties to submit written comments on this notice of proposed rulemaking (NPR).

DATES: Written comments must be received by September 30, 2024.

ADDRESSES:

Written Comments:

Comments related to the Paperwork Reduction Act aspects of the proposed rule should be directed to the Office of Information and Regulatory Affairs, OMB, Attn: CPSC Desk Officer, FAX: 202–395–6974, or emailed to *oira_submission@omb.eop.gov.*

Other written comments in response to the proposed rule, identified by Docket No. CPSC–2021–0015 may be submitted by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *www.regulations.gov.* Follow the instructions for submitting comments. CPSC typically does not accept comments submitted by email, except as described below. CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Mail/Hand Delivery/Courier/Written Submissions: Submit comments by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504–7479. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, courier, or you may email them to: *cpsc-os@cpsc.gov*.

Instructions: All submissions must include the agency name and docket number. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided to: *www.regulations.gov.* Do not submit through this website: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for mail/hand delivery/courier/written submissions.

Docket for NPR: For access to the docket to read background documents or comments received, go to: *www.regulations.gov,* insert the docket number CPSC–2021–0015 into the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Mary Kelleher, Directorate for Health Sciences, Consumer Product Safety Commission, National Product Testing and Evaluation Center, 5 Research Place, Rockville, MD 20850; telephone: 240–429–4894; *mkelleher@cpsc.gov.*

SUPPLEMENTARY INFORMATION: In this NPR, the Commission proposes to declare any aerosol duster canisters containing more than 18 mg of the hazardous chemicals HFC–152a and/or HFC–134a to be banned hazardous substances under the FHSA. From 2012 to 2021, inhalation of these products resulted in 1,039 known deaths and an estimated 21,700 emergency department (ED) treated injuries in the United States. Although aerosol duster products that do not contain these hazardous substances would likely be more expensive, over 30 years the proposed rule is projected to yield net benefits of nearly $2 billion, with more than 16 dollars of benefit for every dollar of cost. Furthermore, aerosol duster products will remain available and affordable alternatives such as electric dusters are also available.

I. Background

On April 2, 2021, Families United Against Inhalant Abuse (FUAIA) submitted a petition requesting that the Commission initiate rulemaking to adopt a mandatory safety standard to address the hazards associated with aerosol duster products used for cleaning electronics and other items containing the chemical 1,1-difluorethane, or any derivative thereof. The petition requested CPSC conduct rulemaking to address the numerous deaths and injuries associated with inhalant abuse of aerosol duster products. Specifically, the petition requested a performance standard requiring that manufacturers add an aversive agent (bitterant other than denatonium benzoate) to all duster aerosol products at a level of 30–40 ppm, and it requested a required warning stating: ''DANGER: DEATH—This product can kill you if you breath [sic] it.'' [1]

On June 29, 2021, the Commission published in the **Federal Register** a request for comments on the petition. 86 FR 34171. On July 20, 2022, staff submitted a briefing package to the Commission regarding the petition.[2] On July 26, 2022, the Commission voted to defer action on the petition to allow staff to conduct further research.[3] On July 26, 2023, staff submitted an updated briefing package to the Commission regarding the petition.[4] The Commission granted the petition on August 1, 2023, directing staff to initiate rulemaking to address the inhalation hazard associated with aerosol duster products.[5]

II. Statutory Authority

This rulemaking is conducted under the provisions of the FHSA and the Consumer Product Safety Act (CPSA). 15 U.S.C. 1261–1278; 15 U.S.C. 2058. The rulemaking proposal involves two elements. First, pursuant to sections 2(f)(1)(A), 2(q)(1)(B), and 3 of the FHSA, the Commission is proposing to ban any aerosol duster product containing more than 18 mg of either of two hydrofluorocarbon propellants—1,1-difluoroethane (HFC–152a, CAS # 75–37–6) and 1,1,1,2-tetrafluoroethane (HFC–134a, CAS # 811–97–2)—or of a combination of these propellants. 15 U.S.C. 1261(f)(1)(A), (q)(1)(B), 1262 (proposed 16 CFR 1500.17(a)(14)). Second, to prevent circumvention of the proposed ban, pursuant to section 9(g)(2) of the CPSA, the Commission is proposing a stockpiling prohibition that would prohibit a manufacturer from stockpiling banned aerosol duster products containing above the specified amount of HFC–152a and/or HFC–134a that are subject to the proposed ban. 15 U.S.C. 2058(g)(2).

More specifically, the Commission is proposing to declare that any aerosol duster canister containing more than 18 mg of HFC–152a and/or HFC–134a to be a ''hazardous substance'' and a ''banned hazardous substance'' within the meaning of sections 2(f)(1)(A) and

[1] The petition is available at *https://www.cpsc.gov/Regulations-Laws--Standards/Rulemaking/Petitions.* The petitioner also requested that CPSC require retailers to limit multiple duster can purchases during a one-month time period; the Commission, however, explained that it does not have rulemaking authority over such personal purchasing decisions. 86 FR 34171, n.1 (June 29, 2021).

[2] *www.cpsc.gov/s3fs-public/Petition-Requesting-Rulemaking-to-Establish-Safety-Standard_0.pdf?VersionId=GNEl7pYZUBOxf1BLSC0f4.X6TlA8gT4f.*

[3] *www.cpsc.gov/s3fs-public/RCA-Petition-Requesting-Rulemaking-to-Establish-Safety-Standard-for-Aerosol-Dusters-Products-Petition-CP-21-1.pdf?VersionId=uD1mraIGCZcjBd9xiyZsanVRbngVzUvP.*

[4] *www.cpsc.gov/s3fs-public/Petition-Requesting-Rulemaking-to-Establish-Safety-Standard-for-Aerosol-Duster-Products-Petition-CP-21-1.pdf?VersionId=.NohA6DG6WsXh_tsjhGuA7RuqMCOvxSW.*

[5] *www.cpsc.gov/s3fs-public/RCAPetitionRequestingRulemakingtoEstablishSafetyStandardforAerosolDusterProductsPetitionCP21_1.pdf?VersionId=nQcgEM4wvCJE97zmhwYCdAkwuluYerIt.*

(q)(1)(B) of the FHSA.[6] 15 U.S.C. 1261(f)(1)(A), (q)(1)(B). Section 2(q)(1)(B) of the FHSA defines a ''banned hazardous substance'' to include any hazardous substance intended, or packaged in a form suitable, for household use which, notwithstanding the precautionary labeling required by the FHSA, presents such a hazard that keeping the substance out of interstate commerce is the only adequate means to protect the public health and safety. 15 U.S.C. 1261(q)(1)(B).

A proceeding to classify a hazardous substance as a ''banned hazardous substance'' under section 2(q)(1)(B) of the FHSA is governed by the requirements set forth in section 3 of the FHSA. *See* 15 U.S.C. 1261(q)(2) and 1262. The proposed rule begins the rulemaking process in accordance with the requirements of sections 3(a) and (h) of the FHSA. See 15 U.S.C. 1262(a) and (h). Pursuant to section 3(a), the Commission is proposing to declare any aerosol duster canister containing more than 18 mg in any combination of HFC–152a and/or HFC–134a to be a hazardous substance. In order to declare that a hazardous substance is banned, section 3(h) of the FHSA requires the Commission to publish in the **Federal Register** the text of a proposed rule, including any alternatives together with a preliminary regulatory analysis containing: (1) a preliminary description of the potential benefits and costs of the proposed rule; (2) a discussion of the reasons why any standard or portion of a standard submitted to the Commission was not published as the proposed rule; (3) a preliminary determination regarding why the voluntary standards process would not, within a reasonable time, result in the development of a voluntary standard that would eliminate or adequately reduce the risk of injury identified in the rule; and (4) a description of any reasonable alternatives to the proposed rule, together with a summary description of the potential benefits and costs, and a brief explanation of why such alternatives should not be published as the proposed rule. 15 U.S.C. 1262(h).

Before issuing a final rule banning any hazardous substance, the Commission must publish the text of the final rule and a final regulatory analysis that includes: (1) a description of the potential benefits and costs of the rule (including costs and benefits that cannot be quantified in monetary terms, and identification of those likely to receive the benefits and bear the costs); (2) a description of alternatives considered by the Commission (including a description of their potential benefits and costs and an explanation of why the alternatives were not chosen); and (3) a summary of significant issues raised by comments on the preliminary regulatory analysis and a summary of the assessment by the Commission of such issues. 15 U.S.C. 1262(i)(1). The Commission must also make findings that: (1) any relevant voluntary standard is unlikely to adequately reduce the risk of injury or substantial compliance with the voluntary standard is unlikely; (2) the expected benefits of the regulation bear a reasonable relationship to expected costs; and (3) the regulation imposes the least burdensome requirement that would adequately reduce the risk of injury. 15 U.S.C. 1262(i)(2).

III. The Product

A. Description of the Product

Aerosol duster products use a trigger or similar means to release a propellant[7] (typically a hydrofluorocarbon) through an orifice or attachment such as a nozzle or straw for the purpose of blowing and removing dust and debris from hard-to-reach places. Although sometimes referred to as ''canned air,'' aerosol duster products actually contain essentially 100 percent propellent,[8] which is typically a chemical such as a hydrofluorocarbon that can be compressed into a liquid for storage. Each such aerosol duster canister typically contains about 3 to 20 ounces (85 g to 567 g) of compressed liquid in equilibrium with a small amount of evaporated gas or vapor of that same chemical. The gas or vapor, consisting of nearly pure propellant chemical, is expelled when the trigger or similar means is activated, which causes more of the liquid to evaporate into gas or vapor within the canister in order to return to equilibrium. This allows multiple uses per canister. Figure 1 below, from US Patent, US–9234123–B2[9] illustrates an example of an aerosol duster product showing the propellent liquid and vapor existing in equilibrium.

[6] The Commission voted 5–0 to publish this proposed rule.

[7] Aerosol propellant is a liquid which exists in equilibrium also as a gas, or compressed gas that is used to expel aerosol content from a pressurized container.

[8] Various aerosol duster products include trace amounts of denatonium benzoate, or other bitterants in order to discourage inhalant abuse.

[9] *https://patentcenter.uspto.gov/applications/13848372.*

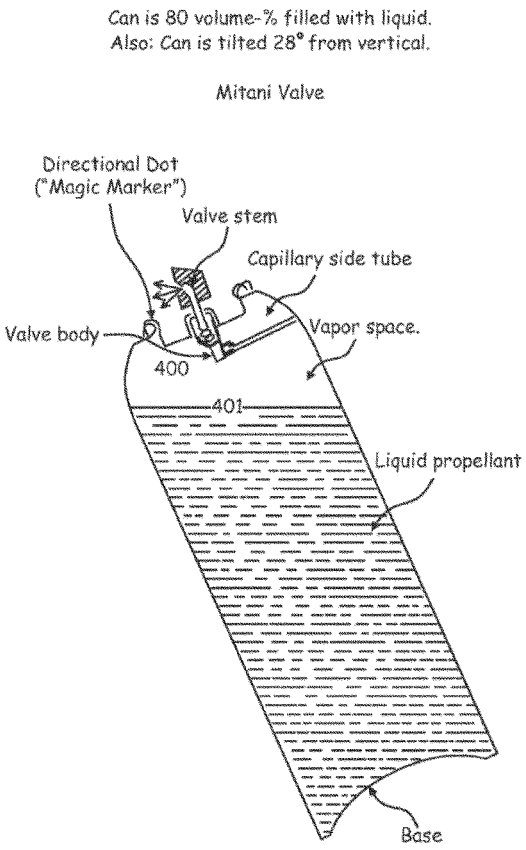


Figure 1: Illustration of the Contents of an Aerosol Duster Product.

Aerosol duster products are sold under a variety of brand names and are available in various brick and mortar stores and online retail locations. They are relatively inexpensive to purchase and easy to obtain either in stores or online. For example, online retailers sell individual canisters for about $8–10 per canister, and some retailers offer a discount when the product is purchased in bulk. Aerosol duster products are often referred to as electronics dusters, computer keyboard cleaners, canned air or compressed air dusters, aerosol cans or spray, and electronics air cleaners, among other names. (See Figure 2 below for examples of 10 oz aerosol duster products).



Figure 2: Aerosol Duster Product Examples.

Aerosol duster products typically use one or more of three propellants: 1,1-difluorethane (HFC–152a, CAS #75–37–6), 1,1,1,2-tetrafluoroethane (HFC–134a, CAS #811–97–2), and/or trans-1,3,3,3-tetrafluoropropene (HFO–1234ze, CAS

#29118–24–9). HFC–152a and HFC–134a are known to be hazardous as explained in this Notice. According to Euromonitor, approximately 87 percent of aerosol duster products available for sale in the U.S. use the propellant HFC–152a and 11 percent use HFC–134a. HFO–1234ze is a new propellant. The abuse potential for HFO–1234ze is unknown due to its relatively low use in consumer applications. Similarly, other effects on humans have not been reported. Further discussion about HFO–1234ze can be found in Tab B of the July 2023 staff petition briefing package.[10]

In order to determine the amount of propellant released from a single use of an aerosol duster product, laboratory sciences staff conducted testing of various aerosol duster products,[11] and based on that testing, determined that a trigger pull from a single aerosol duster canister lasting 5 seconds [12] releases 7.53 grams of propellant, when not using the straw provided with the product. This information regarding the 5 second time per trigger pull helped staff better understand how much propellant inhalant abusers are able to inhale with a single trigger pull of an aerosol duster product.

B. Scope of Products Subject to the NPR

Aerosol duster products are generally intended to be used for cleaning and blowing off dust from electronics as well as other household items. This NPR would apply only to aerosol duster products that contain the propellants HFC–152a or HFC–134a. Aerosol duster products using HFO–1234ze (or other substances) as a propellant are outside the scope of this NPR. Other examples of aerosol products that are outside the scope of this NPR include products that use HFC–152a or HFC–134a as propellants in freeze sprays used to cool circuit boards, automotive refrigerants, and medical freeze sprays used to cool tissue specimens as well as aerosol products that use HFC–152a or HFC–134a as propellants but include substantial additional components (such as air fresheners, paints, lubrication oils, body sprays, and silicone lubricant sprays for food pans).

C. Alternatives to Aerosol Duster Products With HFC–152a and HFC–134a

Alternatives to aerosol duster products are currently being sold for the same purpose as aerosol duster products. For example, alternatives include compressed air dusters which use corded or cordless electric pumps, or hand pumps that compress air and blow and/or vacuum it through a nozzle to remove dirt and debris. According to data collected in 2023, the average price of an electric duster is approximately $56, similar to the price of seven disposable aerosol duster canisters.[13] Staff tested battery operated USB rechargeable duster devices. The goal was to compare air speeds, measured in meters/second (m/s), generated by the battery powered devices to the speeds generated by an aerosol duster product. Three battery powered devices and two name-brand aerosol dusters were chosen for the comparison. Staff concluded that battery powered air duster devices generate comparable air speeds to the propellant speeds of aerosol duster products. See Tab D of the July 26, 2023, staff briefing package for more details on electronic dusters.[14] Carbon dioxide (CO_2) cartridge dusters that use disposable CO_2 cartridges to blow CO_2 through a nozzle to remove dirt and debris are available as well. Consumers can also use vacuum cleaners to remove dust. Thus, a number of alternative products exist that provide similar utility to that provided by aerosol duster products.

IV. Description of the Hazard

Aerosol duster products can cause significant toxicity or death if used as inhalants (Williams, 2007). Inhalants are volatile substances that produce chemical vapors that can be inhaled to induce psychoactive, or mind-altering, effects.[15] The inhalants in aerosol duster products are legally sold for purposes other than use as inhalants, are widely available, and are inexpensive. Inhalant abusers include males and females ranging in age from teenagers to adults in their 60s. Approximately 10 to 50 percent of cases of inhalant abuse may lead to abuse or dependance, depending on the characteristics of the population studied (Perron et al., 2021).

Staff has identified two toxic substances, HFC–152a and HFC–134a, that are commonly used as propellants in aerosol duster products and are widely used for inhalant abuse. Inhalant abusers use propellants to get ''high'' (Koehler and Henninger, 2014). These propellants can be sniffed, snorted or sprayed,[16] huffed,[17] or bagged [18] as inhalants to obtain a rapid euphoric effect (DEA, 2020). The euphoric effect only lasts a few minutes, requiring the repeat use of an aerosol duster product every few minutes to maintain the euphoria. These propellants can damage the heart when abused, making an individual more susceptible to a heart attack or arrhythmia [19] after an individual inhales the propellant. The abuse potential of the propellants HFC–152a and HFC–134a are further discussed below.

A. Inhalants Used in Aerosol Duster Products

1. HFC–152a (1,1-difluorethane)

HFC–152a is widely used as a propellant in the aerosol duster product market.[20] HFC–152a works through specific brain receptors [21] such as glutamate/N-methyl-D-aspartate (NMDA),[22] gamma-aminobutyric acid (GABA),[23] and dopamine [24] to elicit euphoria (Duncan and Lawrence, 2013). Aerosol duster products, especially those containing HFC–152a, are the ''drug of choice'' for many who use inhalants because they are easy to obtain, inexpensive, and contain 100 percent HFC–152a without any additional components such as paint or air freshener in the propellant (Beauvais and Oetting, 1987). After inhalation of

[10] *www.cpsc.gov/s3fs-public/Petition-Requesting-Rulemaking-to-Establish-Safety-Standard-for-Aerosol-Duster-Products-Petition-CP-21-1.pdf?VersionId=.NohA6DG6WsXh_tsjhGuA7RuqMCOvxSW.*

[11] *www.cpsc.gov/s3fs-public/Petition-Requesting-Rulemaking-to-Establish-Safety-Standard-for-Aerosol-Duster-Products-Petition-CP-21-1.pdf?VersionId=.NohA6DG6WsXh_tsjhGuA7RuqMCOvxSW,* July 26, 2023, Table 9, Page 27.

[12] A trigger pull lasting 5 seconds was chosen based on online video research which found users inhaling aerosol dusters without any straw attachment for that length of time: *https://youtu.be/FjlazUNE2-8?si=WsA4nfSbLX_jJ2SR&t=40.* This reference video shows that the euphoric/high effects appear to occur with a single trigger pull of five seconds.

[13] Aerosol Duster Supporting Database, August 2023. (*https://www.cpsc.gov/content/Aerosol-Duster-Supporting-Database*).

[14] *www.cpsc.gov/s3fs-public/Petition-Requesting-Rulemaking-to-Establish-Safety-Standard-for-Aerosol-Duster-Products-Petition-CP-21-1.pdf?VersionId=.NohA6DG6WsXh_tsjhGuA7RuqMCOvxSW.*

[15] See *nida.nih.gov/publications/research-reports/inhalants/what-are-inhalants.*

[16] Inhaling or spraying refers to inhaling the substance into the nose or mouth directly from the container.

[17] Huffing refers to placing a bag saturated with a substance over the mouth and using the nose or mouth to inhale the concentrated fumes.

[18] Bagging refers to concentrating an aerosol in a bag before inhaling.

[19] A heart arrhythmia is an irregular heartbeat caused by electrical problems in the heart.

[20] According to Euromonitor, approximately 87 percent of aerosol duster products available for sale in the U.S. use the propellant HFC–152a and 11 percent use HFC–134a.

[21] Proteins that serve as a sensor for a particulate type of molecules.

[22] The NMDA receptors are a class of receptors that respond to the neurotransmitter N-methyl-D-aspartate.

[23] The GABA receptors are a class of receptors that respond to the neurotransmitter gamma-aminobutyric acid.

[24] Dopamine is a brain neurotransmitter.

such a lipophilic [25] propellant, the substance is rapidly absorbed into the pulmonary vasculature, going directly into the lungs and easily crossing the blood-brain barrier into the brain to exert its euphoric effects. The onset of HFC–152a intoxication is rapid, and the intoxication effects are brief and dose-related, ranging from euphoria, decreased inhibition, motor excitation, and light-headedness (Koehler and Henninger, 2014).

Toxicity in humans can occur after an acute or chronic exposure to HFC–152a (Poisindex, 2021). Severe HFC–152a toxicity can cause a depressed mental state, respiratory depression, pulmonary edema, hepatic injury, and death (Poisindex, 2021). Death can occur due to sudden sniffing death syndrome (SSDS), which was first described in 1970 (Bass, 1970; George et al., 2021). Individuals inhale fluorinated hydrocarbons to become ''high'' and, if physical exertion or stress occurs, the inhaler may collapse and die. (Smeeton and Clark, 1985; Kamm, 1975; Dingle and Williams, 2019; Poisindex, 2021). Predicting the toxicity of inhaling a certain number of aerosol duster canisters is difficult because there is no clear dose-response evident in the medical literature. Death from abusing aerosol duster products is not dose dependent.[26] The medical literature indicates the use of only one canister has resulted in death (Xiong et al., 2004), while in another case inhaling multiple canisters over several years did not cause death (Peicher and Maalofouf, 2017). However, abrupt cessation of HFC–152a abuse can induce withdrawal [27] with tremors, excessive sweating, nausea, vomiting, depression, anxiety, irritability, psychosis, and hallucinations (Custer et al., 2020).

2. HFC–134a (1,1,1,2-tetrafluoroethane)

HFC–134a is another substance used as a propellant in aerosol duster products. HFC–134a is a member of the anesthetic drug class [28] (Shah et al., 2015). HFC–152a and HFC–134a have different binding mechanisms.[29] It is unclear whether the same addictive properties of HFC–152a translate to HFC–134a, but data from CPSC's Consumer Product Safety Risk Management System (CPSRMS) discussed below, show that multiple individuals have died after inhaling HFC–134a. Two other papers from medical literature demonstrate that acute exposure of HFC–134a from inhalation can be harmful (Romero et al., 2022; Burke et al., 2020). Several papers have indicated that inhalation with acute exposure to HFC–134a in humans has resulted in reactive airway dysfunction syndrome,[30] (Doshsti et al., 2016), severe hypotension, loss of consciousness, shock (Vinegar, 1997), cardiac sensitization, neurotoxicity (National Research Council, 2002), and death (Burke et al et al., 2020).

B. Description of the Hazard Pattern

To examine the hazard pattern for inhalation abuse of aerosol duster products, staff conducted 23 in-depth investigations (IDIs) with family members of individuals who died from inhaling aerosol duster products during 2020 and 2021. These IDIs were all related to HFC–152a abuse and included nine females and 14 males, between the ages of 15 to 61 years-old.

The review of the IDIs indicated the number of canisters found at the scene, the victim's history of abuse, and the scene of the incident. In five IDIs [31] only one empty canister was identified, though in some of these IDIs multiple full cans were found at the scene, and the victim had a history of aerosol duster abuse. In twelve incidents,[32] the IDIs reported that more than one completely or partially empty canister was found at the victim's death scene. In several IDIs,[33] twenty or more canisters of aerosol duster product were found with the victim at the death scene. The majority of the victims died at home, while some were found deceased in motels or in parked vehicles.

Based upon staff's review of 23 IDIs and available medical literature, the hazard pattern for inhalation deaths from HFC–152a aerosol duster products includes both males and females; covers a wide age range; indicates that death can occur from inhalation of a single canister or multiple canisters; and shows that most victims died at home, but deaths also occurred in motels and parked vehicles. As stated above, the hazard pattern for HFC–134a is believed to be similar to the hazard pattern for HFC–152a because both propellants are inhalational anesthetics with similar toxicities at high doses.

C. Incident Data

1. Deaths

This section presents information on fatal incidents reported to CPSC that involved inhalation abuse (commonly known as sniffing, spraying or huffing, but referred to here as inhaling or inhalation) of aerosol duster products. The most recent search of the CPSC databases for incidents involving inhalation abuse of aerosol duster products was conducted in February 2024.

CPSC databases (CPSRMS and the National Electronic Injury Surveillance System (NEISS)) do not contain a specific product code for aerosol duster products. Accordingly, the product codes searched in CPSRMS at that time were 1133 (Aerosol containers), 921 (Chemicals not elsewhere classified), and 954 (General-purpose household cleaners). Aerosol duster products are included as a sub-category of product code 954 but may occasionally be sorted into product codes 1133 and 921. Aerosol duster products were identified in CPSRMS incident narratives or product descriptions as dusters, aerosol dusters, computer/keyboard/electronics dusters or cleaners, canned/compressed air, or by specific brand names, including misspelled variants of the above keywords. This review excluded aerosol duster incidents that were exclusively associated with common non-inhalation hazards from aerosol duster products, such as explosions, fires, chemical burns, or respiratory injuries related to the product's intended use.

CPSC's CPSRMS database contains reports for 1,039 unique fatal incidents involving inhalation hazards from aerosol duster products that occurred between January 1, 2012, and December 31, 2021. Data collection is ongoing in CPSRMS and reporting is considered incomplete for more recent years (2022–2024). The number of deaths associated with aerosol duster products reflected in CPSRMS and classified as involving aerosol duster inhalation is almost certainly an underestimate of the actual number of aerosol duster inhalation deaths.

Almost all of the 1,039 deaths were reported from death certificates and

[25] Lipophilic means the tendency to combine with fats.

[26] If the effect is changing with the dose of the drug it is described as dose dependent.

[27] Psychotic symptoms associated with drug cessation.

[28] Substance that induces insensitivity to pain.

[29] Binding of a substance to a receptor molecule changes its shape or activity to transmit a signal.

[30] Breathing symptoms similar to asthma but with an uncertain cause.

[31] IDI numbers 230406HCC1189, 230815HCC1044, 230822HCC1098, 230906HCC1211, 231005HCC3036.

[32] IDI numbers 23071HCC3850, 230329HCC1057, 230707HCC1701, 230720HCC1777, 230725HCC1827, 230808HCC3987, 230822HCC1099, 230906HCC1208, 230906HCC1209, 230929HCC1377, 230329HCC1048, 230711HCC1721.

[33] IDI numbers 230711HCC3850, 230329HCC1057, 230707HCC1701, 230711HCC1721, 230720HCC1777, 230725HCC1827, 230808HCC3987, 230822HCC1099, 230906HCC1208, 230906HCC1209, 230929HCC1377, 230929HCC1048.

Medical Examiners and Coroners Alert Project (MECAP) reports. Among these 1,039 deaths, 775 (75%) were attributed to HFC–152a toxicity, and three were attributed to HFC–134a toxicity. In the remaining incident reports, the specific aerosol duster propellant is not explicitly identified. For several of the deaths that occurred in 2020 and 2021, staff conducted IDIs to learn more about the details surrounding the fatal incident (*i.e.,* victim's history of using aerosol duster products). This death count only includes incidents where the product involved was explicitly identified as an aerosol duster product.

Deaths from HFC–152a toxicity where the specific product was not identifiable, and deaths resulting from the inhalation of unspecified aerosols, are not included in the figures given above. Although HFC–152a is commonly used as a propellant in aerosol duster products, the compound is also used in other aerosol products, such as pesticides and air fresheners. Between 2012–2021, there were an additional 1,031 deaths reported in CPSRMS resulting from HFC–152a toxicity from an unspecified aerosol product. The age, gender, and race/ethnicity distributions of these deaths are similar to those for the aerosol duster product inhalation deaths discussed in this section. Additionally, between 2012–2021, there were at least 63 deaths found in CPSRMS that mentioned inhalation of aerosol products, without giving sufficient information to determine if the product was an aerosol duster product. Because the scope of the data analyses here only includes incidents explicitly mentioning an aerosol duster product, these deaths are not included among the 1,039 fatal incidents in the analyses discussed above.

CPSC is aware of at least seven deaths resulting from HFC–134a toxicity between 2012 and 2021. In three of these deaths, the product involved was identified as an aerosol duster product, and these three deaths are included in the above aerosol duster products fatality count. The remaining four deaths either did not specify the type of product involved, or they involved an unspecified aerosol product. CPSC has also received reports of deaths involving HFC–134a toxicity that occurred between 2006 and 2010, including some that specifically identified an aerosol duster product being involved.

Table 1 below provides an overview of the distribution of aerosol duster inhalation deaths found in CPSRMS, which, as noted, almost certainly understates the actual number of deaths reported to CPSC from these products. Data in CPSRMS are anecdotal in nature and do not necessarily represent all incidents that have actually occurred. Furthermore, death certificates tend to have a greater lag time between the incident/death date and the date the death was reported to CPSC. Therefore, the counts below are subject to increase, especially for the more recent years.

TABLE 1—AEROSOL DUSTER INHALATION DEATHS BY YEAR

[2012–2021]

Year	Total deaths
2012	54
2013	104
2014	90
2015	124
2016	130
2017	127
2018	124
2019	114
2020	89
2021	83
Total	1,039

Source: CPSRMS.
Percentages may not add to 100% due to rounding.

Table 2 below provides an overview of the distributions of aerosol duster product inhalation deaths by age group and gender. Among the identified deaths, almost 70 percent were male, and 94 percent were between the ages of 18 and 54, with ages ranging between 13 and 70 years old.

TABLE 2—DISTRIBUTION OF AEROSOL DUSTER INHALATION VICTIMS BY AGE GROUP AND GENDER

[2012–2021]

Age group (years)	Male	Female	Total
0–17*	4	8	12 (1%)
18–34	296	159	455 (44%)
35–54	376	143	519 (50%)
55 or older	40	12	52 (5%)
Unspecified	1	0	1 (<1%)
Total	717 (69%)	322 (31%)	1,039

Source: CPSRMS.
Percentages may not add to 100% due to rounding.

Race information was reported in 881 (85%) of the 1,039 deaths. Table 3 provides an overview of the distribution of aerosol duster inhalation deaths by race where the data were available. Over 92 percent of the victims were white.

TABLE 3—DISTRIBUTION OF AEROSOL DUSTER INHALATION DEATHS BY RACE

[2012–2021]

Race	Total	Percent
White	814	92
Black/African-American	24	3
American Indian/Alaska Native	17	2
Other*	26	3
Total	881	100

Source: CPSRMS.
* Includes Asian, Native Hawaiian/Pacific Islander and Other race categories.

Ethnicity data for aerosol duster inhalation deaths between 2012 and 2021 are also incomplete. The ethnicity is known for 769 (74%) of the 1,039 deaths. Among the 769 deaths with known ethnicity, 56 (7%) were identified as Hispanic, while 713 (93%) were identified as non-Hispanic.

Table 4 below provides an overview of the distribution of aerosol duster inhalation deaths found in CPSRMS by the incident location of the death. Location information was specified for 891 (88%) of the 1,039 deaths. Most of the deaths (78%) occurred in a housing unit, apartment, or condominium.

TABLE 4—DISTRIBUTION OF AEROSOL DUSTER INHALATION DEATHS

by Incident Location [2012–2021]

Location	Total	Percent
Home/Apartment/Condominium *	711	78
Other Public Property/Office	128	14
Street/Highway	8	1
Place of Recreation or Sports	5	1
Other **	63	7
Total	915	100

Source: CPSRMS.
Percentages may not add to 100% due to rounding.
* Includes mobile and manufactured homes.
** Includes a school, industrial location or any other location.

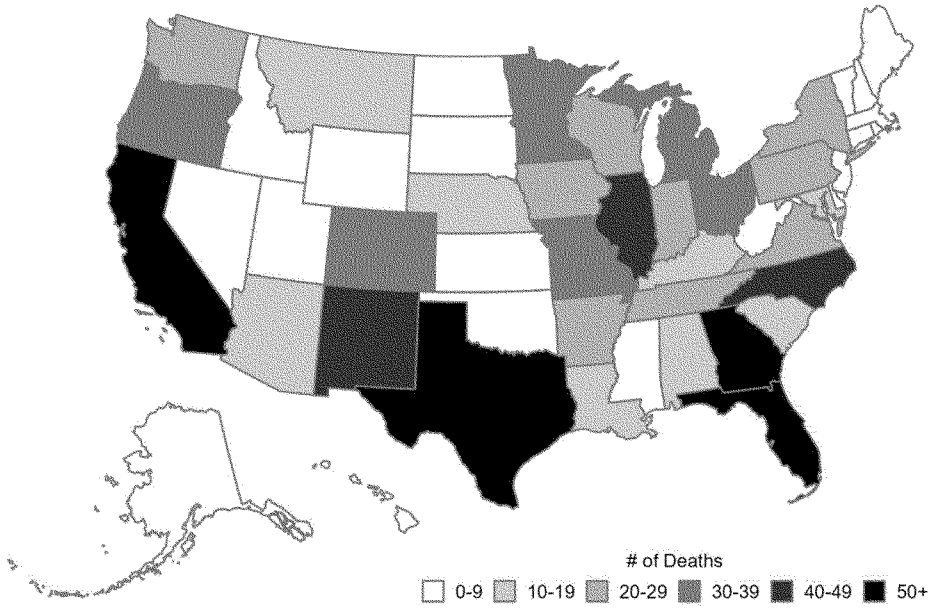
Table 5 and Figure 3 provide an overview of the distribution of aerosol duster product inhalation deaths in CPSRMS by U.S. state. The states with the most reported aerosol duster inhalation deaths are Florida (83), Texas (67), California (67), Georgia (58) and North Carolina (47). Over 30 percent of all aerosol duster inhalation deaths reported to CPSC occurred in these five states.

TABLE 5—NUMBER OF REPORTED FATAL DUSTER INCIDENTS BY STATE

[2012–2021]

State	Deaths	State	Deaths
Florida	83	Arizona	11
California	67	Nebraska	11
Texas	67	Maryland	10
Georgia	58	Montana	10
North Carolina	47	Massachusetts	9
Illinois	46	South Dakota	9
New Mexico	40	Nevada	8
Oregon	37	Oklahoma	8
Minnesota	36	Kansas	7
Colorado	35	Delaware	6
Missouri	33	Mississippi	6
Michigan	30	North Dakota	6
Ohio	30	Wyoming	6
Arkansas	29	Alaska	5
Pennsylvania	28	New Jersey	5
Tennessee	28	Idaho	4
Virginia	28	Maine	4
Indiana	27	New Hampshire	4
New York	25	Connecticut	3
Iowa	21	Hawaii	3
Washington	20	Rhode Island	3
Wisconsin	20	Vermont	3
Louisiana	18	Utah	2
South Carolina	17	West Virginia	*0
Alabama	13	D.C.	*0
Kentucky	13	Total	1,039

Source: CPSRMS.
* CPSC did not receive any reports related to deaths due to aerosol duster inhalation from West Virginia or the District of Columbia that occurred between 2012 and 2021.



Source: CPSRMS.
CPSC did not receive any reports related to deaths due to aerosol duster inhalation from West Virginia or the District of Columbia that occurred between 2012 and 2021.

Figure 3: Number of Reported Fatal Duster Incidents by State (2012-2021)

2. Injury Estimates

This section presents information on emergency department treated injuries resulting from inhalation abuse of aerosol duster products. The estimates are derived from injury cases that were recorded in CPSC's NEISS database,[34] and the injuries were treated during the 10-year period between January 1, 2012, and December 31, 2021. Between 2012–2021, it is estimated that there were 21,700 ED-treated injuries in the United States resulting from inhalation of aerosol duster products. This estimate is based on a sample of 491 NEISS-reported injury cases, three of which were deaths. These three deaths are included among the 1,039 deaths from CPSRMS that are discussed above.

Injury incident cases were included in the sample only if the product being used could reasonably be classified as an aerosol duster product. While CPSRMS incidents typically report product identifying characteristics (*i.e.,* manufacturer, brand, model, retailer, product description), NEISS injury narratives rarely provide such detailed information on the products involved. Thus, NEISS data are likely an underestimate of the true number of ED-treated injuries, as more generic product classifications (*i.e.,* cleaning product, household cleaner, etc.) may be used to describe aerosol duster products. An additional 2,500 estimated ED-treated injuries resulted from ''huffing'' unspecified products, or inhalation of products described as ''aerosol cans,'' ''aerosol cleaners,'' or simply ''aerosols,'' but these injuries are excluded from this analysis because of the non-specificity of the product description and the lack of information on the propellant being inhaled. Other types of injuries not involving aerosol duster inhalation, such as respiratory injuries from the product being sprayed, are not included in the above estimates.

Table 6 below presents yearly estimates of ED-treated injuries in the United States from inhaling aerosol duster products. Between 2012–2021, there is no evidence of a statistically significant linear trend in ED-treated injuries due to aerosol duster inhalation (p-value >0.05).

TABLE 6—NEISS ESTIMATES FOR AEROSOL DUSTER INHALATION INJURIES BY YEAR
[2012–2021]

Year	Estimate[35]	Sample size	CV
2012	**	23	.28
2013	2,000	46	.22
2014	1,500	35	.28
2015	2,500	45	.26
2016	3,000	66	.28

[34] More information about the NEISS sample and estimate calculation can be found here: Explanation Of NEISS Estimates Obtained Through The CPSC website | *CPSC.gov.*

TABLE 6—NEISS ESTIMATES FOR AEROSOL DUSTER INHALATION INJURIES BY YEAR—Continued

[2012–2021]

Year	Estimate [35]	Sample size	CV
2017	2,700	67	.22
2018	2,100	53	.21
2019	2,000	50	.30
2020	**	56	.38
2021	2,000	50	.27
2012–2021	21,700	491	.18

Source: NEISS.
Estimates rounded to nearest 100; estimates that failed to meet NEISS publication criteria are presented as **.
Rows may not add to total due to rounding.

Table 7 below depicts a breakdown of the disposition of the injured patients. A large majority (70%) of the estimated injuries were categorized as ''treated and released'' or ''examined and released without treatment,'' while around 20 percent involved more serious injuries requiring hospitalization or additional observation.

TABLE 7—NEISS ESTIMATES FOR AEROSOL DUSTER INHALATION INJURIES BY DISPOSITION

Disposition	Estimate	Sample size
Treated and released, or Examined and released without treatment	15,200 (70%)	341
Treated and admitted for hospitalization, or Held for observation	4,400 (20%)	103
Left without being seen, or Left without treatment	1,900 (9%)	44
Death *	** (<1%)	3
All Severities	21,700	491

Source: NEISS.* Fatal injury cases in NEISS are also included in CPSRMS data and are thus included in the overall death count.
Estimates rounded to nearest 100; estimates that failed to meet NEISS publication criteria are presented as **.
Rows may not add to total due to rounding.

Table 8 below depicts an overview of the injuries based on age and gender. Around two-thirds of the estimated injuries occurred in males, and around 91 percent of estimated injuries occurred in patients between ages 18 and 54.

TABLE 8—NEISS ESTIMATES FOR AEROSOL DUSTER INHALATION INJURIES BY AGE & GENDER

Age group (years)	Male	Female	Total
0–17	**	**	1,500 (7%)
18–34	6,800	3,300	10,100 (47%)
35–54	6,200	3,400	9,600 (44%)
55 or older	**	**	** (2%)
Total	14,300 (65%)	7,500 (35%)	21,700 (100%)

Source: NEISS.
Estimates rounded to nearest 100; estimates that failed to meet NEISS publication criteria are presented as **.
Estimates and percents may not add to the total due to rounding.

Race and ethnicity data are largely incomplete for aerosol duster product inhalation injury cases between 2012–2021. Race is unknown for around 37 percent of the 21,700 ED-treated injuries during the 10-year period. Among the 13,700 injuries where race is known, white individuals constituted around 83 percent of injuries; Black individuals constituted 6 percent of injuries; and other races constituted the remaining 11 percent. Ethnicity data was added to the NEISS database starting in mid-2018. As such, ethnicity is unknown for the majority (79%) of injuries reported during the period reviewed. Among the 4,500 injuries with known ethnicity, Hispanic individuals constituted 37 percent of injuries, while non-Hispanic individuals constituted the remaining 63 percent.

Approximately 5,700 of the estimated 21,700 ED-treated injuries (26%) occurred at home. Another 6,300 estimated injuries (29%) took place on public property, and 2,200 estimated injuries (10%) took place on a street or highway, at a school, or at a place of recreation. The location for the remaining 7,600 estimated injuries (35%) was either unknown or not recorded.

[35] According to the NEISS publication criteria, an estimate can only be presented if it is 1,200 or greater, is derived from a sample size of at least 20 injury cases and has a coefficient of variation (CV) no greater than 33 percent. As such, estimates that do not meet all three of the above criteria are not presented in any table. CV is calculated by dividing an estimate's standard deviation by the estimate itself.

Approximately 18,700 of the estimated 21,700 ED-treated injuries (86%) were diagnosed primarily as poisonings, while the remaining 3,000 estimated injuries were diagnosed mostly as burns (chemical, thermal or unspecified), anoxia, contusions/abrasions, lacerations, or internal organ injuries. Approximately 18,900 of the estimated 21,700 ED-treated injuries (87%) were considered ''whole body'' injuries (*i.e.,* no specific individual body part injured as a result of inhalation). Another 1,700 estimated injuries (8%) were classified as head, face, or mouth injuries, while the remaining 5 percent of injuries were mostly classified as hand, lower arm, or upper trunk injuries.

D. Availability of Incident Data

Upon publication of the NPR in the **Federal Register**, CPSC will make available for review and comment, to the extent allowed by law, the CPSRMS and NEISS incident reports relied upon and discussed in the NPR, along with the associated IDIs. The data can be obtained by submitting a request to: *https://forms.office.com/g/NK9WAGMhAi.* You will then receive a website link to access the data at the email address you provided. If you do not receive a link within 72 hours, please contact: *cscorpio@cpsc.gov.*

V. Absence of Relevant Voluntary Standard

Two existing voluntary standards, ASTM D3061–97, *Standard Guide for Three-Piece Steel and Tinplate Straight-Wall and Necked-In Aerosol Cans,* and DIN EN 15008:2017, *Aerosol Containers—Aluminum Containers—Dimensions of One-Piece Cans with 25.4 mm Aperture,* apply to aerosol duster products. Both standards provide a list of currently manufactured aerosol canister sizes as well as industry voluntary dimensional guidelines, but neither standard addresses the hazard of intentional inhalant abuse.

On February 27, 2023, ASTM Committee F15 hosted an exploratory meeting discussing potential solutions that would prevent intentional inhalation and abuse of aerosol duster products such as including bitterants, warning labels, and use of alternative propellants and alternative technologies. On March 4, 2024, ASTM Committee F15 hosted a second exploratory meeting to discuss developing a possible future voluntary standard and forming a task group for the prevention of intentional inhalation and abuse of aerosol duster products. To date no such task group has been formed.

VI. Justification for the Proposed Ban

The FHSA defines a hazardous substance to include a substance that is ''toxic.'' 15 U.S.C. 1261(f)(1)(A)(i). A substance is toxic if it ''has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface.'' 15 U.S.C. 1261(g). As discussed in section IV, staff has identified HFC–152a and HFC–134a as two toxic hydrofluorocarbons used as propellants in aerosol duster products. Both hydrofluorocarbons are intentionally inhaled by individuals to experience a euphoric high, resulting in numerous deaths and injuries. Severe HFC–152a toxicity can cause a depressed mental state, respiratory depression, pulmonary edema, hepatic injury, and death (Poisindex, 2021). Symptoms of acute HFC–134a toxicity include severe hypotension, loss of consciousness, shock (Vinegar, 1997), cardiac sensitization, neurotoxicity (National Research Council, 2002), and death (Burke et al., 2020).

Staff researched published medical literature for papers regarding the toxicity of HFC–152a and HFC–134a. While medical literature demonstrates toxicity of the two substances, staff was unable to identify any relevant human data regarding HFC–152a and HFC–134a that would allow for the calculation of a non-toxic human dose. However, that research did provide staff with data to be able to calculate a no observed adverse effect level [36] (NOAEL) in animals for HFC–152a. In toxicology, it is customary to convert animal data to human data in the absence of human data. The Food and Drug Administration (FDA), for example, uses this approach to determine the safe dose of a drug when studying it for the first time in human clinical trials. Based on the generally accepted approach used by FDA, staff converted the NOAEL found in the medical literature to calculate a human equivalent dose (HED) using appropriate scaling factors.[37] Staff used the resulting HED it developed to determine the safe level for the proposed ban after applying a safety factor of 10.[38] Below is a description of the staff approach used in developing the level for the proposed ban on HFC–152a and HFC–134a.

A study was conducted on groups of three rats to mimic the exposure of humans while inhaling HFC–152a (Avella et al., 2010). The rats were exposed to 30 seconds (s) of 20 L/min HFC–152a in an inhalation chamber. During that exposure, all the rats showed signs of intoxication manifested by sedation which began at about 20 s and rapidly progressed to more profound intoxication. At the end of the exposure periods the rats were prostrate and could not get up. The rats remained visibly intoxicated until about four minutes post exposure. Recovery was rapid, and at about eight minutes post exposure, the rats showed no signs of obvious intoxication. Staff calculated a non-toxic human dose of 0.476 mg/kg using the information in the Avella et al., 2010 paper and applying an additional safety factor of 10 for a total safety factor of 100 (see footnote 38 for explanation regarding safety factors). The resulting calculation for a non-toxic human dose is equivalent to 18 mg for 38 kg human (5th percentile weight for 13-year-old female).[39]

Although there are no relevant human inhalation toxicology studies available regarding HFC–134a, the injury and death evidence and properties of HFC–134a discussed above demonstrate a similar hazard to that presented by HFC–152a. HFC–134a has somewhat lower inhalational toxicity in rats compared to HFC–152a (Rusch, 2018). Therefore, the non-toxic dose calculated for HFC–152a will be also protective for HFC–134a.

Based on the assessment that individuals who inhale aerosol duster products inhale a single spray at a time, but may use multiple sprays within a single period of use, and applying the conversion process described above, staff concluded that a single canister of aerosol duster product should be limited to 18 mg or less of HFC–152a and/or HFC–134a to render it non-toxic to humans. Although 18 mg of HFC–

[36] A NOAEL is the highest dose level that does not produce a significant increase in adverse effects in comparison to the control group. The NOAEL is a generally accepted benchmark for safety when derived from appropriate animal studies.

[37] Scaling factors account for differences in size between animals and humans. *See* FDA, 2005, Guidance for Industry Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers (FDA Guidance), available at: *www.fda.gov/regulatory-information/search-fda-guidance-documents/estimating-maximum-safe-starting-dose-initial-clinical-trials-therapeutics-adult-healthy-volunteers.*

[38] A safety factor allows for variability in extrapolating from animal toxicity studies in humans resulting from: (1) different sensitivity of drugs to animals and humans; (2) differing receptor affinity to drugs between animals and humans; (3) unexpected toxicities; and (4) interspecies differences between the metabolism and time course effect of drugs between animals and humans. Ten is a default value for a safety factor. An additional safety factor of 10 could be used to protect sensitive populations.

[39] This dose will be at least as protective for older females and males of the same age and older due to their higher weight. Anthropometric reference data for children and adults: United States, 2015–2018; *https://stacks.cdc.gov/view/cdc/100478.*

152a or HFC–134a is too small an amount to effectively be used as a propellant in an aerosol duster product, because this amount of propellant is not harmful, the Commission is proposing to allow trace amounts of 18 mg or less of HFC–152a and/or HFC–134a in aerosol duster products to allow for low level contamination that may occur during the manufacturing process. For example, if a manufacturer made a propellant change from the manufacture of an unregulated product to a regulated aerosol duster product, leftover contaminant levels remaining in hose lines used to fill aerosol duster products during manufacturing would not result in violative products as long as there is 18 mg or less per canister of the banned propellants. Therefore, the Commission preliminarily finds that any aerosol duster product containing more than 18 mg in any combination of HFC–152a and/or HFC–134a is toxic, and thus, is a hazardous substance under the FHSA.

Under the FHSA, the Commission may classify a hazardous substance that is packaged in a form suitable for use in the household as a ''banned hazardous substance'' if the Commission finds that ''notwithstanding such cautionary labeling as is or may be required under this chapter for that substance, the degree or nature of the hazard involved in the presence or use of such substance in households is such that the objective of the protection of the public health and safety can be adequately served only by keeping such substance, when so intended or packaged, out of the channels of interstate commerce.'' 15 U.S.C. 1261(q)(1)(B). The Commission preliminary makes such a finding for HFC–152a and HFC–134a used in aerosol duster products.

Aerosol duster products are sold to consumers for use in their homes, and almost all aerosol duster products currently on the market display cautionary labeling including at a minimum a signal word (POISON, DANGER, WARNING, CAUTION) and statement(s) of principal hazard(s) such as FLAMMABLE and VAPOR HARMFUL as required by the FHSA and 16 CFR 1500.121. Aerosol duster products on the market also contain statements to inform consumers of intentional misuse, inhalation abuse, and the potential consequences of either activity. Tab C in the July 20, 2022, staff briefing package contains an in-depth analysis regarding the labeling of aerosol duster products.[40]

Although current aerosol duster products on the market contain both FHSA-required labeling, as well as statements identifying the potential hazard of aerosol duster abuse and misuse, these labels have not prevented the more than 1,000 deaths described in section IV of the preamble. The Commission therefore preliminary finds that labeling of aerosol duster products does not effectively address the inhalation hazard presented by aerosol duster products. Because large numbers of deaths and injuries continue to occur despite the cautionary labeling on aerosol duster products, the Commission is proposing to ban the use of toxic propellants HFC–152a and HFC–134a in any aerosol duster canister in amounts above 18 mg.

VII. Description of the Proposed Rule

The proposed rule would amend 16 CFR part 1500 to add a new provision under 16 CFR 1500.17 declaring any canister of aerosol duster product containing more than 18 mg in any combination of HFC–152a and/or HFC–134a to be a banned hazardous substance under the FHSA. The provisions of the proposed ban are described below.

A. Proposed § 1500.17(a)(14)(i)—Ban on Aerosol Duster Products Containing More Than 18 mg in Any Combination of HFC–152a and/or HFC–134a

The proposed rule would add a new paragraph, § 1500.17(a)(14)(i) to 16 CFR 1500.17, that would declare any canister of aerosol duster product containing more than 18 mg in any combination of 1,1-difluoroethane (HFC–152a, CAS #75–37–6) and/or 1,1,1,2-tetrafluoroethane (HFC–134a, CAS #811–97–2) to be a banned hazardous substance under section 2(q)(1) of the FHSA. Section VI of the preamble provides the technical justification for the proposed ban. Proposed § 1500.17(a)(14)(i) also defines ''aerosol duster product'' to mean a product that uses a pressurized canister filled with gas or liquified gas to create a stream of gas propellant that can be used to dislodge or remove dust and debris.

B. Proposed § 1500.17(a)(14)(ii)—Prohibited Stockpiling

Pursuant to section 9(g)(2) of the CPSA, 15 U.S.C. 2058(g)(2), § 1500.17(a)(14)(ii) of the proposed rule would prohibit a manufacturer from ''stockpiling'' or substantially increasing the manufacture or importation of noncompliant aerosol duster products between the date of publication of the final rule and the effective date. Section 9(g)(2) defines stockpiling to mean manufacturing or importing a product between the date of promulgation of a rule, regulation, standard, or ban and its effective date at a rate which is significantly greater than the rate at which such product was produced or imported during a base period ending before the date of promulgation of the rule standard, or ban. The proposed stockpiling provision for hazardous aerosol dusters, which is explained more fully in Tab A of the staff NPR briefing package [41], would prohibit the manufacture or importation of noncompliant aerosol duster products in any one-month period between the date of publication of the final rule and the effective date of the final rule at a rate greater than 105 percent of the rate at which they were manufactured or imported during the base period for the manufacturer or importer. The base period for aerosol duster products is defined in the proposed rule as the average monthly manufacture or import volume for the last 13 months immediately preceding the month of the publication of the final rule.

C. Proposed § 1500.17(a)(14)(iii)—Findings

Proposed § 1500.17(a)(14)(iii) describes the Commission's preliminary findings required under sections 2(q)(1) and 3(h) of the FHSA, including requirements regarding voluntary standards, relationship of benefits to costs, and the least burdensome requirement.

VIII. Preliminary Regulatory Analysis

Pursuant to section 3(h) of the FHSA, publication of a proposed rule must include a preliminary regulatory analysis containing:

- a preliminary description of the potential benefits and potential costs of the proposed rule, including any benefits or costs that cannot be quantified in monetary terms, and an identification of those likely to receive the benefits and bear the costs;
- a discussion of why a relevant voluntary safety standard would not eliminate or adequately reduce the risk of injury addressed by the proposed rule;
- a discussion of the reasons for the Commission's preliminary determination of why the voluntary standards process would not within a reasonable time result in the development of a voluntary standard that would eliminate or adequately

[40] *www.cpsc.gov/s3fs-public/Petition-Requesting-Rulemaking-to-Establish-Safety-Standard_0.pdf?VersionId=GNEl7pYZUBOxf1BLSC0f4.X6TlA8gT4f.*

[41] *https://cpsc.gov/s3fs-public/Briefing-Package-Draft-Proposed-Rule-Aerosol-Duster-Products.pdf?VersionId=m8a.WZmo3DJvX0U3qR.EbOr4yQU9yeps.*

reduce the risk of injury identified in the rule; and

- a description of any reasonable alternatives to the proposed rule, together with a summary description of their potential costs and benefits and why such alternatives should not be published as a proposed rule.

15 U.S.C. 1262(h).

Below is a summary of the preliminary regulatory analysis for the proposed rule. See Tab A of the staff NPR briefing package [42] for the complete preliminary regulatory analysis.

A. Market Information

1. The Product

Aerosol duster products, also known as canned air, are pressurized canisters filled with liquified gas propellant. They utilize the force of compressed gas, released through a nozzle or straw attachment, to create a direct stream of gas that dislodges and blows away debris. Many aerosol duster products are labeled for ''electronics dusting,'' or more generically, as a ''multi-purpose duster.'' These products are marketed for dusting laptops, keyboards, computers, TVs, phones, printers, electronic toys, gaming devices, and other common household products including sewing machines, clocks, watches, musical instruments, and for auto detailing.

Other alternative products that would not be subject to the proposed ban exist for consumers to use for similar dusting purposes, including aerosol duster products using the propellant HFO–1234ze, compressed air dusters which use corded or cordless electric pumps, or even hand pumps, to compress air and blow it through a nozzle, CO_2 cartridge dusters which use disposable CO_2 cartridges to blow CO_2 through a nozzle, as well as vacuum cleaners.

While prices for aerosol duster products vary widely, the average price for a canister of aerosol duster is $8.00 according to a Maia Research market report [43] and $10.19 according to the Aerosol Duster Market Report available on the CPSC website.[44] Aerosol duster products that use HFC–152a as a propellant are most common due to this propellant being less expensive than the less common alternative propellants HFC–134a or HFO–1234ze (*trans*-1,3,3,3-tetrafluoropropene). HFC–134a is non-flammable but is considered a potential greenhouse gas. HFO–1234ze was introduced as an environmentally friendly alternative to HFC–134a, with low global warming potential. (See the staff's preliminary regulatory analysis in Tab A of the staff NPR briefing package for a more complete discussion of aerosol duster products and a complete list of references.)

2. Market Trends for Aerosol Duster Products

Firms that sell aerosol duster products typically engage in either contract manufacturing or are private labelers. Typically, a company that engages in contract manufacturing has another company produce their product for them but remain involved in all components of manufacturing by providing specifications. When a company engages in contract manufacturing, the firm owns the end products for which they have contracted out production. Similarly, private labelers have their production manufactured by a third party; however, the product is owned by that third party and can be sold to other companies, as well. Typically, a private labeler owns a brand name and buys products from the third party to sell it under their established brand. While slightly different in structure, both of these arrangements (contract manufacturing and private labeling) allow firms that produce aerosol duster products to benefit from flexibility in their production processes, and typically avoid large, fixed manufacturing costs to produce their products.

3. Future Market Size for Aerosol Duster Products

Staff forecast aerosol duster products sales for a 30-year study period (2026–2055) using data from a market research report by MAIA Research. In this forecast, staff estimates the number of units of aerosol duster products sold in 2026 will be 18.31 million, absent the regulation of the product described in the proposed rule. In the scenario without the proposed rule, staff estimates the number of units sold in 2055 will be 35.81 million. This estimate is based on a continuation of historical sales growth for the product, which could be affected by a number of unknown factors such as reduced use of computer keyboards or revised environmental regulations.

B. Preliminary Description of Potential Benefits and Costs of the Proposed Rule

Staff conducted a benefits analysis of the proposed rule. The benefits analysis accounted for mitigated deaths and injuries from the proposed rule, which staff monetized using the value of statistical life (VSL) for deaths and the Injury Cost Model (ICM) for injuries. As discussed above, this is likely an undercount of benefits, because staff's count of deaths was limited to cases where the product was explicitly identified as an aerosol duster product. Over a 30-year study period, staff estimated the total annualized net benefits (benefits less costs) from the proposed rule, discounted at 2 percent, to be $1.93 billion due to reduced fatalities and injuries from inhalation. Stated differently, every dollar of cost from the proposed rule is estimated to produce $16.59 of benefits.

The proposed rule would impose three main costs: (1) markup losses to manufacturers/importers of aerosol duster products; (2) increased prices paid by consumers; and (3) deadweight losses or market impacts caused by the increased price associated with compliance with the regulation and the subsequent decline in demand. As detailed in Tab A of the staff NPR briefing package, staff estimates that these costs total $123.73 million over the 30-year study period, discounted at 2 percent.

When the estimated benefits of $2.05 billion are compared to the estimated costs of $123.73 million, the estimated benefits of the rule are far greater than the estimated costs. Staff calculates net benefits (benefits less costs) to be $1.93 billion on an annualized basis, after discounting at 2 percent. However, staff notes that one of the unquantified costs of the proposed rule is the assumed creation of a black market for noncompliant aerosol duster products. Due to the euphoric high experienced with HFC–152a and HFC–134a, consumers who use aerosol duster products as inhalants may still want to purchase noncompliant canisters. This inelastic demand and significant reduction in supply of noncompliant canisters due to the proposed rule would create an incentive for individuals to supply those individuals with noncompliant canisters, such as those that are illegally imported from other countries. The creation of a black market can create significant negative externalities such as increased illicit activity, increased crime and subsequently increased spending on law enforcement, and greater health and safety risks to consumers. Staff cannot estimate the magnitude of these externalities with any certainty. In addition, this analysis does not consider individuals who may stop inhaling aerosol duster products after the rule goes into effect but start using other

[42] *https://cpsc.gov/s3fs-public/Briefing-Package-Draft-Proposed-Rule-Aerosol-Duster-Products.pdf?VersionId=m8a.WZmo3DJvX0U3qR.EbOr4yQU9yeps.*

[43] Maia Research (January 2024). United States Air Duster Industry Market Research Report. 2025 price estimate, deflated to 2023 dollars using CPI.

[44] *www.cpsc.gov/content/Aerosol-Duster-Study-Final-Report.*

intoxicants in its place. If staff were able to forecast and quantify this effect, the impact could reduce the estimated benefits from the proposed rule. However, given the net estimated benefits of $1.93 billion per year in staff's analysis, the benefits of the proposed rule would likely still outweigh the costs even if these externalities occur.

To investigate the impact of using alternative values for some of the key inputs and assumptions of the analysis, staff conducted a sensitivity analysis to compare with the main preliminary regulatory analysis. In the main preliminary regulatory analysis, staff assumes a large number of individuals would continue to use most aerosol duster products obtained on the black market as inhalants due to the euphoric high experienced with HFC–152a and HFC–134a.

In the sensitivity analysis, staff considered an alternative scenario. The sensitivity analysis assumes that the prohibition of HFC–152a and HFC–134a in aerosol duster products results in a greater reduction in inhalant abuse. Staff estimated that, currently, 7.88 percent of aerosol duster products are potentially used by consumers as inhalants. After the regulation goes into effect, staff estimated that there would be an overall reduction in products used as inhalants, but the share of products used as inhalants increases to about 30 percent. In the sensitivity analysis, staff assumes that the share of products used as inhalants is unchanged at 7.88 percent. This change in input inherently assumes that the proposed rule would be more effective at changing the behavior of consumers who use aerosol duster products as inhalants.

This change in assumption increases benefits without affecting the costs. In this scenario, net benefits increase to $2.94 billion when annualized at 2 percent, which boosts the benefit-cost ratio from $16.59 of benefits for every $1 of cost shown in the main preliminary regulatory analysis, to $24.78 of benefit for every $1 of cost show in the sensitivity analysis.

C. Evaluation of Voluntary Standards

Based on the current state of the voluntary standard's process for aerosol duster products discussed in section V of the preamble, the Commission determines that no current U.S. voluntary standard exists to address the inhalation hazard posed by aerosol duster products. Further, there is no indication that any voluntary standards organization has a clear plan to address the inhalant hazard in a new or existing voluntary standard. Therefore, the Commission preliminarily determines at this time that the voluntary standard's process will not within a reasonable time result in the development of a voluntary standard that would eliminate or adequately reduce the risk of injury identified in the proposed rule. No standard or portion of a standard has been submitted to the Commission under sections 3(f)(5) and (6) of the FHSA.

D. Alternatives to the Proposed Rule

The Commission considered four alternatives to the proposed rule: (1) performance requirements; (2) aversive agents (bitterants); (3) labeling; and (4) take no regulatory action and rely upon the voluntary standard's process. The Commission finds that none of these alternatives would adequately address the inhalation hazard associated with aerosol duster products.

1. Performance Requirements

Rather than banning hazardous aerosol duster products under the FHSA, the Commission could in principle mandate a performance requirement under sections 7 and 9 of the CPSA, 15 U.S.C. 2056, 2058, aimed at making aerosol duster products using the propellants HFC–152a and HFC–134a less likely to be used for inhalation. This alternative assumes that an effective performance standard for preventing aerosol duster abuse could be developed. To date, however, suppliers have been unable to develop a performance standard that would effectively prevent the inhalation abuse of aerosol duster products while still allowing for use of the product as intended. Staff is unaware of any existing voluntary standard to address the inhalation hazard. In March 2024, ASTM considered establishing a task group to develop a standard, but no task group was formed. Incident data indicates that victims of injury and death are primarily adults who purchase aerosol duster products with the intended goal of intentionally inhaling the product. Even assuming a performance requirement could be developed, while such a requirement may be effective in preventing young children from releasing the contents of aerosol duster products by adding child-safe features, it would not be effective in preventing adults from abusing and inhaling aerosol duster products, and notably the overwhelming number of injuries and deaths occur among adults. Thus, it would be very difficult, if not impossible, to develop a performance standard that would be effective in addressing inhalant abuse of aerosol duster products. Therefore, the Commission finds this alternative would not address the unreasonable risk of injury associated with aerosol duster products.

2. Aversive Agents (Bitterants)

As FUAIA recommended in its 2021 rulemaking petition, the Commission could adopt a CPSA performance standard to require aversive agents (bitterants) to be used in aerosol duster products. At the petition stage, staff evaluated the use of aversive agents such as bitterants in aerosol duster products and concluded that adding bitterants would not be effective at addressing the inhalant hazard posed by aerosol duster products. Tab B in the July 20, 2022 staff briefing package contains an in-depth analysis regarding the use of bitterants in aerosol duster products.[45] Additionally, many aerosol duster products currently on the market contain bitterants,[46] which appears not to have led to a decline in deaths and injuries associated with inhalant abuse of aerosol duster products. Therefore, the Commission finds this alternative would not adequately address the unreasonable risk of injury associated with aerosol duster products.

3. Labeling

The Commission could require warning and other labels on aerosol duster products. However, most aerosol duster products currently on the market are labeled regarding the inhalation hazard, which appears to have had little impact on deaths and injuries associated with inhalant abuse of aerosol duster products. Additionally, at the petition stage, staff concluded that labeling of aerosol duster products is unlikely to be effective at addressing the inhalation hazard posed by aerosol duster products. In fact, labeling could have the perverse consequence of causing people inclined to abuse inhalants to seek out products with the enhanced warning on the label, thereby facilitating the problem that the label was intended to avoid. Therefore, the Commission finds this alternative would not adequately address the unreasonable risk of injury associated with aerosol duster products.

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[45] *www.cpsc.gov/s3fs-public/Petition-Requesting-Rulemaking-to-Establish-Safety-Standard_0.pdf?VersionId=GNEl7pYZUBOxf1BLSC0f4.X6TlA8gT4f.*

[46] According to the Aerosol Duster Study completed by Euromonitor International in July 2023, approximately 70 percent of all aerosol duster sales are of bitterant-containing products. (*https://www.cpsc.gov/s3fs-public/Aerosol-Duster-Study-2023-Redacted.pdf?VersionId=idRW1RnIfr_5Jkc9sA9mkss8kTyUmZDD*).

4. Take No Regulatory Action and Rely Upon the Voluntary Standard's Process

The Commission could take no regulatory action and rely upon the voluntary standard's process to address the inhalation hazard posed by aerosol duster products. Currently, however, no U.S. voluntary standard exists or is under consideration to address the inhalation hazard posed by aerosol duster products. Therefore, as discussed in section V of this preamble, the Commission finds this alternative would not adequately address the unreasonable risk of injury associated with aerosol duster products.

IX. Initial Regulatory Flexibility Analysis

Whenever an agency publishes an NPR, section 603 of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, requires the agency to prepare an initial regulatory flexibility analysis (IRFA), unless the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The IRFA, or a summary of it, must be published in the **Federal Register** with the proposed rule. Under section 603(b) of the RFA, each IRFA must address:

(1) a description of why action by the agency is being considered;

(2) a succinct statement of the objectives of, and legal basis for, the proposed rule;

(3) a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;

(4) a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and

(5) an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule.

The IRFA must also describe any significant alternatives to the proposed rule that would accomplish the stated objectives and that minimize any significant economic impact on small entities.

A. Reason for Agency Action

The intent of the proposed rulemaking is to reduce deaths and injuries associated with inhalant abuse of aerosol duster products. The Commission is considering the action because of the numerous deaths and injuries associated with the use of aerosol duster products.

B. Objectives of and Legal Basis for the Rule

The Commission proposes this rule to reduce death and injury associated with inhalant abuse from aerosol duster products. This standard is promulgated under the authority of the FHSA. To declare a substance a banned hazardous substance under section 2(q)(1) of the FHSA the Commission must follow the procedural requirements set forth in section 3(f)–(i) of the FHSA. *See* 15 U.S.C. 1261(q)(2) and 1262(f)–(i).

C. Small Entities To Which the Rule Will Apply

The proposed rule would apply to all manufacturers and importers of aerosol duster products. According to estimates by Euromonitor International (Euromonitor), the household consumer market for aerosol duster products was $99.7 million in 2022, and approximately 87 percent of aerosol duster products examined use the propellant HFC–152a and 11 percent use HFC–134a. The remainder use a mixture of these two propellants or an alternative propellant.

According to information collected by staff, in 2024 there were an estimated 31 firms that supply the domestic market for aerosol duster products. Among these firms, 26 are manufacturers and five are importers/wholesalers. Approximately 90 percent of suppliers (28 suppliers) are located domestically in the United States.

D. Compliance, Reporting, and Record-Keeping Requirements of Proposed Rule

In accordance with section 14 of the CPSA, 15 U.S.C. 2063, manufacturers would have to issue a General Certificate of Conformity (GCC) for each aerosol duster product model, certifying that the model complies with the proposed ban. Each GCC must also be based on a test of each product or a reasonable testing program and provided to all distributors or retailers of the product. The manufacturer would have to comply with 16 CFR part 1110 concerning the content of the GCC, retention of the associated records, and any other applicable requirements.

E. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rule

CPSC currently has no regulations regarding the use of HFC–152a and/or HFC–134a in aerosol duster products or any other consumer product. However, the U.S. EPA regulates, or is in the process of regulating, the use of HFC–152a and HFC–134a as hydrofluorocarbons for various uses, including for use in motor vehicle air conditioning, as refrigerants for use in self-chilling cans for household refrigeration, transport refrigeration, vending machines, cold storage warehouses and retail food refrigeration (40 CFR part 82), and as per- and polyfluoroalkyl substances (PFAS) which are broadly used in food, water, and increasingly consumer products, as exposure to some types of PFAS substances are linked to serious health effects. None of EPA's regulations regulating HFC–152a and HFC–134a address the inhalation hazard the proposed rule is intended to address, and thus do not overlap or conflict with the proposed rule.

F. Potential Impact on Small Entities

1. Impact on Small Manufacturers

For the majority of firms in this market, aerosol duster products are ancillary to their manufacturing of products such as degreasers, lubricants and other aerosol products that would not be regulated under the proposed rule. Staff identified 31 firms that would be impacted by the proposed rule. Twenty-six of these firms are manufacturers of aerosol duster products and five are wholesales/importers. Among the 26 manufacturers of aerosol duster products, 20 would be considered small firms according to Small Business Administration (SBA) thresholds.[47] The SBA size standard threshold for NAICS code 325998, All Other Miscellaneous Chemical Product and Preparation Manufacturing, is having fewer than 650 employees in order to be considered small.

Staff identified four small domestic manufacturers of aerosol duster products where the potential impact of the proposed regulation could be significant. These firms enjoy strong brand recognition, and their products are widely used aerosol duster products for electronics. For these firms, their aerosol duster products comprise a large share of their total product offerings. Staff assessed the impact to these small manufacturers to be significant (*i.e.,* greater than one percent of annual revenue) as the proposed rule is expected to increase the price of a canister of aerosol duster product more than threefold, and subsequently cause a steep decline in demand.[48]

[47] Small Business Administration, Table of Size Standards (*https://www.sba.gov/document/support-table-size-standards*).

[48] The proposed rule is expected to cause firms to shift to more expensive propellants, and therefore is expected to increase the price of a canister of aerosol duster product. For a more complete discussion of the expected price increase

Continued

2. Impact on Small Importers

Staff identified five wholesalers/importers of aerosol duster products. The SBA size standard threshold for NAICS code 424690, Other Chemical and Allied Products Merchant Wholesalers, is having fewer than 175 employees in order to be considered small. According to SBA size standards, two of these firms would be considered small and three would be considered large. Staff assessed the impact to these small importers and wholesalers to be significant (*i.e.,* greater than one percent of annual revenue) as the proposed rule is expected to increase the price of a canister of aerosol duster product more than threefold, and subsequently cause a steep decline in demand.

3. Conclusion

Given the significant impact that the proposed rule would have on the market overall, staff assessed that there would be a significant impact on a substantial number of small entities from the proposed rule.

G. Alternatives for Reducing the Adverse Impact on Small Businesses

Section VIII.D Preliminary Regulatory Analysis of this preamble provides a discussion of four alternatives to the proposed rule that were considered and why those alternatives were rejected. While the alternatives could reduce the burden on small entities, none of the alternatives are consistent with achieving the rule's objective of improving consumer safety by protecting consumers from the inhalant risks posed by aerosol duster products. The Commission is not proposing these alternatives because they would not effectively reduce the number of injuries and fatalities associated with aerosol duster products as discussed in section VIII of the preamble.

The Commission welcomes public comments on this IRFA. Small businesses that believe they would be affected by the proposed rule are encouraged to submit comments. The comments should be specific and describe the potential impact, magnitude, and alternatives that could reduce the impact of the proposed rule on small businesses.

X. Paperwork Reduction Act

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA). 44 U.S.C. 3501–3521. We describe the provisions in this section of the document with an estimate of the annual reporting burden. Our estimate includes the time for gathering certificate data and creating General Certificates of Conformity (GCCs), the keeping and maintaining of records associated with the GCCs, and the disclosure of GCCs to distributors and retailers.

CPSC particularly invites comments on: (1) whether the collection of information is necessary for the proper performance of the CPSC's functions, including whether the information would have practical utility; (2) the accuracy of CPSC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) the accuracy of CPSC's estimate of the share of canisters used as inhalants; (4) ways to enhance the quality, utility, and clarity of the information to be collected; (5) ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology; and (6) estimated burden hours associated with label modification, including any alternative estimates.

Title: Ban on Specified Aerosol Duster Products.

Description: The proposed rule would ban any canister of an aerosol duster product containing more than 18 mg in any combination of HFC–152a and/or HFC–134a.

Description of Respondents: Persons who manufacture or import aerosol duster products. Staff estimates the burden of this collection of information as follows in Table 9.

TABLE 9—ESTIMATED ANNUAL REPORTING BURDEN

Burden type	Number of respondents	Frequency of responses	Total annual responses	Minutes per response	Total burden hours
GCC Creation	30	5	150	20	50
Recordkeeping	30	5	150	2	5
Third Party Disclosure	30	500	15,000	5	1,250
Total			15,300		1,305

Section 14(a)(1) of the CPSA, 15 U.S.C. 2063(a)(1), would require manufacturers to certify that their products conform to the proposed rule and issue a GCC. There are 31 known corporate entities supplying aerosol duster products to the U.S. market (consisting of 26 manufacturers and 5 wholesalers/importers), and we assume the majority of these entities would respond annually, though this may be an overestimate.

On average, each entity may respond 5 times per year for collection requirements related to compliant aerosol duster products in the market. Each manufacturer or importer that responds may create 5 certificates annually for a total of 150 responses (30 responses × 5 responses per respondent = 150 annual responses). The estimated time required to create a GCC is about twenty minutes. Therefore, the estimated burden associated with issuance of GCCs is 50 hours (150 responses × 20 minutes per response = 50 hours).

We estimate for the purpose of this burden analysis that records supporting GCC creation, including testing records, would be maintained for a 5-year period. Staff estimates another 150 record-keeping responses, each one of which requires two minutes per year in routine recordkeeping. This adds up to 5 hours (150 records × 2 min per record = 300 minutes or 5 hours).

Section 14(g)(3) of the CPSA also requires that GCCs be disclosed to third party retailers and distributors. We estimate that each respondent will submit 5 GCCs to 100 retailers or distributors annually. Therefore, respondents are estimated to disclose 15,000 GCCs to third party retailers and

and subsequent projected decline in demand, see the full economics memorandum in Tab A.

distributors annually (30 responses × 500 disclosures per year = 15,000 responses). Staff estimates each one of which requires 5 minutes per year. This adds up to 1,205 hours (15,000 responses × 5 minutes per response = 75,000 minutes or 1,250 hours).

Based on this analysis, the proposed ban for aerosol duster products would impose a total paperwork burden to industry of 1,305 hours (50 hours for GCC creation + 5 hours for recordkeeping + 1,250 hours for third-party disclosure). To estimate the cost to industry staff uses total compensation data from the U.S. Bureau of Labor Statistics (BLS) on hourly compensation paid to private industry workers in goods-producing industries of $44.75.[49] At an hourly wage rate of $44.75, the estimated cost of the collection is $58,399 annually (1,305 hours × $44.75 = $58,398.75). There are no operating, maintenance, or capital costs associated with the collection.

Existing aerosol duster product manufactures would incur these costs in the first year following the proposed rule's effective date. In subsequent years, costs could be less, depending on the number of new GCCs issued for aerosol duster products. As required under the PRA (44 U.S.C. 3507(d)), CPSC has submitted the information collection requirements of this proposed rule to the OMB for review. Interested persons are requested to submit comments regarding information collection by September 30, 2024, to the Office of Information and Regulatory Affairs, OMB as described under the **ADDRESSES** section of this notice.

XI. Effective Date

The FHSA does not specify any requirements regarding the setting of an effective date for a rule promulgated pursuant to that authority. The Administrative Procedure Act (APA) generally requires that the effective date of a rule be at least 30 days after publication of a final rule. 5 U.S.C. 553(d).

The Commission preliminarily proposes an effective date of 30 days after publication of the final rule in the **Federal Register**. Pursuant to section 19(a)(2)(D) of the CPSA, once the rule is effective, it would be unlawful to ''sell, offer for sale, manufacture for sale, distribute in commerce, or import into the United States'' any aerosol duster product containing 18 mg in any combination of HFC–152a and/or HFC–134a. 15 U.S.C. 2068(a)(2)(D). Therefore, it would be unlawful to sell any remaining inventory of aerosol duster products containing more than 18 mg of HFC–152a or HFC–134a as of the effective date.

While there are potential vulnerabilities regarding shortages and revenue loss, these potential vulnerabilities are greatly outweighed by the reduction in benefits that would result from delaying the effective date past 30 days. Staff estimates the incremental loss in benefits from a 60-day effective date—30 additional days from the recommended 30-day effective date—to be $45.71 million in net benefits, using a 2 percent discount rate. This loss is the result of 246 additional injuries and 3 additional deaths from delaying the rule for an additional 30 days. Under a 180-day effective date—150 additional days from the recommended 30-day effective date—staff estimates a loss of $228.57 million in net benefits. This estimated further loss is the result of 1,229 additional injuries and 17 additional deaths from delaying the rule for 150 days.

Staff also considered manufacturers' expected actions required to become compliant with the proposed ban in recommending the 30-day effective date. Manufacturers of aerosol duster products would switch to an alternative propellant. Switching to an alternative propellant is a near drop-in replacement, having only minimal changes required to formulations and equipment. As such, while the new propellant itself will be more expensive, the one-time costs of switching propellants will be negligible. The manufacturing process which includes filling, sealing, and crimping the aerosol duster products remains unchanged from current manufacturing practices. It would also require manufacturers to change the labels on their canister to list the alternative propellant, which staff assesses can be accomplished in 30 days. Therefore, the cost of any retooling in the manufacturing process would be minimal. In addition, consumer aerosol duster products that would not be impacted by the proposed rule are already in use, and available for sale. Alternatively, instead of switching to a new propellant in an aerosol duster product, as discussed in section III.C of this preamble, there are manufacturers and importers that currently supply battery powered USB rechargeable duster products to the market, which provide similar utility to consumers as an aerosol duster product. For these reasons, the Commission proposes a 30-day effective date. The Commission invites comments regarding the amount of time needed to come into compliance with a final rule.

XII. Certification

Section 14(a)(1) of the CPSA requires that products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard or regulation under any other act enforced by the Commission, must be certified with a GCC as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a)(1). A final rule establishing a ban under the FHSA would subject aerosol duster products to this requirement. Aerosol duster products would need a certification stating that they do not contain more than 18 mg in any combination of HFC–152a and/or HFC–134a.

XIII. Environmental Considerations

Generally, the Commission's regulations are considered to have little or no potential for affecting the human environment, and environmental assessments and impact statements are not usually required. *See* 16 CFR 1021.5(a). The proposed rule is not expected to have an adverse impact on the environment and is considered to fall within the ''categorical exclusion'' for the purposes of the National Environmental Policy Act. 16 CFR 1021.5(c). In fact, because HFO–1234ze was introduced as an environmentally friendly alternative to HFC–134a, substitution of HFO–1234ze for HFO–134a in aerosol duster products as a result of the proposed rule could have beneficial environmental effects.

XIV. Preemption

Executive Order (E.O.) 12988, Civil Justice Reform (Feb. 5, 1996), directs agencies to specify the preemptive effect of a rule in the regulation. 61 FR 4729 (Feb. 7, 1996). The proposed ban on any aerosol duster canister containing more than 18 mg in any combination of HFC–152a and/or HFC–134a is being promulgated under the authority of the FHSA. 15 U.S.C. 1261–1278. The FHSA provides that, generally, if the Commission issues a banning rule under section 2(q) of the FHSA to protect against a risk of illness or injury associated with a hazardous substance, ''no State or political subdivision of a State may establish or continue in effect a requirement applicable to such substance and designed to protect against the same risk of illness or injury unless such requirement is identical to the requirement established under such regulations.'' 15 U.S.C. 1261 Note. Upon application to the Commission, a State or local standard may be excepted from

[49] U.S. Bureau of Labor Statistics, ''Employer Costs for Employee Compensation,'' December 2023, Table 4, total compensation for private industry working in goods-producing industries: *https://www.bls.gov/news.release/archives/ecec_03132024.pdf.*

this preemptive effect if the State or local standard: (1) provides a higher degree of protection from the risk of injury or illness than the FHSA standard and (2) does not unduly burden interstate commerce. In addition, the Federal government, or a State or local government, may establish and continue in effect a non-identical requirement that provides a higher degree of protection than the FHSA requirement for the hazardous substance for the Federal, State or local government's own use. 15 U.S.C. 1261 note. Thus, with the exceptions noted above for standards that provide higher levels of protection, the proposed rule banning any aerosol duster canister containing more than 18 mg in any combination of HFC–152a and/or HFC–134a would preempt non-identical state or local requirements applicable to such aerosol duster products designed to protect against the same risk of injury.

XV. Request for Comments

We invite all interested persons to submit comments on all aspects of the proposed rule. The Commission specifically seeks comment on the following topics:

- Alternative propellants manufacturers would likely use in aerosol duster products and the intoxicating effects and safety implications of inhaling these alternative propellants;
- Any test methods that can be used to test for compliance of HFC–152a and HFC–134a at the proposed level of 18 mg per single aerosol duster canister;
- Information or data on future market trends, including projected sales, size of the market, growth of firms in the market, forthcoming innovation, or any other information that would inform CPSC of the expected future for the aerosol duster market with or without the proposed rule; and
- The ability of firms to complete these actions to produce compliant products within the proposed effective date.

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List of Subjects in 16 CFR Part 1500

Consumer protection, Hazardous materials, Hazardous substances, Imports, Infants and children, Labeling, Law enforcement, and Reporting and recordkeeping.

For the reasons stated in the preamble, the Commission proposes to amend 16 CFR part 1500 to read as follows:

PART 1500—HAZARDOUS SUBSTANCES AND ARTICLES: ADMINISTRATION AND ENFORCEMENT REGULATIONS

■ 1. The authority for part 1500 continues to read as follows:

Authority: 15 U.S.C. 1261–1278.

■ 2. In § 1500.17, add paragraph (a)(14) to read as follows:

§ 1500.17 Banned hazardous substances.

(a) * * *

(14)(i) *Aerosol Duster Products Containing more than 18 mg in any combination of HFC–152a and/or HFC–134a.* Any canister of an aerosol duster product containing more than 18 mg in any combination of 1,1-difluoroethane (HFC–152a, CAS #75–37–6) and/or 1,1,1,2-tetrafluoroethane (HFC–134a, CAS #811–97–2). The term aerosol duster product means a product that uses a pressurized canister filled with gas or liquified gas to create a stream of gas propellant that can be used to dislodge or remove dust and debris.

(ii) *Prohibited Stockpiling—*

(A) *Prohibited acts.* Manufacturers and importers of aerosol duster products shall not manufacture or import aerosol duster products that do not comply with paragraph (a)(1)(i) in any one-month period between [DATE OF PUBLICATION OF FINAL RULE] and [EFFECTIVE DATE OF THE FINAL RULE] at a rate greater than 105 percent of the rate at which they manufactured or imported aerosol duster products during the base period for the manufacturer or importer.

(B) *Base period.* The base period for aerosol duster products is the average monthly manufacture or import volume for any month within the last 13 months immediately preceding the month of publication of the final rule.

(iii) *Findings—*

(A) *General.* To issue a rule under section 2(q)(1) of the FHSA, 15 U.S.C. 1261(q)(1), classifying a substance or article as a banned hazardous substance, the Commission must make certain findings and include them in the regulation. These findings are discussed in paragraphs (a)(14)(iii)(B) through (D) of this section.

(B) *Voluntary standard.* No voluntary standard currently exists to address the potential for death and injury posed by inhalant abuse of aerosol duster products containing HFC–152a or HFC–134a. The Commission finds that there is no evidence that a voluntary standard will be adopted and implemented within a reasonable period of time that would eliminate or adequately reduce the risk of injury regarding the potential for death and injury posed by the intentional inhalant abuse of aerosol duster products.

(C) *Relationship of benefits to costs.* The Commission estimates that the ban will be effective in reducing the potential for injury and death from compliant aerosol duster products. When benefits are compared to costs, the estimated benefits of the rule are greater than the estimated costs. Net benefits (benefits less costs) are estimated to be $1.93 billion on an annualized basis. Staff performed a 30-year prospective cost analysis (2026–2055) on all cost categories and estimated the total annualized cost from the proposed rule to be $123.73 million. Staff estimated the total annualized benefits from the proposed to be $2.05 billion, discounted at 2 percent.

(D) *Least burdensome requirement.* The Commission considered the following alternatives: require a performance requirement for aerosol duster products preventing inhalation of their propellant; require aversive agents (bitterants); require warning labels; and take no action and rely on a voluntary standard. The Commission finds none of the alternatives considered would adequately reduce the risk of death or injury. Therefore, the Commission finds that a ban on any aerosol duster product containing more than 18 mg in any combination of 1,1-difluoroethane (HFC–152a, CAS #75–37–6) and/or 1,1,1,2-tetrafluoroethane (HFC–134a, CAS #811–97–2) is the least burdensome requirement that would prevent or adequately reduce the risk of death or injury.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2024–16716 Filed 7–30–24; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2022–0221]

RIN 1625–AA09

Drawbridge Operation Regulation; Rancocas Creek, Burlington County, NJ

AGENCY: Coast Guard, DHS.

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to modify the operating schedule that governs the US Route 543 (Riverside-Delanco) Bridge across Rancocas Creek, mile 1.3, at Burlington County, NJ. The proposed rule allows the drawbridge to change its operating schedule to reduce the number of bridge openings during off-peak hours. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must reach the Coast Guard on or before August 30, 2024.

ADDRESSES: You may submit comments identified by docket number USCG–2022–0221 using Federal Decision Making Portal at *https://www.regulations.gov.*

See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments. This notice of proposed rulemaking with its plain-language, 100-word-or-less proposed rule summary will be available in this same docket.

FOR FURTHER INFORMATION CONTACT: If you have questions on this supplemental proposed rule, call or email Mr. Hal R. Pitts, Fifth Coast Guard District Chief Bridge Branch (dpb); telephone 571–607–8298, email *Hal.R.Pitts@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
SNPRM Supplemental notice of proposed rulemaking
Pub. L. Public Law
§ Section
U.S.C. United States Code

II. Background, Purpose and Legal Basis

On May 23, 2022, we published a Test Deviation entitled Drawbridge Operation Regulation; Rancocas Creek, Burlington County, NJ, in the **Federal Register** (87 FR 31182). Having received no comments from the Test Deviation, we published an NPRM on April 24, 2023, in the **Federal Register** (88 FR 24739). We received no comments on the proposed rule.

The US Route 543 (Riverside-Delanco) Bridge across Rancocas Creek, mile 1.3, at Burlington County, NJ, and has a vertical clearance of 4 feet above mean high water in the closed-to-navigation position. The bridge currently operates under 33 CFR 117.745(b).

The Rancocas Creek is used predominately by recreational vessels and pleasure crafts. The bridge is currently required to open on signal from 7 a.m. to 11 p.m. from April 1 through October 31 and with 24-hour advance notice from November 1 through March 31. The bridge is allowed to remain closed to navigation at all other times.

The three-year, monthly average number of bridge openings from 7 a.m. to 3 p.m., Monday through Friday, 7 a.m. to 1 p.m., Saturday and Sunday, and from 8 p.m. to 11 p.m., daily, as drawn from the data contained in the bridge tender logs, is presented below.

April to October (2018, 2019 and 2020)	Average monthly openings
Monday–Friday, 7 a.m. to 3 p.m	4
Saturday & Sunday, 7 a.m. to 1 p.m	2
Daily, 8 p.m. to 11 p.m	7

III. Discussion of Comments and Change

As mentioned above, we received no comments from either the Test Deviation or the NPRM, however we noticed that we had not properly conveyed the new operating schedule of the bridge during the months from April

1 to October 31. Explanation of the change is provided in the below section.

IV. Discussion of Proposed Rule

In the NPRM we proposed to modify the drawbridge operating schedule to open on signal from 3 p.m. to 8 p.m., Monday through Friday, and from 1.p.m. to 8 p.m., Saturday and Sunday, from April 16 through October 15. However, the dates did not coincide with the regulation in 33 CFR 117.745(b)(2). The dates that were proposed in the NPRM left a gap of 15 days from March 31 to April 16 and another 15 day gap from October 15 to November 1. During those two 15 day periods, the bridge would fall under the operating requirements of 33 CFR 117.5 requiring the bridge to open on demand at all times. This was an oversight and was not our intention. Given the error on the dates proposed in the NPRM and the length of time from the publication of the NPRM, we are publishing this supplemental notice with request for comment regarding the new proposed dates.

In this SNPRM, we propose to modify the drawbridge operating schedule to open on signal from 3 p.m. to 8 p.m., Monday through Friday, and from 1 p.m. to 8 p.m., Saturday and Sunday, from April 1 through October 31. We are also adding clarifying language to both paragraphs (b)(1) and (2) that the bridge need not open for the passage of vessels at all other times during the dates in those paragraphs, except as provided in 33 CFR 117.745(a)(1).

V. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on these statutes and Executive orders.

A. Regulatory Planning and Review

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

This regulatory action determination is based on the ability that vessels can still transit the bridge given during the appropriate time and proper notice. Notice.

B. Impact on Small Entities

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

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

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rulemaking would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rulemaking would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rulemaking would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.).

D. Federalism and Indian Tribal Government

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rulemaking under Department of Homeland Security Management Directive 023–01, Rev.1, associated implementing instructions, and Environmental Planning Policy COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f). The Coast Guard has that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule promulgates the operating regulations or procedures for drawbridges. Normally such actions are categorically excluded from further review, under paragraph L49, of Chapter 3, Table 3–1 of the U.S. Coast Guard Environmental Planning Implementation Procedures.

Neither a Record of Environmental Consideration nor a Memorandum for the Record are required for this rulemaking. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

VI. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Decision-Making Portal at *https://www.regulations.gov.* To do so, go to *https://www.regulations.gov,* type USCG–2022–0221 in the search box and click ''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select ''Supporting & Related Material'' in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the *https://www.regulations.gov* Frequently Asked Questions web page. Also, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted, or a final rule is published of any posting or updates to the docket.

We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; DHS Delegation No. 00170.1, Revision No. 01.3.

■ 2. Amend § 117.745 by revising paragraph (b) to read as follows:

§ 117.745 Rancocas Creek

* * * * *

(b) The drawspan for the Riverside-Delanco/SR#543 Drawbridge, mile 1.3, at Riverside must operate as follows:

(1) From April 1 through October 31 open on signal from 3 p.m. to 8 p.m., Monday through Friday, and from 1 p.m. to 8 p.m., Saturday and Sunday. The bridge need not open for the passage of vessels at all other times during those dates, except as provided in paragraph (a)(1) of this section.

(2) From November 1 through March 31 from 7 a.m. to 11 p.m., open on signal if at least 24 hours' notice is given and need not open for the passage of vessels at all other times during those dates, except as provided in paragraph (a)(1) of this section.

* * * * *

Dated: July 25, 2024.

J.C. Vann,

Rear Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. 2024–16824 Filed 7–30–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0111]

Heavy Weather and Disaster Risk Management; Los Angeles-Long Beach Captain of the Port Zone

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

ACTION: Notification of inquiry; request for comments; notice of meeting.

SUMMARY: We are requesting your comments on establishing port conditions and heavy weather safety zones throughout the Los Angeles-Long Beach Captain of the Port Zone. Safety zones and port conditions would establish safe practices in the event natural or manmade disasters affect navigable waterways. We seek your comments on which weather or disaster parameters would necessitate changing port conditions or establishing safety zones based on individual harbors throughout the Los Angeles-Long Beach Captain of the Port Zone (COTP Zone) from San Clemente to Morro Bay. We also plan to host a public meeting on August 12, 2024.

DATES: Your comments and related material must reach the Coast Guard on or before August 31, 2024.

A public meeting will be held 10 a.m. August 12, 2024. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further details.

ADDRESSES: You may submit comments identified by docket number USCG–2024–0111 using the Federal portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

The public meeting will be held virtually. Please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section for call-in information.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of inquiry or about the virtual meeting call-in information, call or email LCDR Kevin Kinsella, Waterways Management, U.S. Coast Guard Sector Los Angeles-Long Beach; telephone (310) 357–1603, email *D11-SMB-SectorLALB-WWM@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
U.S.C. United States Code

II. Background and Purpose

Southern California has the potential to be affected by hurricanes, tropical storms, and other natural disasters on a yearly basis, especially between the months of June and November. The Captain of the Port (COTP) Los Angeles-Long Beach proposes establishing safety zones to provide for the safety of life during and after such storms. In August of 2023, heavy weather from Tropical Storm Hilary was expected to make landfall along the coast of the Los Angeles-Long Beach COTP Zone producing 35 or higher knot winds. At the time there were no established heavy weather procedures for the COTP Zone and the COTP implemented necessary measures derived from other related plans and procedures.

The purpose of this notification of inquiry is to solicit public input to help the Coast Guard prepare to protect

mariners, port infrastructure, and the environment during and after extreme weather and other natural disasters. We seek your comments on which weather or disaster parameters would necessitate changing port conditions or establishing safety zones based on individual harbors throughout the Los Angeles-Long Beach Captain of the Port Zone (COTP Zone) from San Clemente to Morro Bay. After considering the comments from this notification and public meeting, the Coast Guard will publish a notice of proposed rulemaking with opportunity for additional comments if we determine that there is a need to pursue a rulemaking.

III. Information Requested

The Coast Guard requests comments on the following questions:

1. Do you agree or disagree with the need for establishing safety measures with regards to heavy weather and disasters on the navigable waters throughout the Los Angeles-Long Beach COTP Zone? If so or if not, what is your reason?

2. What weather parameters do you think specific harbors should limit or control vessel traffic movement? (*Example:* Port Condition WHISKEY means a condition set by the COTP when weather advisories indicate sustained gale force winds (39–54 mph/34–47 knots) from a tropical or hurricane force storm are predicted to make landfall at the port within 72 hours.)

3. What control measures do you think should be in place for the corresponding port conditions? (*Example:* Port Condition WHISKEY. All vessel and port facilities must exercise due diligence in preparation for potential storm impacts. Ports and waterfront facilities must begin removing all debris and securing potential flying hazards. Oceangoing vessels 500 gross tons (GT) and above must make plans to depart no later than the setting of Port Condition Yankee unless authorized by the COTP. Vessels wishing to remain in port are required to submit a Notice of Intent to Remain in Port to the COTP prior to setting Port Condition X-Ray.)

IV. Public Participation and Request for Comments

We encourage you to submit comments in response to this notification of inquiry through the Federal Decision Making portal at *https://www.regulations.gov.* To do so, go to *https://www.regulations.gov,* type USCG–2024–0111 in the search box and click ''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. In your submission, please include the docket number for this notification of inquiry and provide a reason for each suggestion or recommendation. If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Public comments will also be placed in our online docket and can be viewed by following instructions on the *https://www.regulations.gov* Frequently Asked Questions web page. We review all comments received, but we may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

We plan to hold one public meeting virtually. The public meeting will take place at 10 a.m. on August 12, 2024. For information on facilities or services for individuals with disabilities or to request special assistance at the public meeting, contact the person named in the **FOR FURTHER INFORMATION CONTACT** section, above.

This document is issued under authority of 5 U.S.C. 552(a).

Dated: July 26, 2024.

S.L. Crecy,

Captain, U.S. Coast Guard,Captain of the Port Sector Los Angeles-Long Beach.

[FR Doc. 2024–16846 Filed 7–30–24; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2022–0974; FRL–12039–03–R5]

Air Plan Approval; Minnesota; Second Period Regional Haze Plan; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of public comment period.

SUMMARY: The Environmental Protection Agency (EPA) is extending the comment period for a proposed rule published July 11, 2024. The current comment period for the proposed rule was scheduled to close on August 12, 2024. In response to a request in a public comment, EPA is extending the comment period for the proposed action to September 11, 2024.

DATES: The comment period for the proposed rule published on July 11, 2024, at 89 FR 56827 is extended. Comments must be received on or before September 11, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2022–0974 at *https://www.regulations.gov,* or via email to *langman.michael@epa.gov.* Additional instructions to comment can be found in the notice of proposed rulemaking published July 11, 2024 (89 FR 56827).

FOR FURTHER INFORMATION CONTACT: Matt Rau, Air and Radiation Division (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6524, *rau.matthew@epa.gov.*

SUPPLEMENTARY INFORMATION: On July 11, 2024, EPA proposed to approve the Regional Haze State Implementation Plan revision submitted by the Minnesota Pollution Control Agency on December 20, 2022, as satisfying applicable requirements under the Clean Air Act and EPA's Regional Haze Rule for the program's second implementation period. In response to a request in a public comment, EPA is extending the comment period for 30 days.

Dated: July 25, 2024.

Debra Shore,

Regional Administrator, Region 5.

[FR Doc. 2024–16754 Filed 7–30–24; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

48 CFR Parts 3009 and 3052

[Docket No. DHS–2024–0023]

RIN 1601–AB14

Homeland Security Acquisition Regulation, Rescinding Reserve Officer Training Corps and Military Recruiting on Campus Clause (HSAR Case 2024–001)

AGENCY: Office of the Chief Procurement Officer, Department of Homeland Security (DHS).

ACTION: Proposed rule.

SUMMARY: DHS is proposing to amend the Homeland Security Acquisition Regulation (HSAR). Specifically, DHS proposes to remove and reserve a HSAR clause and subpart. These provisions

contain regulatory requirements, which prohibits the award of certain Federal contracts to institutions of higher education that prohibit Reserve Officer Training Corps units or military recruiting on campus. DHS believes these HSAR provisions are no longer needed in light of amendments made in the Federal Acquisition Regulation (FAR), which DHS has adhered to since December 2020.

DATES: Comments on the proposed rule should be submitted in writing to one of the addresses shown below on or before September 30, 2024, to be considered in the formation of the final rule.

ADDRESSES: Submit comments identified by HSAR Case 2024–001, Rescinding Reserve Officer Training Corps and Military Recruiting on Campus Clause, using any of the following methods:

- *Regulations.gov: http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by entering ''HSAR Case 2024–001'' under the heading ''Enter Keyword or ID'' and select ''Search.'' Select the link ''Submit a Comment'' that corresponds with ''HSAR Case 2024–001.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''HSAR Case 2024–001'' on your attached document.

- *Fax:* (202) 447–0520.
- *Mail:* Department of Homeland Security, Office of the Chief Procurement Officer, MS 0080, ATTN: Ms. Ellen Murray, 6595 Springfield Center Dr., Springfield, VA 20598–0080.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Ellen Murray, Procurement Analyst, DHS, Office of the Chief Procurement Officer, Acquisition Policy and Legislation at (202) 603–3791 or email *HSAR@hq.dhs.gov.* When using email, include HSAR Case 2024–001 in the ''Subject'' line.

SUPPLEMENTARY INFORMATION:

I. Background

On December 4, 2003, DHS published an interim final rule to establish the Department of Homeland Security Acquisition Regulation (HSAR).[1] On May 2, 2006, DHS published a final rule, which adopted the interim rule with some changes in response to public comment (HSAR final rule).[2] The HSAR final rule finalized, among other provisions, HSAR clause 3052.209–71, Reserve Officer Training Corps and Military Recruiting on Campus (48 CFR 3052.209–71). This regulatory requirement is consistent with 10 U.S.C. 983, which prohibits the award of certain Federal contracts to institutions of higher education that prohibit Reserve Officer Training Corps units or military recruiting on campus.

HSAR clause 3052.209–71 requires certain contractors to represent at time of contract award that it does not have and agrees that during performance of a contract it will not adopt, any policy or practice that prohibits or prevents the maintenance, establishment, or operation of a Senior Reserve Officer Training Corps (ROTC) unit at the institution; students at that institution from enrolling in a unit of the Senior ROTC at another institution of higher education; the Secretary of a military department or Secretary of Homeland Security from gaining access to campuses, or students on campuses, for military recruiting purposes; or access by military recruiters, for the purposes of military recruiting, to certain information pertaining to students enrolled at the institution.[3]

The clause also lists the two statutory exceptions to the prohibition concerning the award of a contract found in 10 U.S.C. 983(c).[4] These exceptions are when the Secretary of Defense determines that the institution has ceased the prohibited policy or practice or that the institution has a long-standing policy of pacifism based on historical religious affiliation.

On October 23, 2020, the Department of Defense (DoD), the General Services Administration (GSA), and National Aeronautics and Space Administration (NASA) jointly issued a final rule entitled Federal Acquisition Regulation (FAR) Reserve Officer Training Corps and Military Recruiting on Campus (''FAR final rule'').[5] The FAR final rule, among other amendments, codified for all affected Federal agencies a requirement to include, where applicable, a clause that prohibits the award of certain Federal contracts to institutions of higher education that prohibit Reserve Officer Training Corps units or military recruiting on campus.[6]

DHS notes that the DHS Chief Procurement Officer can issue HSAR deviations when necessary to allow components to deviate from the HSAR.[7] On December 8, 2020, DHS issued HSAR Class Deviation 21–02, Reserve Officer Training Corps and Military Recruiting on Campus.[8] The deviation explained that the FAR final rule ''effective November 23, 2020, added FAR 9.110 that provides the policy and procedures for complying with the 10 U.S.C. 983 prohibition, including FAR clause 52.209–14.'' [9] The deviation then directed DHS contracting officers to follow the FAR when complying with the requirements of 10 U.S.C. 983 and suspended use of HSAR 3009.470 and HSAR clause 3052.209–71.

As a result of the FAR revision, HSAR clause 3052.209–71 is no longer being used to comply with 10 U.S.C. 983. Therefore, DHS is proposing to remove and reserve HSAR clause 3052.209–71 and subpart 3009.4.

II. Discussion and Analysis

As explained previously, DHS currently complies with the requirements of 10 U.S.C. 983 by following the regulatory provisions of the FAR final rule. Until December 8, 2020, DHS had formerly complied with this statutory provision by following 48 CFR 3052.209–71 and 48 CFR 3009.470.[10]

As a result of the amendments made in the FAR final rule that standardize compliance with 10 U.S.C. 983 for all affected Federal agencies, and the directives of HSAR Class Deviation 21–02, DHS has determined that HSAR clause 3052.209–71 and subpart 3009.4 are not needed to comply with the requirements of 10 U.S.C. 983.[11] Therefore, DHS is proposing to remove and reserve 48 CFR 3052.209–71 and subpart 3009.4 of 48 CFR part 3009. These proposed changes would also be consistent with the guidance in the HSAR Deviation.

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[1] *See Department of Homeland Security Acquisition* Regulation, 68 FR 67868 (Dec. 4, 2003).

[2] *See Revision of Department of Homeland Security Acquisition Regulation,* 71 FR 25759 (May 2, 2006).

[3] *See* 48 CFR 3052.209–71.

[4] *See* 48 CFR 3052.209–71.

[5] *See* 85 FR 67619 (Oct. 23, 2020).

[6] *See* 85 FR 67619 (Oct. 23, 2020).

[7] *See* HSAR Deviations, available at: *https://www.dhs.gov/publication/current-hsar-deviations* (last accessed May 28, 2024).

[8] *See HSAR Deviation 21–02, Reserve Officer Training Corps and Military Recruiting on Campus,* available at: *https://www.dhs.gov/sites/default/files/publications/hsarclassdeviation_21_02_3009.470_12-8-2020.pdf* (last accessed May 28, 2024).

[9] *See HSAR Deviation 21–02, Reserve Officer Training Corps and Military Recruiting on Campus,* available at: *https://www.dhs.gov/sites/default/files/publications/hsarclassdeviation_21_02_3009.470_12-8-2020.pdf* (last accessed May 28, 2024).

[10] DHS notes that 48 CFR 3009.470–3009.470–4 currently constitutes all the regulatory text contained in 48 CFR part 3009, subpart 3009.4.

III. Regulatory Analyses

A. Executive Orders 12866, 13563, and 14094

Executive Orders 12866 (Regulatory Planning and Review), as amended by Executive Order 14094 (Modernizing Regulatory Review), and 13563 (Improving Regulation and Regulatory Review) direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

The Office of Management and Budget (OMB) has not designated this rule a significant regulatory action, under section 3(f) of Executive Order 12866, as amended by Executive Order 14094. Accordingly, OMB has not reviewed this regulatory action.

There are no quantified costs or cost savings to this rule as it simply rescinds HSAR requirements that DoD, GSA and NASA have already incorporated in the FAR. DHS believes there would be efficiency and streamlining benefits from this rule as it would remove agency specific provisions from the HSAR.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, (Mar. 29, 1996), requires Federal agencies to consider the potential impact of regulations on small businesses, small governmental jurisdictions, and small organizations during the development of their rules. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, or governmental jurisdictions with populations of less than 50,000. This proposed rule would rescind HSAR clause 3052.209–71 and would not impose new requirements on small entities. As such, DHS certifies this proposed change would not result in a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*

C. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501–3521).

D. National Environmental Policy Act

Section 102 of the National Environmental Policy Act of 1969 (NEPA), Public Law 91–190, 83 Stat. 852 (Jan. 1, 1970) (42 U.S.C. 4321 *et seq.*), as amended, requires Federal agencies to evaluate the impacts of a proposed major Federal action that may significantly affect the human environment, consider alternatives to the proposed action, provide public notice and opportunity to comment, and properly document its analysis. DHS and its agency components analyze proposed actions to determine whether NEPA applies to them and, if so, what level of documentation and analysis is required.

DHS Directive 023–01, Rev. 01 and DHS Instruction Manual 023–01–001–01, Rev. 01 (Instruction Manual) establish the policies and procedures DHS and its component agencies use to comply with NEPA and the Council on Environmental Quality regulations for implementing NEPA codified in 40 CFR parts 1500–1508. The CEQ regulations allow Federal agencies to establish, in their implementing procedures, with CEQ review and concurrence, categories of actions (''categorical exclusions'') that experience has shown do not, individually or in the aggregate, have a significant effect on the human environment and, therefore, do not require preparation of an environmental assessment or environmental impact statement. 40 CFR 1501.4, 1507.3(e)(2)(ii). Appendix A of the Instruction Manual lists the DHS categorical exclusions.

Under DHS NEPA implementing procedures, for an action to be categorically excluded, it must satisfy each of the following three conditions: (1) the entire action clearly fits within one or more categorical exclusions; (2) the action is not a piece of a larger action; and (3) no extraordinary circumstances exist that create the potential for a significant environmental effect.

The proposed rule, if finalized, would amend the HSAR to remove and reserve HSAR clause 3052.209–71 and subpart 3009.4. As stated previously, this HSAR clause and its corresponding policy that the rule proposes to remove are now obsolete given that a FAR clause has been implemented to create a single standard for all agencies subject to 10 U.S.C. 983 to comply with the statutory requirements.

DHS is not aware of any significant impact on the environment, or any change in environmental effect that will result from this proposed rule. DHS finds promulgation of the rule clearly fits within categorical exclusion A3, established in the Department's NEPA implementing procedures as removing and reserving HSAR clause 3052.209–71 and subpart 3009.4 would be strictly administrative in nature.

This proposed rule is a standalone rule and is not part of any larger action. This proposed rule would not result in any major Federal action that would significantly affect the quality of the human environment. Furthermore, DHS has determined that no extraordinary circumstances exist that would create the potential for significant environmental effects. Therefore, this proposed rule is categorically excluded from further NEPA review and documentation.

List of Subjects in 48 CFR Parts 3009 and 3052

Government procurement.

Accordingly, for the reasons set forth in the preamble, DHS proposes to amend 48 CFR parts 3009 and 3052 as follows:

PART 3009—CONTRACTOR QUALIFICATIONS

■ 1. The authority citation for part 3009 continues to read as follows:

Authority: 5 U.S.C. 301–302, 41 U.S.C. 1303, 41 U.S.C. 1707, 41 U.S.C. 1702, and 48 CFR subpart 1.3.

3009.4 [Removed and Reserved]

■ 2. Remove and reserve subpart 3009.4.

PART 3052—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 3. The authority citation for part 3052 continues to read as follows:

Authority: 5 U.S.C. 301–302, 41 U.S.C. 1707, 41 U.S.C. 1702, 41 U.S.C. 1303(a)(2), 48 CFR part 1, subpart 1.3, and DHS Delegation Number 0702.

3052.209–71 [Removed and Reserved]

■ 4. Remove and reserve section 3052.209–71.

Paul Courtney,

Chief Procurement Officer, Department of Homeland Security.

[FR Doc. 2024–16419 Filed 7–30–24; 8:45 am]

BILLING CODE 9112–FE–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R5–ES–2023–0014; FF09E22000 FXES1113090FEDR 245]

RIN 1018–BD66

Endangered and Threatened Wildlife and Plants; Removal of Northeastern Bulrush From the Federal List of Endangered and Threatened Plants

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to remove the northeastern bulrush (*Scirpus ancistrochaetus*) from the Federal List of Endangered and Threatened Plants. After a review of the best available scientific and commercial information, we find that delisting the species is warranted. Our review indicates that the threats to the northeastern bulrush have been eliminated or reduced to the point that the species no longer meets the definition of an endangered or threatened species under the Endangered Species Act of 1973, as amended (Act). Accordingly, we propose to delist the northeastern bulrush. If we finalize this rule as proposed, the prohibitions and conservation measures provided by the Act, particularly through Sections 7 and 9 would no longer apply to the northeastern bulrush.

DATES: We will accept comments received or postmarked on or before September 30, 2024. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. eastern time on the closing date. We must receive requests for public hearings, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by September 16, 2024.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *https://www.regulations.gov.* In the Search box, enter FWS–R5–ES–2023–0014, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the Document Type heading, check the Proposed Rule box to locate this document. You may submit a comment by clicking on ''Comment.''

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS–R5–ES–2023–0014, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *https://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Information Requested, below, for more information).

Availability of supporting materials: This proposed rule and supporting documents, including the 5-year reviews, the Recovery Plan, and the species status assessment (SSA) report, are available at *https://www.regulations.gov* under Docket No. FWS–R5–ES–2023–0014.

FOR FURTHER INFORMATION CONTACT: Audrey Mayer, Field Supervisor, New England Ecological Services Field Office, 70 Commercial Street, Suite 300, Concord, NH 03301; telephone 603–223–2541. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. Please see Docket No. FWS–R5–ES–2023–0014 on *https://www.regulations.gov* for a document that summarizes this proposed rule.

SUPPLEMENTARY INFORMATION:

Information Requested

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other concerned governmental agencies, Native American Tribes, the scientific community, industry, or any other interested parties concerning this proposed rule.

We particularly seek comments concerning:

(1) Reasons we should or should not remove the northeastern bulrush from the List of Endangered and Threatened Plants.

(2) Relevant data concerning any threats (or lack thereof) to the northeastern bulrush, particularly any data on the possible effects of climate change as it relates to habitat, as well as the extent of State protection and management that would be provided to this plant as a delisted species;

(3) Current or planned activities within the geographic range of the northeastern bulrush that may have either a negative or positive impact on the species; and

(4) Considerations for post-delisting monitoring, including monitoring protocols and length of time monitoring is needed, as well as triggers for reevaluation.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for, or opposition to, the action under consideration without providing supporting information, although noted, do not provide substantial information necessary to support a determination. Section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered species or a threatened species must be made solely on the basis of the best scientific and commercial data available.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via *https://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *https://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *https://www.regulations.gov.*

Our final determination may differ from this proposal because we will consider all comments we receive during the comment period as well as any information that may become available after this proposal. For example, based on the new information we receive (and if relevant, any comments on that new information), we may conclude that the species should remain listed as endangered, or we may conclude that the species should be reclassified from endangered to threatened. We will clearly explain our rationale and the basis for our final

decision, including why we made changes, if any, that differ from this proposal.

Public Hearing

Section 4(b)(5) of the Act provides for a public hearing on this proposal, if requested. Requests must be received by the date specified in **DATES**. Such requests must be sent to the address shown in **FOR FURTHER INFORMATION CONTACT**. We will schedule a public hearing on this proposal, if requested, and announce the date, time, and place of the hearing, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing. We may hold the public hearing in person or virtually via webinar. We will announce any public hearing on our website, in addition to the **Federal Register**. The use of these virtual public hearings is consistent with our regulation at 50 CFR 424.16(c)(3).

Peer Review

A species status assessment (SSA) team prepared an SSA report for the northeastern bulrush. The SSA team was composed of Service biologists, in consultation with other species experts. The SSA report represents a compilation of the best scientific and commercial data available concerning the status of the species, including the impacts of past, present, and future factors (both negative and beneficial) affecting the species.

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review of listing and recovery actions under the Act, we solicited independent scientific review of the information contained in the northeastern bulrush SSA report. The Service sent the SSA report to 3 independent peer reviewers and received 2 responses. Results of this structured peer review process can be found at *https://www.regulations.gov* under Docket No. FWS–R5–ES–2023–0014. In preparing this proposed rule, we incorporated the results of these reviews, as appropriate, into the final SSA report, which is the foundation for this proposed rule.

Summary of Peer Reviewer Comments

As discussed in Peer Review above, we received comments from 2 peer reviewers on the draft SSA report. We reviewed all comments we received from the peer reviewers for substantive issues and new information regarding the information contained in the SSA report. Overall, the comments were supportive of the approach, analyses, and projections of the SSA. Information was presented that helped to improve the assessment and inform this proposed rule. Such information included new references, comments regarding using a spatial assessment of climate change projections, discussion of population responses to weather events, and new information to help inform our analysis of synergistic impacts to bulrush viability.

Previous Federal Actions

On May 7, 1991, we published in the **Federal Register** (56 FR 21091) a final rule listing the northeastern bulrush as an endangered species under the Act. On August 25, 1993, we approved the northeastern bulrush recovery plan (Service 1993, entire). On September 24, 2009, we completed a 5-year review (Service 2009, entire) of the status of the northeastern bulrush, which recommended reclassification from endangered to threatened status based on the increased number and status of known extant populations. On August 28, 2019, we completed a second 5-year review (Service 2019b, entire), resulting in a recommendation to delist the species, because, based on the species' current representation, resiliency, and redundancy, and our analysis of threats that may influence its future condition, the species no longer met the statutory definition of an endangered or a threatened species.

Background

Species Information

For more information on the description, biology, ecology, genetics, and habitat of the northeastern bulrush, please refer to the final listing rule (56 FR 21091; May 7, 1991), the northeastern bulrush (*Scirpus ancistrochaetus*) recovery plan (Service 1993, pp. 1–31), and the SSA report (Service 2019a, entire). These documents will be available as supporting materials at *https://www.regulations.gov* under Docket No. FWS–R5–ES–2023–0014.

Taxonomy and Species Description

The northeastern bulrush is a member of the Cyperaceae (sedge) family. It is a tall (80 to 120 centimeter), leafy, perennial herb that produces stems and leaves from short, thick, underground rhizomes. It is distinguished from other *Scirpus* species by its drooping, clustered, fruiting heads; dark, chocolate-brown florets; achene bristles that are barbed to the base; and broad bracts (Schuyler 1962, pp. 44–46).

Population size may vary from year to year. In some cases, plants are absent above ground for several years before re-emerging (Service 2019a, p. 10). This is likely due to changes in environmental conditions, although the exact causal mechanisms are not well understood. When water levels and/or light availability are not favorable, the population becomes stressed, dwindles in size, and sometimes becomes completely absent above ground. When favorable habitat conditions return, the population may re-emerge.

The northeastern bulrush is a wetland obligate plant occurring in acidic to almost neutral wetlands including sinkhole ponds, wet depressions, and vernal pools (collectively, seasonal or ephemeral wetlands); American beaver (*Castor canadensis*) flowages; and other riparian areas found in hilly country (Schuyler 1962, p. 47). Optimal habitat includes abundant sunlight, higher organic matter (Lentz and Dunson 1999, p. 165), and seasonally and/or annually fluctuating water levels, although prolonged periods with too much or too little water may be detrimental.

Distribution

At the time of listing in 1991, only 13 populations of the northeastern bulrush scattered across 6 U.S. States were known to exist (Service 1991, entire); however, the species is now known from 148 extant populations in 8 States (Service 2019a, p. 2). The populations can be loosely organized into a northern region and a southern or Appalachian region, with a large gap in the distribution in southeastern New York. The northern region includes extreme eastern New York and the New England States of Vermont, New Hampshire, and Massachusetts; and the southern or Appalachian region includes southwestern New York, Pennsylvania, Maryland, Virginia, and West Virginia. The vast majority of populations are in Pennsylvania (59.5 percent), Vermont (20.9 percent), and New Hampshire (9.5 percent).

Recovery Criteria

Section 4(f) of the Act directs us to develop and implement recovery plans for the conservation and survival of endangered and threatened species unless we determine that such a plan will not promote the conservation of the species. Under section 4(f)(1)(B)(ii), recovery plans must, to the maximum extent practicable, include objective, measurable criteria which, when met, would result in a determination, in accordance with the provisions of section 4 of the Act, that the species be

removed from the Lists of Endangered and Threatened Wildlife and Plants.

Recovery plans provide a roadmap for us and our partners on methods of enhancing conservation and minimizing threats to listed species, as well as measurable criteria against which to evaluate progress towards recovery and assess the species' likely future condition. However, they are not regulatory documents and do not substitute for the determinations and promulgation of regulations required under section 4(a)(1) of the Act. A decision to revise the status of a species or to delist a species is ultimately based on an analysis of the best scientific and commercial data available to determine whether a species is no longer an endangered species or a threatened species, regardless of whether that information differs from the recovery plan.

There are many paths to accomplishing recovery of a species, and recovery may be achieved without all of the criteria in a recovery plan being fully met. For example, one or more criteria may be exceeded while other criteria may not yet be accomplished. In that instance, we may determine that the threats are minimized sufficiently and that the species is robust enough that it no longer meets the definition of an endangered species or a threatened species. In other cases, we may discover new recovery opportunities after having finalized the recovery plan. Parties seeking to conserve the species may use these opportunities instead of methods identified in the recovery plan. Likewise, we may learn new information about the species after we finalize the recovery plan. The new information may change the extent to which existing criteria are appropriate for identifying recovery of the species. The recovery of a species is a dynamic process requiring adaptive management that may, or may not, follow all of the guidance provided in a recovery plan.

The objective identified in the northeastern bulrush recovery plan (Service 1993, p. 37), when there were 33 known extant populations, was to reclassify the species from endangered to threatened, and the plan provides three criteria for doing so: (1) 20 populations are permanently protected; (2) annual monitoring over a 10-year period shows that 20 representative populations are stable or increasing; and (3) life-history and ecological requirements are understood sufficiently to allow for effective protection, monitoring, and management. The recovery plan does not contain delisting criteria.

In the 2009 5-year review (Service 2009, entire), the Service determined that the downlisting criteria were partially met and recommended a change in listing status to threatened, because (1) the number of extant populations was three times greater than when the species was listed; [1] (2) approximately half of all known populations were on public lands; and (3) approximately half of the extant populations appeared to be stable or increasing. In the 2019 5-year review (Service 2019b, entire), the Service recommended delisting the northeastern bulrush, because it no longer meets the Act's definition of an endangered or a threatened species. While the recovery plan does not include delisting criteria, our analysis presented in the SSA report (Service 2019a, entire) shows that the intent of the recovery plan's downlisting criteria (Service 1993, p. 37) has been exceeded substantially, supporting our conclusion that the species is neither endangered nor threatened.

The purpose and intent of the first downlisting criterion calling for permanent protection of 20 populations was to provide evidence that a reasonable number of populations were reliably protected from development, which was identified as a threat to the species' viability. Currently, 89 (approximately 60 percent) of the 148 known extant populations occur on public lands, which affords consistent and reliable protection through a management structure conducive to conservation. In addition, although development was identified as an important threat at the time of listing, that threat appears to have diminished. Currently, oil and gas development in Pennsylvania is perhaps the most likely development threat; however, no available information indicates any populations are under known threat from oil and gas development. Although other types of activities such as road construction, forestry, recreation, and plant competition are factors that may affect the species, data indicate they are not primary factors influencing the viability of the northeastern bulrush. Also, because the species occurs in wetland habitats, which are provided some protections under State laws, the species is protected from many sources of impacts from human activities. As a result, the need for further affirmative protection from these threats on both public and private lands is less than previously determined at the time the recovery plan was issued in 1993. Together these factors lead to our conclusion that the purpose and intent of the first downlisting criterion of permanent protection for 20 populations has been substantially exceeded.

The intent of the second downlisting criterion calling for 20 stable or increasing populations was to demonstrate and ensure the species was not in active decline. This element of the recovery plan has also been exceeded by a wide margin. There are 148 known extant populations of the northeastern bulrush in 8 States, an increase of 31 percent from the 113 known extant populations in 7 States at the time of the 2009 5-year review. Our analysis of these populations in the SSA report (Service 2019a, p. 27) indicates that 132 (89 percent) of the 148 known extant populations demonstrate excellent, good, and fair resiliency, and only 16 (11 percent) of the populations demonstrate poor resiliency or have been extirpated. We determined that the recovery plan's terms ''stable'' and ''increasing'' are not appropriate for describing a species whose populations may naturally fluctuate dramatically in response to environmental stochasticity; for this reason, the number of populations in excellent, good, or fair condition is a better measure of the intent of this criterion. Also, because the number of populations in fair or better condition is an order of magnitude higher than the number of stable or increasing populations called for in the second downlisting criterion, we conclude that the intent of this criterion has been substantially exceeded.

The third downlisting criterion calling for increased understanding of the life-history and ecological requirements of the northeastern bulrush has been achieved in that we have sufficient information to support long-term management of populations. Research by State, Federal, and university partners on the effects of hydrology, shading, herbivory, genetics, propagation, transplantation, and nutrients on germination and plant growth has provided better understanding of how to more effectively protect, monitor, and manage the species. Therefore, lack of knowledge to support long-term management of populations no longer contributes a substantial risk to the species.

Regulatory and Analytical Framework

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and the implementing regulations in

[1] There were 13 known extant populations at listing in 1991, 33 at the time of the recovery plan in 1993, and 113 in 2009 when the 5-year review was completed. To clarify the 2009 5-year review, the number of extant populations in 2009 was 8.7 times the number of populations known in 1991.

title 50 of the Code of Federal Regulations set forth the procedures for determining whether a species is an endangered species or a threatened species, issuing protective regulations for threatened species, and designating critical habitat for endangered and threatened species. On April 5, 2024, jointly with the National Marine Fisheries Service, the Service issued a final rule that revised the regulations in 50 CFR 424 regarding how we add, remove, and reclassify endangered and threatened species and what criteria we apply when designating listed species' critical habitat (89 FR 24300). This final rule is now in effect and is incorporated into the current regulations. The Act defines an ''endangered species'' as a species that is in danger of extinction throughout all or a significant portion of its range, and a ''threatened species'' as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether any species is an endangered species or a threatened species because of any of the following factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects. The determination to delist a species must be based on an analysis of the same five factors.

We use the term ''threat'' to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term ''threat'' includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term ''threat'' may encompass—either together or separately—the source of the action or condition or the action or condition itself.

However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an ''endangered species'' or a ''threatened species.'' In determining whether a species meets either definition, we must evaluate all identified threats by considering the species' expected response and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species—such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the definition of an ''endangered species'' or a ''threatened species'' only after conducting this cumulative analysis and describing the expected effect on the species now and in the foreseeable future.

The Act does not define the term ''foreseeable future,'' which appears in the statutory definition of ''threatened species.'' Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis which is further described in the 2009 Memorandum Opinion on the foreseeable future from the Department of the Interior, Office of the Solicitor (M–37021, January 16, 2009; ''M-Opinion,'' available online at *https://www.doi.gov/sites/doi.opengov.ibmcloud.com/files/uploads/M-37021.pdf*). The foreseeable future extends as far into the future as the U.S. Fish and Wildlife Service and National Marine Fisheries Service (hereafter, the Services) can make reasonably reliable predictions about the threats to the species and the species' responses to those threats. We need not identify the foreseeable future in terms of a specific period of time. We will describe the foreseeable future on a case-by-case basis, using the best available data and taking into account considerations such as the species' life-history characteristics, threat-projection timeframes, and environmental variability. In other words, the foreseeable future is the period of time over which we can make reasonably reliable predictions. ''Reliable'' does not mean ''certain''; it means sufficient to provide a reasonable degree of confidence in the prediction, in light of the conservation purposes of the Act.

Analytical Framework

The SSA report documents the results of our comprehensive biological review of the best scientific and commercial data regarding the status of the species, including an assessment of the potential threats to the species. The SSA report does not represent our decision on whether the species should be proposed for delisting. However, it does provide the scientific basis that informs our regulatory decisions, which involve the further application of standards within the Act and its implementing regulations and policies.

To assess northeastern bulrush viability, we used the three conservation biology principles of resiliency, redundancy, and representation (Shaffer and Stein 2000, pp. 306–310). Briefly, resiliency is the ability of the species to withstand environmental and demographic stochasticity (for example, wet or dry, warm or cold years); redundancy is the ability of the species to withstand catastrophic events (for example, droughts, large pollution events), and representation is the ability of the species to adapt to both near-term and long-term changes in its physical and biological environment (for example, climate conditions, pathogen). In general, species viability will increase with increases in resiliency, redundancy, and representation (Smith et al. 2018, p. 306). Using these principles, we identified the species' ecological requirements for survival and reproduction at the individual, population, and species levels, and described the beneficial and risk factors influencing the species' viability.

The SSA process can be categorized into three sequential stages. During the first stage, we evaluated individual species' life-history needs. The next stage involved an assessment of the historical and current condition of the species' demographics and habitat characteristics, including an explanation of how the species arrived at its current condition. The final stage of the SSA involved making predictions about the species' responses to positive and negative environmental and anthropogenic influences. Throughout all of these stages, we used the best available information to characterize viability as the ability of a species to sustain populations in the wild over time which we then used to inform our regulatory decision.

The following is a summary of the key results and conclusions from the SSA report; the full SSA report can be found

at Docket No. FWS–R5–ES–2023–0014 on *https://www.regulations.gov.*

Summary of Biological Status and Threats

In this discussion, we review the biological condition of the species and its resources, and the threats that influence the species' current and future condition, in order to assess the species' overall viability and the risks to that viability. In addition, the SSA report (Service 2019a, entire) and most recent 5-year review (Service 2019b, entire) document our comprehensive biological status review for the species, including an assessment of the potential threats to the species.

The following is a summary of this status review and the best available information gathered since that time that have informed this decision.

The northeastern bulrush is a wetland obligate plant occurring in acidic to almost neutral wetlands including sinkhole ponds, wet depressions, vernal pools (collectively, seasonal or ephemeral wetlands), beaver flowages, and other riparian areas found in hilly country (Schuyler 1962, p. 47). Optimal habitat includes abundant sunlight, higher organic matter (Lentz and Dunson 1999, p. 165), and seasonally and/or annually fluctuating water levels, although prolonged periods with too much or too little water may be detrimental. The northeastern bulrush may be found in a wide range of water depths from just a few centimeters up to a meter in depth, depending on seasonal fluctuations in water levels (Thompson 1991, p. 5). Plants typically grow in open areas surrounded by forest. Light availability is known to influence plant growth, reproduction, and distribution (Boardman 1977, p. 372; Lentz and Cipollini 1998, p. 126). Shaded plants are often taller, but at the expense of the roots and other organs (Lentz and Cipollini 1998, pp. 127, 129), and the species usually is absent from the highly shaded perimeter of wetlands.

Current Condition

As stated previously, when the northeastern bulrush was listed in 1991, only 13 populations were known to exist; however, the species is now known from 148 extant populations in 8 States (Service 2019a, p. 2). The populations can be loosely organized into a northern region and a southern or Appalachian region, with a large gap in the distribution in southeastern New York. As described in chapter 4 of the SSA report (Service 2019a, pp. 25–31), we used element occurrence (E.O.) rank to assess and describe the current resiliency of northeastern bulrush populations. E.O. rankings document the status and quality of plant population occurrences and assess the probability of an occurrence persisting. We consider the E.O. rank to be the most meaningful way to describe a population's status, as it requires an in-person observation and combines multiple components of a population's condition into a single metric. E.O. ranks are assigned by a surveyor based on observations beyond just population size, but also habitat conditions at the site at the time of the survey, conditions over time since its last observation, and probability of persistence. Our analysis of these populations (Service 2019a, p. 27) indicates that 132 (89 percent) of the 148 known extant populations demonstrate excellent, good, and fair resiliency, and only 16 (11 percent) of the populations demonstrate poor resiliency or have been extirpated.

Factors Influencing Viability

At the time of listing (see 56 FR 21091; May 7, 1991), habitat disturbance and destruction from development and other anthropogenic impacts, especially on private land, was identified as an important threat to the northeastern bulrush, even though there were only a few examples of populations that were under imminent threat from these activities. Since listing, one population has been lost to development, but overall, the anticipated threat of habitat loss from development has not materialized and has a much lower overall impact risk because of the increased number of known populations.

A search of the Service's Tracking and Integrated Logging System, which has information dating back approximately 15 years, revealed relatively few consultations under section 7 of the Act between the Service and Federal agencies on Federal actions that may affect the northeastern bulrush. Consultations often consider proposals for development, road construction and/or maintenance, or other habitat disturbance, and none of the consultations that included northeastern bulrush anticipated adverse effects to the species. While these search results do not capture non-Federal actions on private land, in the available survey and monitoring data, surveyors did not identify any northeastern bulrush populations as being under threat of extirpation as a result of development activities since regular surveys began. Moreover, there is no evidence that the lack of development impacts to the extant populations is attributable to the protections afforded by the Act.

At this time, oil and gas development in Pennsylvania is perhaps the most likely development threat; however, we are not aware of any information, such as project proposals, that indicates any populations are under threat from oil and gas development. Accordingly, we conclude that the threat of the destruction, modification, or curtailment of the northeastern bulrush's habitat from development is less than previously thought, and not a significant factor impacting the continued viability of the species. Although other types of activities such as road construction, forestry, and recreation are factors that may affect the species, to date they have not proved to be significant factors contributing to the risk of extinction of the northeastern bulrush. The 88 northeastern bulrush populations that occur on publicly owned land (approximately 60 percent of known populations) are provided long-term protection from risk of development. Publicly owned lands include State Game Lands, National Wildlife Refuges, National Park Service units, and lands protected by non-governmental organizations such as The Nature Conservancy. A description of these factors can be found in the SSA report (Service 2019a, pp. 21–24).

Native species are known to modify habitat for the northeastern bulrush and can have meaningful, although mostly temporary, impacts on populations. Beavers can create flood conditions that negatively impact the species through increasing water depth by constructing or adding to a dam and raising the water level in a wetland occupied by the northeastern bulrush. However, beavers also have a long-term positive effect on habitat quality by harvesting trees and other woody vegetation for food and shelter, thereby creating open canopy and increasing light availability. Trampling by white-tailed deer (*Odocoileus virginianus*) and trampling and wallowing by American black bears (*Ursus americanus*) have been noted in some northeastern bulrush populations, and these activities can have mixed, sometimes substantial, impacts, especially where bulrush populations are very small. Trampling and soil compaction occur as deer and bears move through northeastern bulrush sites. Bears excavate wallows near the edge of wetlands, and some northeastern bulrush populations have been impacted by this activity. Wallows can be big enough to affect entire populations if the populations are very small; however, wallows also can be beneficial as they help create areas of open water, which are important during

dry periods. These factors affect a small number of populations, and it appears that the timing, location, and scale of the trampling and wallows that would need to align to extirpate a population occur with such infrequency as to be discountable. Therefore, while beaver activity, trampling, and wallowing can cause substantial localized impacts to individual northeastern bulrush populations, these are not significant factors contributing to the risk of extinction.

There is no evidence the species is used for commercial or recreational purposes, or that the scientific and/or educational uses (*e.g.,* seed collection, surveys, etc.) have significant impacts. Similarly, disease has not been documented as a factor affecting the species. Browsing by white-tailed deer has been noted in some northeastern bulrush populations in the Appalachian region; although it has not been reported in the northern region, it likely occurs rangewide at a similar scale as the Appalachian region. Deer browsing may affect plant fitness, particularly if other factors, such as decreased light availability, are affecting the population. Deer browsing impacts under these conditions likely affects a small number of populations, and it appears that the timing, location, and scale of the browsing that would need to align to extirpate a population occur with such infrequency as to be discountable. Therefore, overutilization, disease, and predation do not constitute a risk to the northeastern bulrush.

The wetland habitats in which the northeastern bulrush occurs are protected by State statutes and regulations, although these mechanisms typically include a permitting process that allows direct impacts to wetlands. Some States have additional statutes or regulations or both that protect the northeastern bulrush or its habitat. For example, Vermont, New York, and Massachusetts require protection of upland buffers and permits to work within wetlands; however, State protection of upland areas around the wetlands is inconsistent, and disturbance such as roads or other development near wetlands can cause indirect effects such as sedimentation, altered hydrology, and introduction of invasive species.

The species is designated as State endangered throughout its range, except in West Virginia, and these State designations are independent of the species' Federal status. West Virginia does not have a State law to protect endangered species, but only three northeastern bulrush populations occur in West Virginia. The States that currently protect the northeastern bulrush under State law require, at a minimum, project proponents to coordinate with State resource agencies to develop minimization measures for projects that may affect the northeastern bulrush or its habitat. The *Regulatory Protection* discussion in the SSA report (Service 2019a, pp. 17–21) includes a summary of our current understanding of the laws and regulations regarding wetlands and buffers in States where the northeastern bulrush occurs. The best available information indicates that the northeastern bulrush is not threatened by inadequacy of existing regulatory mechanisms.

Climate change, especially in the southern portion of its range, is the primary factor influencing the viability of the northeastern bulrush. Although the species exists in wetlands that regularly experience fluctuating water levels, the northeastern bulrush and its habitat are susceptible to floods and droughts. Based on global, regional, and local climate models (Service 2019a, chapter 5), we expect that changes in climate will impact the northeastern bulrush's habitat by changing the amount, timing, and severity of precipitation and drought, and the number of extreme precipitation events. Higher temperatures, without increasing summer precipitation, may cause wetlands to dry up earlier, and an extended growing season may allow other vegetation to encroach upon, compete with, and increase shading of, northeastern bulrush plants. We expect these impacts to be more noticeable in populations that occur in seasonal wetlands. We expect beaver activity may at least partially mitigate effects of changing climate by regulating water levels through damming, maintaining larger wetlands and open area compared to seasonal wetlands, and removing trees and reducing shading at the wetland perimeter.

The 13 populations (8.7 percent of known extant populations) in seasonal wetlands that are currently in poor condition are the most vulnerable to the effects of changing climate and have a high risk of extirpation. However, the populations in beaver wetlands are much less vulnerable to the effects of changing climate and have a low risk of extirpation. Rangewide, most populations (78 percent) occur in seasonal wetlands, but the distribution is geographically disparate. In the New England region, 60.4 percent of populations (29 of 48) occur in beaver wetlands, while in the Appalachian region, 97 percent of populations (97 of 100) occur in seasonal wetlands (Service 2019a, p. 29). Additional information on the effects of climate change on the northeastern bulrush can be found in the SSA report (Service 2019a, pp. 33–34).

Future Condition Analysis

We modeled a single scenario to assess the potential future viability of the northeastern bulrush in the context of the factors influencing species viability and resiliency, representation, and redundancy. Due to uncertainties with factors such as fluctuating water levels, climatic stochasticity, light availability, and regulatory protection, we used EO rank to assess future resiliency condition, consistent with our current condition analysis.

We explored plausible changes in the factors considered in an EO ranking, such as population size, biotic factors, abiotic factors, and landscape context (Hammerson *et al.* 2008) to anticipate future changes in EO rank at each population. We were unable to explicitly predict changes in population size; however, we were able to use existing climate models to qualitatively anticipate effects of changing climate on biotic and abiotic factors (*i.e.,* habitat type and quality). We used the same population resiliency scoring model for future condition that we used for current condition. Accordingly, to describe plausible future viability, we model future resiliency at the population level and reasonably reliable trends in redundancy and representation at the rangewide scale (see Service 2019a, pp. 32–39).

We considered the potential consequences of climate change and carried the scenario approximately 30 years into the future (2050) to be considered our foreseeable future because we have information to reasonably reliably predict changes in climate within this timeframe. We first modeled the response of northeastern bulrush habitat to changes in climate consistent with representative concentration pathway (RCP) 8.5. The best available information, as summarized in the SSA report, generally presents this scenario as a plausible, high-emissions scenario anticipating greater changes in climate than moderate climate scenarios, such as RCP 4.5. Available information also suggests the probability of scenarios worse than RCP 8.5 is low. Therefore, RCP 8.5 presents a worst case, but still plausible, scenario for northeastern bulrush habitat. As our analysis using RCP 8.5 resulted in the northeastern bulrush not meeting the Act's definition of an endangered or a threatened species, it follows that additional analyses using RCP 4.5 or another

moderate-emissions climate model would result in lower magnitude effects on the species' habitat and, ultimately, the same listing determination. Therefore, we did not bracket our analysis with lower emissions climate models.

We generally anticipate, and modeling reflects, that climate change is likely to impact the species' habitat through higher water levels early in the growing season followed by hotter summers and a faster drying cycle. For the northeastern bulrush, this will affect fluctuating water levels, climatic stochasticity, and light availability, resulting in neutral effects on beaver wetlands and negative effects on seasonal wetlands. We expect beavers to mitigate anticipated climate changes at beaver wetlands by thinning canopy cover and regulating water levels by damming. In addition, while we are not aware of climate studies examining specific effects on beavers, beavers occur within and outside the range of the northeastern bulrush in diverse landscapes, some of which are hotter and have different precipitation regimes. Accordingly, we anticipate beavers will remain within the range of the northeastern bulrush through 2050. Therefore, we expect no reduction in northeastern bulrush population representation in beaver wetlands before 2050 beyond that which could occur through normal beaver use and disuse of wetlands.

Our future scenario anticipated moderate negative effects on resiliency, a slight decline in representation and redundancy, and extirpation of 13 populations (2 in the northern region and 11 in the Appalachian region) from seasonal wetlands. In 2050, approximately 135 populations would remain distributed across a large geographical range in at least three physiographic provinces, two habitat types, and all currently occupied States. The number of future populations could be slightly higher if new populations are discovered. The species likely would retain low genetic diversity, especially in the northern region. The species' apparent limited dispersal capacity will reduce its ability to shift its range in response to changing climate. However, the species would retain its redundancy driven by a wide geographic distribution and retain representation via the use of a variety of environmental settings (habitat and physiographic provinces).

We note that, by using the SSA framework to guide our analysis of the scientific information documented in the SSA report, we have analyzed the cumulative effects of identified threats and conservation actions on the species. To assess the current and future condition of the species, we evaluate the effects of all the relevant factors that may be influencing the species, including threats and conservation efforts. Because the SSA framework considers not just the presence of the factors, but to what degree they collectively influence risk to the entire species, our assessment integrates the cumulative effects of the factors and replaces a standalone cumulative-effects analysis.

Conservation Efforts and Regulatory Mechanisms

There are many conservation measures that benefit the northeastern bulrush's viability. These measures are consistent with those described in the recovery plan (Service 1993, entire) and include protection through State endangered species laws, protection through State wetland protection laws, protection of sites through perpetual conservation easements and public land ownership, surveys to monitor known populations and to locate additional populations, research efforts to better understand the species' life history, propagation and transplantation efforts, canopy thinning, invasive species control measures, and active management to address shrub encroachment.

Determination of Northeastern Bulrush Status

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species meets the definition of an endangered species or a threatened species. The Act defines an ''endangered species'' as a species that is in danger of extinction throughout all or a significant portion of its range, and a ''threatened species'' as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether a species meets the definition of an endangered species or a threatened species because of any of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) Overutilization for commercial, recreational, scientific, or educational purposes; (C) Disease or predation; (D) The inadequacy of existing regulatory mechanisms; or (E) Other natural or manmade factors affecting its continued existence.

Status Throughout All of Its Range

After evaluating threats to the species and assessing the cumulative effect of the threats under the Act's section 4(a)(1) factors, we listed the northeastern bulrush in 1991 (see 56 FR 21091; May 7, 1991). At that time, there were only 13 known occurrences, and the species faced threats from habitat loss primarily due to land conversion for development. The northeastern bulrush has been the subject of recovery efforts since it was listed under the Act, and the discovery of previously unknown populations, research leading to the understanding of the species' needs, and identification of management actions that support those needs have led to a revised assessment of the status of the species since that time.

As explained above, while the recovery plan does not include delisting criteria, our analysis presented in the SSA report (Service 2019a, entire) shows that the intent of the recovery plan's downlisting criteria (Service 1993, p. 37) has been exceeded substantially, supporting our conclusion that the species is neither endangered nor threatened. The underlying purpose and intent of each of the three downlisting criteria has been exceeded by a wide margin. At the time of listing in 1991, there were 13 known extant populations in 6 States. By the time the recovery plan was approved 2 years later, in 1993, 33 extant populations had been identified. Largely due to increased survey effort, there are presently 148 known extant populations in 8 States; this amounts to a 4-fold increase in known populations since the downlisting criteria were established. The first downlisting criterion in the recovery plan calls for permanent protection of 20 populations. Eighty-nine (approximately 60 percent) of the 148 known extant populations occur on public lands. This number greatly exceeds the protected populations called for in the first downlisting criterion, and we have also determined that the threat from development is less than projected at the time we completed the recovery plan (1993). Accordingly, we conclude that the intent of this criterion has been substantially exceeded. The second criterion calls for 20 stable or increasing populations. Of the 148 extant populations, 132 are in excellent, good, or fair condition, which is an order of magnitude higher than the number of stable or increasing populations called for in the second downlisting criterion. The third downlisting criterion calls for increased understanding of the species' life-

history and ecological requirements. Research on the effects of hydrology, shading, herbivory, genetics, propagation, transplantation, and nutrients on germination and plant growth has provided understanding that is sufficient to support long-term management of northeastern bulrush populations (*e.g.,* Lentz and Cipollini 1998, entire; Lentz and Dunson 1998, entire).

As discussed, under current conditions, there are 148 known populations of northeastern bulrush distributed throughout 4 physiographic provinces in 8 States—New Hampshire, Vermont, Massachusetts, New York, Pennsylvania, Maryland, Virginia, and West Virginia. The increase in known populations since listing is due primarily to increased survey effort, and it is possible that more populations will be found in the future. Despite the dynamic nature of the species' life history, there have been only a few (9) documented extirpations of extant populations (Service 2019a, p. 27). Some populations have benefited from habitat management, but we are not aware of any populations that were newly established or re-established after extirpation as a result of outplanting or other restoration efforts. Our analysis of these populations in the SSA report (Service 2019a, p. 27) indicates that 89 percent of the populations demonstrate excellent, good, and fair resiliency, and only 11 percent of the populations demonstrate poor resiliency.

Development activities are no longer considered a significant threat. Deer browsing and trampling, as well as trampling and wallowing by black bears, have been noted in some populations, and these activities can have detrimental effects on a population, particularly if other factors, such as decreased light availability, are affecting the population. However, these factors affect only a small number of populations, and the likelihood is low that browsing, trampling, or wallowing would occur in a particular population with poor resiliency and with sufficient magnitude to affect the entire population. Accordingly, we conclude that browsing, trampling, and wallowing either individually or cumulatively are not likely to cause the extirpation of a population and, therefore, are not significant factors contributing to the risk of extinction of the northeastern bulrush.

Regulatory protections afforded to the northeastern bulrush include State wetland protections and State endangered species regulations. These protections apply independently of the species' Federal status under the Act and, at a minimum, require project proponents to coordinate with State resource agencies to develop minimization measures for projects that may affect the northeastern bulrush or its habitat. A description of the States' regulatory protections can be found in the SSA report (Service 2019a, pp. 17–21).

Since the listing of the northeastern bulrush in 1991, we have become aware of the potential for the effects of climate change to affect organisms and ecosystems, including the northeastern bulrush. To inform our understanding of the species' risk of extinction, we modeled a single future scenario detailed above in *Summary of Biological Status and Threats.* This future scenario, by itself, does not provide an estimate of the species' risk of extinction, but it does help us better understand the extent to which threats would have to further affect the species to cause extinction, considering the present population figures and resiliency status. Based on the best information regarding the species' current condition and threats, we projected how the threats would manifest under this ''worst case'' scenario and how the species would respond.

To summarize, our greater knowledge regarding the prevalence of northeastern bulrush populations and the impacts of natural and artificial systems and disturbances on the species results in a conclusion that the overall extinction risk for the northeastern bulrush is much lower than we had previously determined it to be at the time the species was listed in 1991 (see 56 FR 21091; May 7, 1991). Considering our modeled ''worst case'' future scenario, it is apparent that the risk of threats manifesting in such a way as to cause extinction of the species is very low. Known impacts at the time of listing, such as habitat loss due to development and inadequate regulatory protections, that could have resulted in the extirpation of populations have either been reduced or have not materialized since listing. Through our assessment of future condition, including the status of known stressors and probable impacts of climate change, we anticipate that 88 percent of populations across the range of the species would maintain high, moderate, or fair resiliency over a timeframe of approximately 30 years into the future. We, therefore, conclude the previously recognized impacts to the northeastern bulrush from present or threatened destruction, modification, or curtailment of its habitat or range; overutilization for commercial, recreational, scientific, or educational purposes; disease or predation; the inadequacy of existing regulatory mechanisms; and other natural or manmade factors affecting its continued existence do not rise to a level of significance, either individually or in combination, such that the species is in danger of extinction now or likely to become so within the foreseeable future. Thus, after assessing the best available scientific information, we conclude that the northeastern bulrush is not in danger of extinction now or likely to become so within the foreseeable future throughout all of its range.

Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so in the foreseeable future throughout all or a significant portion of its range. Having determined that the northeastern bulrush is not in danger of extinction or likely to become so in the foreseeable future throughout all of its range, we now consider whether it may be in danger of extinction (*i.e.,* endangered) or likely to become so in the foreseeable future (*i.e.,* threatened) in a significant portion of its range—that is, whether there is any portion of the species' range for which both (1) the portion is significant; and, (2) the species is in danger of extinction or likely to become so in the foreseeable future in that portion. Depending on the case, it might be more efficient for us to address the ''significance'' question or the ''status'' question first. We can choose to address either question first. Regardless of which question we address first, if we reach a negative answer with respect to the first question that we address, we do not need to evaluate the other question for that portion of the species' range.

In undertaking this analysis for northeastern bulrush, we choose to address the status question first. We began by identifying portions of the range where the biological status of the species may be different from its biological status elsewhere in its range. For this purpose, we considered information pertaining to the geographic distribution of (a) individuals of the species, (b) the threats that the species faces, and (c) the resiliency condition of populations.

We evaluated the range of the northeastern bulrush to determine if the species is in danger of extinction now or likely to become so in the foreseeable future in any portion of its range. The range of a species can theoretically be divided into portions in an infinite number of ways. We focused our

analysis on portions of the species' range that may meet the definition of an endangered species or a threatened species. For northeastern bulrush, we considered whether the threats or their effects on the species are greater in any biologically meaningful portion of the species' range than in other portions such that the species is in danger of extinction now or likely to become so in the foreseeable future in that portion.

We examined the following threats and cumulative impacts of these threats: (1) habitat disturbance and destruction from development; (2) beaver activity; (3) deer and bear activities, such as trampling, browsing, and wallowing; and (4) climate change. As stated previously under *Summary of Biological Status and Threats,* when this species was listed, habitat disturbance and destruction from development and other anthropogenic impacts was identified as an important threat to the northeastern bulrush. However, since listing, the anticipated threat of habitat loss from development has not materialized in any portion of the range, and we conclude that the threat of habitat disturbance and destruction from development does not rise to a level that threatens the species now or into the future. Similarly, while we identified threats of beaver activity, trampling, and wallowing that can cause localized impacts to individual northeastern bulrush populations, these factors are not occurring at a significant level in any portion of the species' range.

The effects of climate change differ between the northern and southern portions of the range of the northeastern bulrush, as most populations in the southern portion of the range occur in seasonal wetlands while populations in the northern portion are more evenly distributed between seasonal wetlands and beaver marshes. Changing climatic conditions will include more precipitation during winters, higher temperatures throughout the species' range, and an increased frequency of extreme precipitation events. We project these conditions will have more negative effects on seasonal wetlands and neutral effects on beaver marshes, equating to a slightly elevated risk from climate change in the southern portion of the range. As described in the SSA report (Service 2019a, pp. 32–39), climate change under a worst-case scenario could contribute to extirpation of 13 populations (2 populations in the northern portion and 11 in the southern portion) across the species' range. However, there are still projected to be 135 populations remaining: 46 populations in the northern portion (96% of extant populations) and 89 in the southern portion (89%), providing representation and redundancy within each portion and across the species' range. Moreover, it is projected that the southern and northern portions of the range will each retain strong resiliency, with more than 85 percent of populations in the southern portion and 93 percent in the northern portion projected to maintain high, moderate, or fair resiliency.

Our conclusion regarding the current and future viability of the species is supported by multiple, sufficiently resilient populations distributed across representative ecological settings and physiographic provinces and encompassing most of the species' known genetic diversity. We found no biologically meaningful portion of the northeastern bulrush's range where the condition of the species differs from its condition elsewhere in its range such that the status of the species in that portion differs from its status in any other portion of the species' range.

Therefore, we find that the species is not in danger of extinction now or likely to become so in the foreseeable future in any significant portion of its range. This does not conflict with the courts' holdings in *Desert Survivors* v. *U.S. Department of the Interior,* 321 F. Supp. 3d 1011, 1070–74 (N.D. Cal. 2018) and *Center for Biological Diversity* v. *Jewell,* 248 F. Supp. 3d. 946, 959 (D. Ariz. 2017) because, in reaching this conclusion, we did not apply the aspects of the Final Policy on Interpretation of the Phrase ''Significant Portion of Its Range'' in the Endangered Species Act's Definitions of ''Endangered Species'' and ''Threatened Species'' (79 FR 37578; July 1, 2014), including the definition of ''significant'' that those court decisions held to be invalid.

Determination of Status

Our review of the best scientific and commercial data available indicates that the northeastern bulrush does not meet the definition of an endangered species or a threatened species in accordance with sections 3(6) and 3(20) of the Act. In accordance with our regulations at 50 CFR 424.11(e)(2), currently in effect, the species has recovered to the point at which it no longer meets the definition of an endangered species or a threatened species. Therefore, we propose to remove northeastern bulrush from the Federal List of Endangered and Threatened Plants.

Effects of This Rule

This proposed rule, if made final, would revise 50 CFR 17.12(h) by removing northeastern bulrush [species] from the Federal List of Endangered and Threatened Plants. The prohibitions and conservation measures provided by the Act, particularly through sections 7 and 9, would no longer apply to this species. Federal agencies would no longer be required to consult with the Service under section 7 of the Act in the event that activities they authorize, fund, or carry out may affect northeastern bulrush.

There is no critical habitat designated for this species, so there would be no effect to 50 CFR 17.96.

Post-Delisting Monitoring

Section 4(g)(1) of the Act requires us, in cooperation with the States, to implement a monitoring program for not less than 5 years for all species that have been recovered. Post-delisting monitoring (PDM) refers to activities undertaken to verify that a species delisted due to recovery remains secure from the risk of extinction after the protections of the Act no longer apply. The primary goal of PDM is to monitor the species to ensure that its status does not deteriorate, and if a decline is detected, to take measures to halt the decline so that proposing it as endangered or threatened is not again needed. If at any time during the monitoring period data indicate that protective status under the Act should be reinstated, we can initiate listing procedures, including, if appropriate, emergency listing.

We will coordinate with other Federal agencies, State resource agencies, interested scientific organizations, and others as appropriate to develop and implement an effective PDM plan for northeastern bulrush. The PDM plan will build upon current research and effective management practices that have improved the status of the species since listing. Ensuring continued implementation of proven management strategies that have been developed to sustain the species will be a fundamental goal for the PDM plan. The PDM plan will identify measurable management thresholds and responses for detecting and reacting to significant changes in northeastern bulrush numbers, distribution, and persistence. If declines are detected equaling or exceeding these thresholds, the Service, in combination with other PDM participants, will investigate causes of these declines. The investigation will be to determine if the northeastern bulrush warrants expanded monitoring, additional research, additional habitat protection, or resumption of Federal protection under the Act.

We appreciate any information on what should be included in post-

delisting monitoring strategies for these species (see Information Requested, above).

Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

References Cited

A complete list of references cited in this rulemaking is available on the internet at *https://www.regulations.gov* and upon request from the New England Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the Fish and Wildlife Service's Species Assessment Team and the New England Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Plants, Reporting and recordkeeping requirements, Transportation, Wildlife.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

§ 17.12 [Amended]

■ 2. In § 17.12, amend paragraph (h) by removing the entry for ''*Scirpus ancistrochaetus*'' under FLOWERING PLANTS from the List of Endangered and Threatened Plants.

Martha Williams,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2024–16417 Filed 7–30–24; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register
Vol. 89, No. 147
Wednesday, July 31, 2024

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

DEPARTMENT OF AGRICULTURE

Forest Service

Proposed Recreation Fee Sites

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: The Fremont-Winema National Forest is proposing to establish several recreation fee sites. Proposed recreation fees collected at the proposed recreation fee sites would be used for operation, maintenance, and improvement of the sites. An analysis of nearby recreation fee sites with similar amenities shows the proposed recreation fees that would be charged at the new recreation fee sites are reasonable and typical of similar recreation fee sites in the area.

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

ADDRESSES: Fremont-Winema National Forest, Attention: Recreation Fees, 1301 South G Street, Lakeview, OR 97630.

FOR FURTHER INFORMATION CONTACT: Scott Stoffel, Forest Recreation Program Manager, (541) 947–2151 or *sm.fs.Fee_Proposal@usda.gov.*

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

A proposed expanded amenity recreation fee of $10 per night and $5 per extra vehicle fee would be charged for Rye Spur Horse Camp and Sevenmile Equestrian Camp and Trailhead. A proposed expanded amenity recreation fee of $10 per night and $2 per extra vehicle fee would be charged for Jones Crossing, Happy Camp, and Willow Creek Campgrounds. An expanded amenity recreation fee of $5 per extra vehicle would be charged at Walt Haring Campground. A proposed expanded amenity recreation fee of $20 per night and $5 per extra vehicle would be charged for Annie Creek Campground and Sno-Park. In addition, a proposed expanded amenity recreation fee of $100 per night would be charged for rental of Pelican and Sevenmile Guard Stations.

A proposed standard amenity recreation fee of $5 per day per vehicle would be charged at Cold Springs, Malone Springs, Odessa, Rocky Point, Sevenmile Marsh, Summit Sno-Park/Pacific Crest Trail, and Wood River developed recreation sites. The Annual Northwest Forest Pass, National Forest Recreation Day Pass, National Forest Recreation ePass, and the America the Beautiful—the National Parks and Federal Recreational Lands Pass would be honored at these standard amenity recreation fee sites.

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

Dated: July 26, 2024.

Jacqueline Emanuel,

Associate Deputy Chief, National Forest System.

[FR Doc. 2024–16868 Filed 7–30–24; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Proposed New Recreation Fee Sites

AGENCY: Forest Service, USDA.

ACTION: Notice.

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

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

ADDRESSES: Chippewa National Forest, Attention: Michelle Heiker, 200 Ash Avenue NW, Cass Lake, Minnesota 56633.

FOR FURTHER INFORMATION CONTACT: Michelle Heiker, Recreation Program Manager, (218) 259–2664 or *michelle.heiker@usda.gov.*

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

An expanded amenity recreation fee of $40 per night would be charged for rental of Joyce and Mary Louise Cabins.

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

decision and implementation. Reservations for the cabins could be made online at *www.recreation.gov* or by calling (877)–444–6777. Reservations would cost $8.00 per reservation.

Dated: July 26, 2024.

Jacqueline Emanuel,

Associate Deputy Chief, National Forest System.

[FR Doc. 2024–16867 Filed 7–30–24; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Proposed Recreation Fee Site

AGENCY: Forest Service, USDA.

ACTION: Notice.

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

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

ADDRESSES: Kaibab National Forest, Attention: Recreation Fees, 742 Clover Road, Williams, AZ 86046.

FOR FURTHER INFORMATION CONTACT: Kevin Lehto, Recreation Program Manager, (928) 635–8200 or *kevin.lehto@usda.gov.*

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

A proposed expanded amenity recreation fee of $70 per night would be charged for rental of Grandview Cabin.

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

Dated: July 26, 2024.

Jacqueline Emanuel,

Associate Deputy Chief, National Forest System.

[FR Doc. 2024–16850 Filed 7–30–24; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–475–818]

Certain Pasta From Italy: Notice of Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review

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

SUMMARY: The U.S. Department of Commerce (Commerce) is initiating a changed circumstances review (CCR) of the antidumping duty (AD) order on certain pasta (pasta) from Italy. Further, Commerce preliminarily determines that Gruppo Milo SpA (Gruppo Milo) is the successor-in-interest to Gruppo Alimentare Mediterraneo Milo Srl (GRAMM) and should be assigned the same AD cash deposit rate as GRAMM for purposes of the AD order on pasta from Italy. Interested parties are invited to comment on these preliminary results.

DATES: Applicable July 31, 2024.

FOR FURTHER INFORMATION CONTACT: Peter Zukowski, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0189.

SUPPLEMENTARY INFORMATION:

Background

On July 24, 1996, Commerce published the AD order on pasta from Italy in the **Federal Register**.[1] On June 6, 2024, Commerce received a request on behalf of Gruppo Milo for a CCR, pursuant to section 751(b)(1) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.216(b), to establish Gruppo Milo as the successor-in-interest to GRAMM, an Italian producer and exporter of pasta and, thus, entitle it to GRAMM's AD cash deposit rate.[2] We received no comments from other interested parties concerning this request. On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.[3] The deadline for the initiation is now July 29, 2024.

Scope of the Order[4]

The scope of this *Order* covers shipments of certain non-egg dry pasta in packages of five pounds four ounces or less, whether or not enriched or fortified or containing milk or other optional ingredients such as chopped vegetables, vegetable purees, milk, gluten, diastasis, vitamins, coloring and flavorings, and two percent egg white. The pasta covered by the scope of the *Order* is typically sold in the retail market, in fiberboard or cardboard cartons, or polyethylene or polypropylene bags of varying dimensions.

Excluded from the scope of this *Order* are refrigerated, frozen, or canned pastas, as well as all forms of egg pasta, with the exception of non-egg dry pasta containing up to two percent egg white. Multicolored pasta, imported in kitchen display bottles of decorative glass that are sealed with cork or paraffin and bound with raffia, is excluded from the scope of the *Order*.[5] Pursuant to Commerce's August 14, 2009, changed circumstances review, effective July 1, 2008, gluten free pasta is also excluded from the scope of the *Order*.[6] Effective January 1, 2012, ravioli and tortellini filled with cheese and/or vegetables are

[1] *See Notice of Antidumping Duty Order and Amended Final Determination of Sales at Less Than Fair Value: Certain Pasta from Italy,* 61 FR 38547 (July 24, 1996) (*Order*).

[2] *See* Gruppo Milos's Letter, ''Certain Dry Pasta from Italy—Request for Changed Circumstances Review,'' dated June 6, 2024 (CCR Request).

[3] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,'' dated July 22, 2024.

[4] *See Certain Pasta from Italy: Final Results of Antidumping and Countervailing Duty Changed Circumstances Reviews,* 82 FR 4291 (January 13, 2017), where Commerce aligned the scope language across the AD and countervailing duty orders on pasta from Italy.

[5] *See* Memorandum to Richard Moreland, dated August 25, 1997, which is on file in the Central Records Unit.

[6] *See Certain Pasta from Italy: Notice of Final Results of Antidumping Duty Changed Circumstances Review and Revocation, in Part,* 74 FR 41120 (August 14, 2009).

also excluded from the scope of the *Order*.[7]

Also excluded are imports of organic pasta from Italy that are certified by an EU authorized body in accordance with the United States's Department of Agriculture's National Organic Program for organic products. The organic pasta certification must be retained by exporters and importers and made available to U.S. Customs and Border Protection or the Department of Commerce upon request.

The merchandise subject to this *Order* is currently classifiable under items 1901.90.9095 and 1902.19.20 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and Customs purposes, the written description of the merchandise subject to the *Order* is dispositive.

Initiation of CCR

Pursuant to section 751(b)(1)(A) of the Act and 19 CFR 351.216(d), Commerce will conduct a CCR upon receipt of information concerning, or a request from, an interested party for a review of an AD order which shows changed circumstances sufficient to warrant a review of the order. In the past, Commerce has used CCRs to address the applicability of cash deposit rates after there have been changes in the name or structure of a respondent, such as a merger or spinoff (''successor-in-interest'' or ''successorship'' determinations).[8] Based on a review of Gruppo Milo's request, and in accordance with section 751(b)(1)(A) of the Act and 19 CFR 351.216(d), we find that the information submitted in the CCR Request supporting Gruppo Milo's request that it should be treated as the successor-in-interest to GRAMM is sufficient to warrant a review to determine whether Gruppo Milo is entitled to GRAMM's AD cash deposit rate.

Preliminary Results

Section 351.221(c)(3)(ii) of Commerce's regulations authorizes Commerce to combine the notice of initiation of a CCR and the notice of preliminary results if Commerce concludes that expedited action is warranted. In this instance, because the record contains information necessary to make a preliminary finding and no interested parties have summitted comments on Gruppo Milo's request, we find that expedited action is warranted and have combined the notice of initiation and the notice of preliminary results.

Pursuant to section 751(b) of the Act, we have conducted a CCR using a successor-in-interest analysis in response to Gruppo Milo's request. In making a successor-in-interest determination, Commerce examines several factors, including, but not limited to, changes in the following: (1) management and ownership; (2) production facilities; (3) supplier relationships; and (4) customer base.[9] While no single factor or combination of factors will necessarily provide a dispositive indication of a successor-in-interest relationship, generally, Commerce will consider the new company to be the successor to the previous company if the new company's resulting operation is not materially dissimilar to that of its predecessor.[10] Thus, if the evidence demonstrates that, with respect to the production and sales of the subject merchandise, the new company operates essentially the same business entity as the former company, Commerce will accord the new company the same antidumping treatment as its predecessor.[11] In accordance with 19 CFR 351.216, we preliminarily determine that Gruppo Milo is the successor-in-interest to GRAMM for purposes of the *Order* and is entitled to GRAMM's AD cash deposit rate.

1. Management

Gruppo Milo submitted evidence of its management before and after its name change. Gruppo Milo's evidence indicates that the board of directors, organizational chart, and ownership structure all remain the same before and after the change to its name and corporate form.[12]

2. Production Facilities

Gruppo Milo submitted evidence of its production facilities, including names of the facilities, addresses, what is produced at the facilities, and contact information. Gruppo Milo's evidence indicates that there were no changes to its production facilities as a result of the changes to its name and corporate form, as Gruppo Milo operates the same three production facilities that were operated by GRAMM.[13]

3. Supplier Relationships and Customer Base

Gruppo Milo provided lists of both its suppliers[14] and U.S. customers[15] before and after the name change to support its assertion that there have been no material changes to GRAMM's suppliers or its customer base. This documentation shows that the top suppliers and customers are the same both before and after the changes to its name and corporate form.

In addition to the evidence above, Gruppo Milo provided documentation demonstrating approval of GRAMM's name change by GRAMM's shareholders on March 8, 2024 (the shareholders remained unchanged from prior to the name change).[16] Further, as support, Gruppo Milo provided the ''Visura,'' or company registration report for Gruppo Milo SpA from the Milan Chamber of Commerce as it appears in the Italian Business Register—Company Registration Office.[17] Gruppo Milo also provided the Visura for GRAMM for comparative reference, which shows that the basic purpose and structure of the company remains unchanged.[18] The continuity between Gruppo Milo's Visura and GRAAM's Visura supports the claim that Gruppo Milo's operations with respect to sales of subject merchandise have not materially changed as a result of its name change.

[7] *See Certain Pasta from Italy: Final Results of Antidumping Duty and Countervailing Duty Changed Circumstances Reviews and Revocation, in Part,* 79 FR 58319, 58320 (September 29, 2014).

[8] *See, e.g., Diamond Sawblades and Parts Thereof from the People's Republic of China: Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review,* 82 FR 51605, 51606 (November 7, 2017) (*Diamond Sawblades from China Preliminary*), unchanged in *Diamond Sawblades and Parts Thereof from the People's Republic of China: Final Results of Antidumping Duty Changed Circumstances Review,* 82 FR 60177 (December 19, 2017) (*Diamond Sawblades from China Final*).

[9] *See, e.g., Diamond Sawblades from China Preliminary,* unchanged in *Diamond Sawblades from China Final; see also Certain Frozen Warmwater Shrimp from India: Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review,* 83 FR 37784 (August 2, 2018), unchanged in *Certain Frozen Warmwater Shrimp from India: Notice of Final Results of Antidumping Duty Changed Circumstances Review,* 83 FR 49909 (October 3, 2018).

[10] *Id.*

[11] *See, e.g., Notice of Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review: Certain Frozen Warmwater Shrimp from India,* 77 FR 64953 (October 24, 2012), unchanged in *Final Results of Antidumping Duty Changed Circumstances Review: Certain Frozen Warmwater Shrimp from India,* 77 FR 73619 (December 11, 2012); and *Circular Welded Non-Alloy Steel Pipe from the Republic of Korea; Preliminary Results of Antidumping Duty Changed Circumstances Review,* 63 FR 14679 (March 26, 1998), unchanged in *Circular Welded Non-Alloy Steel Pipe from Korea: Final Results of Antidumping Duty Changed Circumstances Review,* 63 FR 20572 (April 27, 1998), in which Commerce found that a company which only changed its name and did not change its operations is a successor-in-interest to the company before it changed its name.

[12] *See* CCR Request at Exhibit 3.

[13] *Id.* at Exhibit 4.

[14] *Id.* at Exhibit 5.

[15] *Id.* at Exhibit 6.

[16] *Id.* at Exhibit 1.

[17] *Id.* at Exhibit 2.

[18] *Id.*

Therefore, based on the record evidence discussed above, we preliminarily determine that Gruppo Milo is the successor-in-interest to GRAMM, as the change in the business' name and corporate form was not accompanied by changes to its management and ownership, production facilities, supplier relationships, or customer base. Thus, we preliminarily determine that Gruppo Milo is entitled to the same AD cash deposit rate with respect to subject merchandise as its predecessor.

Should our final results remain unchanged from these preliminary results, we will instruct U.S. Customs and Border Protection to assign entries of subject merchandise exported by Gruppo Milo the AD cash deposit rate applicable to GRAMM. Commerce will issue its final results of the review in accordance with the time limits set forth in 19 CFR 351.216(e).

Public Comment

In accordance with 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs not later than 14 days after the date of publication of this notice in the **Federal Register**.[19] Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than five days after the case briefs, in accordance with 19 CFR 351.309(d)(1) and (2). Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[20] All comments must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the day it is due.[21] Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[22]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this CCR, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[23] Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results of this CCR. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request via ACCESS within 14 days of publication of this notice.[24] Hearing requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective briefs. If a request for a hearing is made, Commerce will inform parties of the scheduled date for the hearing.[25] Parties should confirm the date and the time of the hearing two days before the scheduled date.

Final Results

Unless the deadline is extended, pursuant to 19 CFR 351.216(e), Commerce intends to issue the final results of this CCR no later than 270 days after the date on which this review was initiated, or within 45 days if all parties agree to our preliminary finding.

Notification to Interested Parties

This notice is published in accordance with sections 751(b)(1) and 777(i) of the Act and 351.221(b)(1) and 351.221(c)(3)(ii).

Dated: July 25, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2024–16893 Filed 7–30–24; 8:45 am]

BILLING CODE 3510–DS–P

[19] Commerce is exercising its discretion under 19 CFR 351.309(c)(1)(ii) to alter the time limit for the filing of case briefs.

[20] *See* 19 CFR 351.309(c)(2) and (d)(2).

[21] *See* 19 CFR 351.303(b).

[22] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule,* 88 FR 67069 (September 29, 2023).

[23] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[24] Commerce is exercising its discretion under 19 CFR 351.310(c) to alter the time limit for requesting a hearing.

[25] *See* 19 CFR 351.310(d)(1).

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Recipient Reporting Information Collection Request (ICR)

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on 07/21/2023 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Institute of Standards and Technology (NIST), Commerce.

Title: Recipient Reporting.

OMB Control Number: 0693–XXXX.

Form Number(s): None.

Type of Request: Regular. This is a new collection.

Number of Respondents: 90.

Average Hours per Response: 16 hours, 4 times per year.

Burden Hours: 5,760 hours per year.

Needs and Uses: The CHIPS Program Office (CPO) is collecting information from recipients of CHIPS funding for the purposes of monitoring award performance; ensuring compliance with the terms of an award; general programmatic financial management activities, including decisions to disburse funds; and executing long-term program evaluation initiatives. The CPO will collect information via regular reporting and event-driven reporting. Information will be collected via an awardee's Salesforce portal and recipients will only report on information that is part of the terms of their award. Information in the following topic areas may be collected: project health, construction, operations and production, financials, research and development, workforce, national security, community investments and inclusive opportunities for businesses, project milestones, and environment.

Affected Public: Business or other for-profit organizations.

Frequency: Recurring during lifespan of an award on quarterly submission schedule.

Respondent's Obligation: Mandatory to receive and maintain CHIPS Act funding.

Legal Authority: CHIPS Act of 2022 (Division A of Pub. L. 117–167) (the Act).

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

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0693–XXXX.

Sheleen Dumas,

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

[FR Doc. 2024–16779 Filed 7–30–24; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Application Forms for Membership on a National Marine Sanctuary Advisory Council

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

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. This notice pertains to a requested revision and extension of the approved collection of information for national marine sanctuary advisory council applications. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before September 30, 2024.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at *NOAA.PRA@noaa.gov.* Please reference OMB Control Number 0648–0397 in the subject line of your comments. All comments received are part of the public record and will generally be posted on *https://www.regulations.gov* without change. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Sage Riddick, National Advisory Council Coordinator, Office of National Marine Sanctuaries, 1305 East West Highway, SSMC4, 10th Floor, Silver Spring, MD 20910, (240) 560–3365, and *sage.riddick@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This is a request for revision and extension of an approved information collection. Section 315 of the *National Marine Sanctuaries Act* (NMSA) (16 U.S.C. 1445a) allows the Secretary of Commerce to establish one or more advisory councils to advise and make recommendations to the Secretary regarding the designation and management of national marine sanctuaries. Executive Order 13178 (December 4, 2000) similarly established a Coral Reef Ecosystem Reserve Council pursuant to the NMSA for the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve. Councils are individually chartered for each site, or for the sanctuary system, to meet its specific needs. Once an advisory council has been chartered, a sanctuary superintendent starts a process to recruit members for that council by providing notice to the public and requesting interested parties to apply for the available seat(s) (*e.g.,* Research, Education) and position(s) (*i.e.,* council member or alternate). The information obtained through this application process will be used to determine the qualifications of the applicant for membership on the advisory council.

Two application forms are currently associated with this information collection: (a) National Marine Sanctuary Advisory Council Application form; and (b) National Marine Sanctuary Advisory Council Youth Seat Application form. Application form instructions will specify requirements imposed upon the agency when reviewing applicants as potential council members or alternates. Questions posed to applicants have been reviewed and an additional two questions are being added to solicit information on eligibility for a potential stipend program to decrease financial barriers to joining advisory councils. An additional section for demographic questions is also being added to include the newly updated *Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity* and *Recommendations on the Best Practices for the Collection of Sexual Orientation and Gender Identity Data on Federal Statistical Surveys,* and to learn more about our applicants. Existing questions may be reordered, reworded, and at times, condensed to improve the organization of applicant responses and, thereby, simplify the applicant review process. We do not believe that such revisions to the application would appreciably change the average annual number of respondents or the reporting burden for the information requirements supporting solicitation of new advisory council members. To request and obtain a copy of the proposed application forms without charge, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section.

II. Method of Collection

Complete applications may be submitted electronically via email (with attachments), by mail, online application, or by facsimile transmission.

III. Data

OMB Control Number: 0648–0397.

Form Number(s): None.

Type of Review: Regular submission (revision and extension of a currently approved collection).

Affected Public: Individuals or households; business or other for-profit organizations; not-for-profit institutions.

Estimated Number of Respondents: 900.

Estimated Time per Response: 1.25 hours.

Estimated Total Annual Burden Hours: 1,125 hours.

Estimated Total Annual Cost to Public: $450.00.

Respondent's Obligation: Voluntary.

Legal Authority: National Marine Sanctuaries Act (16 U.S.C. 1445a).

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

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

[FR Doc. 2024–16770 Filed 7–30–24; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Alaska Saltwater Sportfishing Economic Survey

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

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before September 30, 2024.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at *NOAA.PRA@noaa.gov.* Please reference OMB Control Number 0648–0639 in the subject line of your comments. All comments received are part of the public record and will generally be posted on *https://www.regulations.gov* without change. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Dr. Russel Dame, Industry Economist, NOAA/NMFS, 7600 Sand Point Way NE, Bldg. 4, Seattle, WA 98115–6349, (206) 526–4432, *russel.a.dame@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for reinstatement with changes of a previously approved information collection.

The National Marine Fisheries Service (NMFS) previously collected survey data in 2007, 2012, and 2017 for conducting economic analyses of marine sport fishing in Alaska. These surveys were necessary to understand the factors that affect marine recreational fishing and its economic value. Relative to the previously approved information collection, this information collection focuses on collecting data from a subset of the Alaska saltwater angler population targeted in previous collections, specifically all Alaska saltwater anglers fishing by charter boat rather than all Alaska saltwater anglers. The focus on charter anglers excludes anglers who fish from a private boat or from shore. The focus on the charter angler subpopulation is due to that population being of primary concern for fishery managers. Charter anglers fishing for federally-regulated Pacific halibut are subject to different regulations and management actions compared with other Alaska saltwater anglers. Harvest regulations (*e.g.,* daily bag limits) for the unguided (non-charter) sector for Pacific halibut off Alaska have been unchanged for decades and are unlikely to change in the foreseeable future. Charter fishing for halibut in Alaska, on the other hand, has experienced a number of important changes that affect both charter anglers and the charter fishing businesses providing charter fishing services. The proposed data collection is needed to improve estimates of fishing trip values and fishing behavior potentially affected by changes in federal recreational fisheries off Alaska, including recent declines in populations of Pacific halibut and subsequent measures to manage harvest in the Alaska recreational charter fishing sector. Numerous questions in the survey have been updated to better reflect, and understand the effects of, recent changes in Alaska marine recreational fisheries.

The Federal Government is responsible for the management of the Pacific halibut sport fishery off Alaska, while the State of Alaska manages the salmon sport fisheries (Chinook, coho, sockeye, chum, and pink), as well as several other saltwater sport fisheries. The updated survey's scope covers marine sport charter fishing for Pacific halibut, salmon, and other popular marine sport species in Alaska (*e.g.,* lingcod and rockfish). The data collected from the survey will be used to update estimates of the demand for and value of Pacific halibut fishing to charter anglers and to analyze how the type of fish caught, fishery regulations, and other factors affect fishing values and anglers' decisions to participate in Alaska marine charter fishing activities. The economic information provided from the survey will help inform fishery managers about the economic values of Alaska marine charter halibut fisheries and the changes to participation in these fisheries with proposed regulations.

II. Method of Collection

Data will be collected through a push-to-web survey. A random sample of sport anglers who have fished in Alaska via a charter or for-hire boat will be mailed instructions and a personalized URL or QR code to access and complete the password protected web-based survey. Follow-ups to the initial mailing will be done to encourage a response from those who have not completed the survey. Among the follow-up efforts will be a postcard reminder, a second mailing, and a telephone or email contact with non-responding license holders for whom we have telephone numbers or email addresses to encourage response and gather data for assessing non-response behavior.

III. Data

OMB Control Number: 0648–0639.

Form Number(s): None.

Type of Review: Regular submission. Reinstatement with revisions.

Affected Public: Individuals or households.

Estimated Number of Respondents: 3,700.

Estimated Time per Response: 28.7 minutes.

Estimated Total Annual Burden Hours: 1,770 hours.

Estimated Total Annual Cost to Public: $0.

Respondent's Obligation: Voluntary.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

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

[FR Doc. 2024–16786 Filed 7–30–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE016]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Marine Site Characterization Surveys Off the Coast of Delaware

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

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that NMFS has issued an incidental harassment authorization (IHA) to Orsted Wind Power North America, LLC (Orsted) to incidentally harass marine mammals during marine site characterization surveys conducted off the coast of Delaware in the Bureau of Ocean Energy Management (BOEM) Commercial Lease of Submerged Lands for Renewable Energy Development on the Outer Continental Shelf (OCS) Lease Areas OCS–A 0482 and 0519 (Lease Areas), and the associated export cable route (ECR) area.

DATES: This authorization is effective from August 1, 2024, through July 31, 2025.

ADDRESSES: Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-other-energy-activities-renewable.* In case of problems accessing these documents, please call the contact listed below.

FOR FURTHER INFORMATION CONTACT: Alyssa Clevenstine, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are proposed or, if the taking is limited to harassment, a notice of a proposed IHA is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to in shorthand as ''mitigation''); and requirements pertaining to the monitoring and reporting of the takings. The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

History of Request

On October 1, 2021, Orsted, a limited liability company registered in the State of Delaware, submitted a request on behalf of Garden State Offshore Energy, LLC (Garden State) and Skipjack Offshore Energy, LLC (Skipjack), both subsidiaries of Orsted and both registered in the State of Delaware, for an IHA to take marine mammals incidental to marine site characterization surveys off the coast of Delaware in OCS–A 0482 and 0519, and along potential ECRs to landfall locations in Delaware and New Jersey. NMFS published a notice of the proposed IHA in the **Federal Register** on March 21, 2022 (87 FR 15922). Subsequently, the final notice of issuance of the IHA was published in the **Federal Register** (87 FR 30182, May 18, 2022), announcing effective dates of that IHA from May 10, 2022, through May 9, 2023 (2022 IHA). The specified activities were expected to result in the take, by Level B harassment, of 15 species (16 stocks) of marine mammals. The work was expected to be completed within the 1-year timeframe of the IHA. However, no work was completed under the original IHA.

On February 23, 2023, Orsted submitted a request that NMFS re-issue the previously issued IHA with the only change being new effective dates. NMFS published a notice of re-issuance of that IHA, announcing effective dates of May 10, 2023, through May 9, 2024 (88 FR 30278, May 11, 2023) (2023 IHA). The

specified activity, specific geographical region, the type of equipment or survey activities, amount of take requested by Orsted and later authorized by NMFS, as well as the planned mitigation, monitoring, and requirements remained unchanged from the 2022 IHA. Orsted completed a portion of the survey work that was covered by the 2023 IHA and submitted a preliminary monitoring report demonstrating that the required mitigation and monitoring requirements were satisfied, no impacts of a scale or nature not previously analyzed or authorized occurred as a result of the activities conducted, and the IHA holder did not exceed the authorized levels of take under that IHA (88 FR 30278, May 11, 2023).

On March 6, 2024, NMFS received a letter from Orsted requesting renewal of the re-issued 2023 IHA (2024 request) to conduct the same site characterization surveys within the same survey areas using the same type of survey equipment that was previously analyzed under the 2022 IHA and re-issued 2023 IHA. While Orsted's planned activity would ordinarily qualify for a renewal of the IHA, NMFS determined that a renewal of the 2023 IHA is not appropriate due to availability of substantially updated marine mammal density data for all species since issuance of the 2022 IHA (*https://seamap.env.duke.edu/models/Duke/EC/*), which NMFS determined represents the best available scientific data and which serves as the basis for updating the estimated take numbers. Marine mammal density estimates in the survey area (animals/km^2) were obtained using the most recent model results for all taxa (Roberts *et al.,* 2023). The updated models incorporate sighting data, including sightings from NOAA's Atlantic Marine Assessment Program for Protected Species (AMAPPS) surveys. After discussions with the applicant, NMFS received a revised request incorporating the new information, which was deemed adequate and complete on April 12, 2024. In evaluating the 2024 request, and where applicable, NMFS relies on the information previously presented in notices associated with issuance of the 2022 IHA (87 FR 15922, March 21, 2022; 87 FR 30182, May 18, 2022). There are no changes from the proposed IHA to the final IHA.

Description of the Activity and Anticipated Impacts

Overview

Orsted will conduct marine site characterization surveys, including high-resolution geophysical (HRG) surveys and geotechnical surveys, in BOEM Lease Areas OCS–A 0482 and 0519, and the associated ECRs. The purpose of the marine site characterization surveys is to collect data concerning seabed (geophysical, geotechnical, and geohazard), ecological, and archeological conditions within the footprint of offshore wind facility development. Surveys are also conducted to support engineering design and to map unexploded ordnance (UXO). Underwater sound resulting from Orsted's planned activities, specifically HRG surveys, has the potential to result in incidental take of 15 species (16 stocks) of marine mammals, in the form of Level B harassment only. The IHA covers the same specified activities previously described in Orsted's application for the 2022 IHA and subsequent documents. NMFS refers the public to the documents and supplemental materials related to the 2022 **Federal Register** notice of proposed IHA (87 FR 15922; March 21, 2022), the notice of issuance of the original 2022 IHA (87 FR 30182, May 18, 2022), the notice of re-issuance of that IHA (88 FR 30278, May 11, 2023), and 2024 notice of proposed IHA (89 FR 46073, May 28, 2024). The descriptions and analyses contained in those documents remain accurate with the exception of the minor modifications described herein.

Dates and Duration

The specified activities are planned to begin August 1, 2024. The duration of the planned activity remains unchanged from the 2022 IHA and the re-issued 2023 IHA and is expected to require up to 350 survey days across a maximum of three vessels operating concurrently over the course of a single year (''survey day'' defined as a 24-hr activity period in which the assumed number of line km are surveyed). The number of anticipated survey days was calculated as the number of days needed to reach the overall level of effort required to meet survey objectives assuming any single vessel travels 4 knots (kn) (7.4 kilometers per hour (km/hr)) and surveys cover, on average, 70 line km per 24-hr period.

Specific Geographic Region

The specific geographic region remains unchanged from the previously issued 2022 IHA and re-issued 2023 IHA. The planned activities will occur within the Project Area, which includes the Lease Areas and potential ECRs to landfall locations in Delaware. The combined Lease Areas OCS–A 0482 and 0519 comprise approximately 568 square kilometers (km^2) within the Wind Energy Area of BOEM's Mid-Atlantic Planning Area and the overall Project Area, including potential ECRs, is approximately 4,510 km^2. Water depths in the Lease Areas range from approximately 15–40 meters (m). Water depths within the ECR area extend from the shoreline (0 m depth) to approximately 40 m.

Detailed Description of the Specified Activity

A detailed description of the planned activities can be found in the previous **Federal Register** notices (87 FR 15922, March 21, 2022; 87 FR 30182, May 18, 2022) and related-supplemental documents. The nature of the specified activities, including the types of HRG equipment planned for use (*e.g.,* CHIRPs, boomers, and sparkers), daily trackline distances (70 line km per 24-hr period), and number of survey vessels (up to three operating concurrently), are identical to those described in the previous notices.

Comments and Responses

A notice of NMFS' proposal to issue an IHA to Orsted was published in the **Federal Register** on May 28, 2024 (89 FR 46073). That notice described, in detail, Orsted's activity, the marine mammal species that may be affected by the activity, and the anticipated effects on marine mammals while referencing the previous notices (87 FR 15922; March 21, 2022; 87 FR 30182, May 18, 2022; 88 FR 30278, May 11, 2023). In the May 28, 2024, notice, we requested public input on the request for authorization described therein, our analyses, the proposed authorization, and requested that interested persons submit relevant information, suggestions, and comments. This proposed notice was available for a 30-day public comment period.

In total, NMFS received three comments from two private citizens and from an organization (Clean Ocean Action (COA)). Some of these comments were out-of-scope or not applicable to the project (*e.g.,* general opposition to offshore wind projects, concerns for other species outside NMFS' jurisdiction) and are not described herein or discussed further. We do not specifically address comments expressing general opposition to activities related to wind energy development or respond to comments that are out of scope of the proposed IHA (89 FR 46073, May 28, 2024), such as comments on other Federal agency processes and activities not planned under this IHA.

All comments received during the public comment period which

contained relevant points were considered by NMFS and are described and responded to below. All relevant comment letters are available on NMFS' website (*https://www.fisheries.noaa.gov/action/incidental-take-authorization-orsted-wind-power-north-america-llcs-site-characterization*).

Comment 1: COA disagrees with NMFS' initial conclusion that National Environmental Policy Act (NEPA) Categorical Exclusion B4 is applicable to this action due to (1) uncertainty regarding the environmental impacts of the action, (2) a lack of justification regarding how this action does not cumulatively have the potential for significant impacts on the quality of the environment, and (3) a lack of justification as to why no extraordinary circumstances apply to this action.

Response: NMFS does not agree with the commenters. A categorical exclusion (CE) is a category of actions that an agency has determined does not individually or cumulatively have a significant effect on the quality of the human environment and is appropriately applied for such categories of actions so long as there are no extraordinary circumstances present that would indicate that the effects of the action may be significant. Extraordinary circumstances are situations for which NOAA has determined further NEPA analysis is required because they are circumstances in which a normally excluded action may have significant effects. A determination of whether an action that is normally excluded requires additional evaluation because of extraordinary circumstances focuses on the action's potential effects and considers the significance of those effects in terms of both context (consideration of the affected region, interests, and resources) and intensity (severity of impacts). Potential extraordinary circumstances relevant to this action include (1) adverse effects on species or habitats protected by the MMPA that are not negligible; (2) highly controversial environmental effects; (3) environmental effects that are uncertain, unique, or unknown; and (4) the potential for significant cumulative impacts when the proposed action is combined with other past, present, and reasonably foreseeable future actions.

The relevant NOAA CE associated with issuance of incidental take authorizations is CE B4, issuance of incidental harassment authorizations under section 101(a)(5)(A) and (D) of the MMPA for the incidental, but not intentional, take by harassment of marine mammals during specified activities and for which no serious injury or mortality is anticipated. This action falls within CE B4. In determining whether a CE is appropriate for a given incidental take authorization, NMFS considers the applicant's specified activity and the potential extent and magnitude of takes of marine mammals associated with that activity along with the extraordinary circumstances listed in the Companion Manual for NOAA Administrative Order (NAO) 216–6A and summarized above.

The issuance of this IHA will not result in highly controversial environmental effects or result in environmental effects that are uncertain, unique, or unknown because numerous entities have been engaged in site characterization surveys that result in Level B harassment of marine mammals in the United States. This type of activity is well documented; prior authorizations and analysis demonstrate issuance of an IHA for this type of action only affects the marine mammals that are the subject of the specific authorization and, thus, no potential for significant cumulative impacts are expected, regardless of past, present, or reasonably foreseeable actions, even though the impacts of the action may not be significant by itself. Based on this evaluation, we concluded that the issuance of the IHA qualifies to be categorically excluded from further NEPA review.

The evaluation of whether extraordinary circumstances (if present) have the potential for significant environmental effects is limited to the decision NMFS is responsible for, which is issuance of the incidental take authorization. While there may be environmental effects associated with the underlying action, potential effects of NMFS' action are limited to those that would occur due to the authorization of incidental take of marine mammals. NMFS prepared numerous EAs analyzing the environmental impacts of the categories of activities encompassed by CE B4, which resulted in Findings of No Significant Impacts (FONSI) and, in particular, numerous EAs prepared in support of issuance of IHAs related to similar survey actions are part of NMFS' administrative record supporting CE B4. These EAs demonstrate the issuance of a given incidental harassment authorization does not affect other aspects of the human environment because the action only affects the marine mammals that are the subject of the incidental harassment authorization. These EAs also addressed factors in 40 CFR 1508.27 regarding the potential for significant impacts and demonstrate the issuance of incidental harassment authorization for the categories of activities encompassed by CE B4 do not individually or cumulatively have a significant effect on the human environment.

Specifically for this action, NMFS independently evaluated the use of the CE for issuance of Orsted's IHA, which included consideration of extraordinary circumstances. As part of that analysis, NMFS considered whether this IHA issuance would result in cumulative impacts that could be significant. In particular, the issuance of an IHA to Orsted is expected to result in minor, short-term behavioral effects on marine mammal species due to exposure to underwater sound from site characterization survey activities. Behavioral disturbance is expected to occur intermittently in the vicinity of Orsted's survey area during the 1-year timeframe. Level B harassment will be reduced through use of mitigation measures described herein. Additionally, as discussed elsewhere, NMFS has determined that Orsted's activities fall within the scope of activities analyzed in the Greater Atlantic Regional Office's (GARFO) programmatic consultation regarding geophysical surveys along the U.S. Atlantic coast in the 3 Atlantic Renewable Energy Regions (completed June 29, 2021; revised September 2021), which concluded surveys such as those planned by Orsted are not likely to adversely affect ESA-listed species or adversely modify or destroy critical habitat. Accordingly, NMFS has determined that the issuance of this IHA will result in no more than negligible (as that term is defined by the Companion Manual for NAO 216–6A) adverse effects on species protected by the ESA and the MMPA.

Comment 2: COA noted a preliminary monitoring report by the applicant was not made publicly available with the supporting documents on the project website and that NMFS should make monitoring and compliance reports publicly available with a schedule of when such reports will be released.

Response: The preliminary report submitted by the applicant and noted in the **Federal Register** notice (89 FR 46073, May 28, 2024) proposing this action was a requirement under the BOEM Project Design Criteria (PDC) and Best Management Practices (PDC 8), not the final reporting requirements under the 2023 IHA (88 FR 30278, May 11, 2023), therefore, it was not made publicly available. NMFS agrees with the need for reporting and indeed, the MMPA calls for IHAs to incorporate reporting requirements and a final

marine mammal monitoring report is required for the 2023 IHA. As included in the proposed IHA, the final IHA includes requirements for reporting that supports COA's recommendations, as well as timeframes for when reports will be considered complete and subsequently made publicly available. Orsted is required to submit a monitoring report to NMFS within 90 days after completion of survey activities that fully documents the methods and monitoring protocols, summarizes the data recorded during monitoring. All final reports and associated data submitted to NMFS are included on the website for public inspection. However, NMFS does not concur with the suggestions that draft reports be made publicly available.

Comment 3: COA provided comments suggesting that this IHA is a renewal. COA also noted that multiple IHAs, including renewals, have been requested by Orsted for the same project activities and stated that, in circumstances when it is not clear how long the proposed activities would span, a Letter of Authorization (LOA) is more appropriate than an IHA. COA stated that, given past delays, it is not clear how long the proposed activities would occur and that it is unrealistic and unreasonable to expect survey activities will actually cease after 1 year.

Response: As NMFS stated in the notice of the proposed IHA, the proposed action for which we requested comments was not for a renewal IHA. As described in the proposed **Federal Register** notice (89 FR 46073, May 28, 2024), we determined that a renewal IHA was not appropriate due to the release of comprehensively updated Duke University density information (Roberts *et al.,* 2023). Instead, we have issued a new IHA relying substantially on information and analysis produced in support of the previously issued 2022 IHA, as project details remain the same (also as described in the proposed **Federal Register** notice (89 FR 46073, May 28, 2024)). As we noted in the proposed notice and in this final notice for the 2024 IHA, Orsted has the option for a renewal if specific conditions and criteria are met.

Regarding clarification on authorizations, as described on our website, IHAs are 1-year authorizations and Incidental Take Regulations (ITR) are 5-year regulations that allow for the issuance of LOA. An ITR must be used if authorization of take by mortality is necessary. However, both options are available for applicants requesting authorization of harassment only. While applicants may request a 5-year regulation for HRG survey activities, NMFS has not received any such requests to date and there is no expectation presented in the MMPA or Congressional record that activities continuing for more than 1 year must seek ITR and authorization under 101(a)(5)(A) of the MMPA. Therefore, a determination of which option to take is not dependent on any expectation regarding whether the activity will continue for more than 1 year or not.

Comment 4: COA stated the information provided in the proposed (89 FR 46073, May 28, 2024) and previous notices (87 FR 15922; March 21, 2022; 87 FR 30182, May 18, 2022; 88 FR 30278, May 11, 2023) for this action regarding vessel strike is insufficient for NMFS to claim the probability of vessel strike due to HRG survey vessels is low enough to be discountable. COA noted the North Atlantic Right Whale (NARW) Speed Zone Dashboard does not clearly indicate whether HRG survey vessels are included and which vessel type category HRG survey vessels fall under, nor does the proposed notice specify the number of trips HRG survey vessels would take to complete the survey activities. COA stated this IHA cannot be issued without consideration and correction of these issues.

Response: Orsted did not request authorization for take incidental to vessel strike during marine site characterization surveys. Nevertheless, NMFS analyzed the potential for vessel strikes to occur during the survey, and determined that the potential for vessel strike is so low as to be discountable. NMFS does not authorize any take of marine mammals incidental to vessel strike resulting from the survey. If Orsted were to strike a marine mammal with a vessel, this would be an unauthorized take and be in violation of the MMPA. This gives Orsted a strong incentive to operate its vessels with all due caution and to effectively implement the suite of vessel strike avoidance measures called for in the IHA. Orsted proposed a very conservative suite of mitigation measures related to vessel strike avoidance, including measures specifically designed to avoid impacts to NARWs. Section 4(f) in the IHA contains a suite of non-discretionary requirements pertaining to vessel strike avoidance, including vessel operation protocols and monitoring. To date, NMFS is not aware of any site characterization vessels from surveys reporting a vessel strike within the United States despite intensive requirements for visual monitoring at all times during survey activity. When considered in the context of low overall probability of any vessel strike by Orsted vessels, given the limited additional survey-related vessel traffic relative to existing traffic in the survey area, the comprehensive visual monitoring, and other additional mitigation measures described herein, NMFS believes these measures are sufficiently protective to avoid vessel strike. These measures are described fully in the Mitigation section below, and include, but are not limited to: training for all vessel observers and captains, daily monitoring of NARW Sighting Advisory System, WhaleAlert app, and U.S. Coast Guard Channel 16 for situational awareness regarding NARW presence in the survey area, communication protocols if whales are observed by any Orsted personnel, vessel operational protocol should any marine mammal be observed, and visual monitoring.

Comment 5: COA believes that preserving the existence of NARW warrants pausing offshore development off the Atlantic coast and states NMFS needs to consider the cumulative impact, including the total number, speed, and distance of vessel trips required for marine site characterization survey activities, for all concurrent projects in the region and adjust the permitted activities accordingly.

Response: NMFS reiterates our action concerns only the authorization of marine mammal take incidental to the planned surveys—NMFS' authority under the MMPA does not extend to the specified activities themselves. COA did not provide any new or compelling evidence that suggests that wind energy development activities have the potential to negatively impact NARW. NMFS notes the cumulative effects of substantially similar activities in the northwest Atlantic Ocean have been analyzed in the past under section 7 of the ESA when NMFS engaged in formal intra-agency consultation, such as the 2013 programmatic Biological Opinion for Bureau of Ocean Energy Management Lease and Site Assessment Rhode Island, Massachusetts, New York, and New Jersey Wind Energy Areas (*https://repository.library.noaa.gov/view/noaa/29291*). Analyzed activities include those for which NMFS issued previous IHAs (82 FR 31562, July 7, 2017; 85 FR 21198, April 16, 2020; 86 FR 26465, May 10, 2021), which are similar to those planned by Orsted under this current IHA request.

NMFS reiterates that there is no evidence that acoustic noise resulting from offshore wind development-related activities could potentially cause marine mammal stranding, and there is no evidence linking recent marine mammal

mortalities an currently ongoing offshore wind development activities. This point has been well supported by other agencies, including the Bureau of Ocean Energy Management and the Marine Mammal Commission (Marine Mammal Commission Newsletter, Spring 2023). In addition, a recent study by Thorne and Wiley (2024) reviewed spatiotemporal patterns of strandings, mortalities, and serious injuries of humpback whales along the U.S. east coast from 2016–2022 and found vessel strikes to be the major driver in the increase of humpback whale strandings, mortalities, and serious injuries. Based upon the spatiotemporal analysis, no evidence was found that offshore wind development played a role in the increased number of strandings over time; for example, spatiotemporal patterns between strandings and site assessment surveys did not seem associated. In fact, the potential for vessel strike increased from 2016–2022 in association with increased container vessel traffic that overlapped with whales in new and shallow foraging areas. This potential for vessel strike also seemed to increase with the increased presence of juvenile humpback whales foraging off the Mid-Atlantic States. Under the IHA, NMFS requires Orsted to abide by vessel speed restrictions and maintain separation distances between vessels and marine mammals that are intended to minimize the risk of any potential vessel strikes.

There is an ongoing UME for humpback whales along the Atlantic coast from Maine to Florida, which includes animals stranded since 2016. Partial or full necropsy examinations were conducted on approximately half of the whales. Necropsies were not conducted on other carcasses because they were too decomposed, not brought to land, or stranded on protected lands (*e.g.,* national and state parks) where responders had limited or no access to the carcasses. Of the roughly 90 whales examined, about 40 percent had evidence of human interaction (*i.e.,* vessel strike or entanglement). The remaining 50 necropsied whales either had an undetermined cause of death due to a limited examination or decomposition of the carcass, or had other causes of death (*e.g.,* parasite-caused organ damage and starvation). Ongoing UMEs are also occurring for North Atlantic right whales and minke whales, both since 2017. NMFS will continue to gather data to help us determine the cause of death for these stranded whales. Vessel strikes and entanglement in fishing gear continue to be the greatest human threats to large whales.

For NMFS' response on cumulative impacts, please see our response to *Comment 1.*

Changes From Proposed to Final IHA

No changes were made from the proposed IHA to the final IHA.

Description of Marine Mammals in the Area of Specified Activities

A description of the marine mammals in the area of the specified activities can be found in the previous documents and notices for the 2022 IHA (87 FR 15922, March 21, 2022; 87 FR 30182, May 18, 2022), which remains applicable to this IHA. NMFS reviewed the most recent SARs (found on NMFS' website at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*), including the draft 2023 SARs, up-to-date information on relevant Unusual Mortality Events (UMEs; *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-unusual-mortality-events*), and recent scientific literature and determined that the new information does not change our original analysis of impacts supporting issuance of the 2022 IHA.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS's stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS's U.S. Atlantic and Gulf of Mexico SARs (*e.g.,* Hayes *et al.,* 2024). All values presented in table 1 are the most recent available at the time of publication, including, as applicable, from the draft 2023 SARs. NMFS notes that since the issuance of the 2022 IHA, new SARs are available for all species with the exception of humpback whale (Gulf of Maine stock), bottlenose dolphin (Northern Migratory Coastal stock), and harbor seal (Western North Atlantic stock). All new information is provided in table 1 and updated density data (Roberts *et al.,* 2023) are incorporated into take estimations (see Sections 3 and 6 of the updated application). Additionally, the new SARs data do not change our analysis of impacts, as described under the 2022 IHA.

Additionally, on August 1, 2022, NMFS announced proposed changes to the existing NARW vessel speed regulations (87 FR 46921, August 1, 2022) to further reduce the likelihood of mortalities and serious injuries to endangered NARWs from vessel collisions, which are a leading cause of the species' decline and a primary factor in an ongoing UME. Should a final vessel speed rule be issued and become effective during the effective period of this authorization (or any other MMPA incidental take authorization), the authorization holder will be required to comply with any and all applicable requirements contained within the final vessel speed rule. Specifically, where measures in any final vessel speed rule are more protective or restrictive than those in this or any other MMPA authorization, authorization holders will be required to comply with the requirements of the vessel speed rule. Alternatively, where measures in this or any other MMPA authorization are more restrictive or protective than those in any final vessel speed rule, the measures in the MMPA authorization will remain in place. The responsibility to comply with the applicable requirements of any vessel speed rule will become effective immediately upon the effective date of any final vessel speed rule.

TABLE 1—SPECIES AND STOCKS LIKELY IMPACTED BY THE SPECIFIED ACTIVITIES [1]

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) [2]	Stock abundance (CV, N_{min}, most recent abundance survey) [3]	PBR	Annual M/SI [4]
Order Artiodactyla—Cetacea—Mysticeti (baleen whales)						
Family Balaenidae:						
North Atlantic right whale [5]	*Eubalaena glacialis*	Western Atlantic	E, D, Y	340 (0, 337, 2021); 356 (346–363, 2022).	0.7	27.2

TABLE 1—SPECIES AND STOCKS LIKELY IMPACTED BY THE SPECIFIED ACTIVITIES [1]—Continued

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) [2]	Stock abundance (CV, N_{min}, most recent abundance survey) [3]	PBR	Annual M/SI [4]
Family Balaenopteridae (rorquals):						
Fin whale	*Balaenoptera physalus*	Western N Atlantic	E, D, Y	6,802 (0.24, 5,573, 2021)	11	2.05
Humpback whale	*Megaptera novaeangliae*	Gulf of Maine	-, -, N	1,396 (0, 1380, 2016)	22	12.15
Minke whale	*Balaenoptera acutorostrata*	Canadian Eastern Coastal	-, -, N	21,968 (0.31, 17,002, 2021)	170	9.4
Sei whale	*Balaenoptera borealis*	Nova Scotia	E, D, Y	6,292 (1.02, 3,098, 2021)	6.2	0.6
Odontoceti (toothed whales, dolphins, and porpoises)						
Family Physeteridae:						
Sperm whale	*Physeter macrocephalus*	N Atlantic	E, D, Y	5,895 (0.29, 4,639, 2021)	9.28	0.2
Family Delphinidae:						
Long-finned pilot whale	*Globicephala melas*	Western N Atlantic	-, -, N	39,215 (0.30, 30,627, 2021)	306	5.7
Short-finned pilot whale	*Globicephala macrorhynchus*	Western N Atlantic	-, -, Y	18,726 (0.33, 14,292, 2021)	143	218
Atlantic spotted dolphin	*Stenella frontalis*	Western N Atlantic	-, -, N	31,506 (0.28, 25,042, 2021)	250	0
Atlantic white-sided dolphin.	*Lagenorhynchus acutus*	Western N Atlantic	-, -, N	93,233 (0.71, 54,443, 2021)	544	28
Bottlenose dolphin	*Tursiops truncatus*	Northern Migratory Coastal	-, -, Y	6,639 (0.41, 4,759, 2016)	48	12.2–21.5
Bottlenose dolphin	*Tursiops truncatus*	Western N Atlantic Offshore	-, -, N	64,587 (0.24, 52,801, 2021)	507	28
Risso's dolphin	*Grampus griseus*	Western N Atlantic	-, -, N	44,067 (0.19, 30,662, 2021)	307	18
Common dolphin	*Delphinus delphis*	Western N Atlantic	-, -, N	93,100 (0.56, 59,897, 2021)	1,452	414
Family Phocoenidae (porpoises):						
Harbor porpoise	*Phocoena*	Gulf of Maine/Bay of Fundy	-, -, N	85,765 (0.53, 56,420, 2021)	649	145
Order Carnivora—Pinnipedia						
Family Phocidae (earless seals):						
Gray seal [6]	*Halichoerus grypus*	Western N Atlantic	-, -, N	27,911 (0.20, 23,624, 2021)	1,512	4,570
Harbor seal	*Phoca vitulina*	Western N Atlantic	-, -, N	61,336 (0.08, 57,637, 2018)	1,729	339

[1] Information on the classification of marine mammal species can be found on the web page for The Society for Marine Mammalogy's Committee on Taxonomy (*https://marinemammalscience.org/science-and-publications/list-marine-mammal-species-subspecies/*).

[2] ESA status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds potential biological removal (PBR) or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[3] NMFS marine mammal stock assessment reports online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports-region.* CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance.

[4] These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, vessel strike). Annual mortality or serious injury (M/SI) often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

[5] Linden (2023) estimated the population size in 2022 as 356 individuals, with a 95 percent credible interval ranging from 346 to 363. NMFS acknowledges this most recent estimation in addition to the 2023 draft SAR stock abundance estimate.

[6] NMFS's stock abundance estimate (and associated PBR value) applies to the U.S. population only. Total stock abundance (including animals in Canada) is approximately 394,311. The annual M/SI given is for the total stock.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

A description of the potential effects of the specified activities on marine mammals and their habitat may be found in the documents supporting the 2022 IHA (87 FR 15922, March 21, 2022; 87 FR 30182, May 18, 2022). At present, there is no new information on potential effects that would change our analysis.

Estimated Take of Marine Mammals

A detailed description of the methods used to estimate take anticipated to occur incidental to the project is found in the previous **Federal Register** notices (87 FR 15922, March 21, 2022; 87 FR 30182, May 18, 2022). The methods of estimating take are identical to those used in the 2022 IHA. We have updated the marine mammal densities based on new information (Roberts *et al.,* 2023), available online at: *https://seamap.env.duke.edu/models/Duke/EC/.* We refer the reader to table 3 in the 2024 IHA request from Orsted for specific density values used in the analysis. The 2024 IHA request is available online at: *https://www.fisheries.noaa.gov/action/incidental-take-authorization-orsted-wind-power-north-america-llcs-site-characterization.*

The take NMFS has authorized can be found in table 2, below. Table 2 presents the results of Orsted's updated density-based calculations for the Project Area. For comparative purposes, we have provided the 2022 IHA authorized take (87 FR 30182, May 18, 2022). No take by Level A harassment was requested and none is anticipated. Therefore, NMFS has not authorized any take by Level A harassment. Mortality or serious injury (M/SI) is neither anticipated nor authorized.

TABLE 2—ESTIMATED TAKE NUMBERS AND TOTAL TAKE AUTHORIZED

Common name	Stock	Estimated abundance	Take authorized under previous 2022 IHA	Total calculated take	Authorized take	Estimated take as a percentage of population
North Atlantic right whale	Western Atlantic	340	11	4	4	1.18
Fin whale	Western N Atlantic	6,802	7	6	6	<1
Humpback whale	Gulf of Maine	1,396	4	5	5	<1

TABLE 2—ESTIMATED TAKE NUMBERS AND TOTAL TAKE AUTHORIZED—Continued

Common name	Stock	Estimated abundance	Take authorized under previous 2022 IHA	Total calculated take	Authorized take	Estimated take as a percentage of population
Minke whale	Canadian Eastern Coastal	21,968	2	10	10	<1
Sei whale	Nova Scotia	6,292	1	1	1	<1
Sperm whale	N Atlantic	5,895	3	0	[a] 2	<1
Long-Finned pilot whale	Western N Atlantic	39,215	20	1	[a] 8	<1
Atlantic spotted dolphin	Western N Atlantic	31,506	15	6	[a] 24	<1
Atlantic white-sided dolphin	Western N Atlantic	93,233	50	16	16	<1
Bottlenose dolphin [b]	Northern Migratory Coastal	6,639	2,752	4,118	[c] 4,118	62.0
Bottlenose dolphin [b]	Western N Atlantic Offshore	64,587	2,752	4,118	([c])	<7
Risso's dolphin	Western N Atlantic	44,067	20	1	[a] 7	<1
Common dolphin	Western N Atlantic	93,100	400	98	[a] 302	<1
Harbor porpoise	Gulf of Maine/Bay of Fundy	85,765	82	79	79	<1
Gray seal	Western N Atlantic	27,911	4	13	[d] 13	<1
Harbor seal	Western N Atlantic	61,336	4	13	[d] 13	<1

[a] Adjustments to the requested take numbers for the marked species are based on the average group size from AMAPPS survey data (NEFSC, 2023) and recommended values represent averages of all AMAPPS sightings, for species for which the calculated take was lower than the estimated group size, except common dolphins. For common dolphins, the AMAPPS group size was used in conjunction with the number of encounters of common dolphin groups in past PSO reports.

[b] Take estimate is based on the maximum number of calculated instances of take for either stock and is assumed to apply to all bottlenose dolphins potentially present in the survey area. Therefore, takes could consist of individuals from either the WNA Offshore or the WNA Northern Migratory Coastal stock.

[c] Although unlikely, for purposes of calculating maximum percentage of population, we assume all takes could be allocated to either stock (*i.e.,* total estimated take for ''bottlenose dolphins'' is 4,118) and that multiple repeated takes of the same individuals from each stock may occur. Please see Determinations for additional information.

[d] Roberts *et al.* (2023) only provides density estimates for seals without differentiating by species. Harbor seals and gray seals are assumed to occur equally in the survey area; therefore, density values were split evenly between the two species, *i.e.,* total estimated take for ''seals'' is 13.

Mitigation, Monitoring, and Reporting Measures

The mitigation measures, and monitoring and reporting requirements are identical to those included in the **Federal Register** notice announcing the final 2022 IHA (87 FR 30182, May 18, 2022), and the discussion of the least practicable adverse impact included in that document remains accurate. The measures included in this authorization are found below.

Mitigation

The following mitigation measures must be implemented during Orsted's marine site characterization surveys. Pursuant to section 7 of the ESA, Orsted must also be required to adhere to relevant Project Design Criteria (PDC) of the NMFS GARFO programmatic consultation (specifically PDCs 4, 5, and 7) regarding geophysical surveys along the U.S. Atlantic coast (see NOAA GARFO, 2021; *https://www.fisheries.noaa.gov/new-england-mid-atlantic/consultations/section-7-take-reporting-programmatics-greater-atlantic#offshore-wind-site-assessment-and-site-characterization-activities-programmatic-consultation*).

Marine Mammal Exclusion Zones and Harassment Zones

Marine mammal exclusion zones (EZs) must be established around the HRG survey equipment and monitored by NMFS-approved protected species observers (PSO):

- 500 m EZ for NARWs during operation of specified acoustic sources (*e.g.,* sparkers, boomers); and
- 100 m EZ for all other marine mammals, with certain exceptions (see *Shutdown Procedures*), during operation of specified acoustic sources (*e.g.,* sparkers, boomers).

If a marine mammal is detected approaching or entering the EZs during the HRG survey, the vessel operator must adhere to the shutdown procedures described below to minimize noise impacts on the animals. These stated requirements must be included in the site-specific training to be provided to the survey team. The Level B harassment zones for each sound source are listed in table 3 and remain the same as the initial IHA (see table 4 of the **Federal Register** notice of the final authorization (87 FR 30182, May 18, 2022)).

TABLE 3—LEVEL B HARASSMENT ZONES

Equipment	Distance to Level B harassment threshold (m)
ET 216 CHIRP	9
ET 424 CHIRP	4
ET 512i CHIRP	6
GeoPulse 5430	21
TB CHIRP III	48
Pangeo SBI	22
AA Triple plate S-Boom (700/1,000 J)	34
AA, Dura-spark UHD Sparkers	141
GeoMarine Sparkers	141

Note: AA = Applied Acoustics; CHIRP = compressed high-intensity radiated pulses; ET = edgetech; J = joule; SBI = sub-bottom imager; TB = Teledyne benthos; UHD = ultra-high definition.

Pre-Start Clearance

Marine mammal clearance zones must be established around the HRG survey equipment and monitored by PSOs:

- 500 m for all ESA-listed marine mammals; and
- 100 m for all other marine mammals.

Orsted must implement a 30-minute pre-start clearance period prior to the initiation of ramp-up of specified HRG equipment. During this period, clearance zones must be monitored by PSOs, using the appropriate visual technology. Ramp-up may not be initiated if any marine mammal(s) is within its respective clearance zone. If a marine mammal is observed within a clearance zone during the pre-start clearance period, ramp-up may not begin until the animal(s) has been observed exiting its respective EZ or until an additional time period has elapsed with no further sighting (*i.e.,* 15 minutes for small odontocetes and pinnipeds, 30 minutes for all other species).

Ramp-Up of Survey Equipment

A ramp-up procedure, involving a gradual increase in source level output, is required at all times as part of the activation of the acoustic source when technically feasible. The ramp-up procedure must be used at the beginning of HRG survey activities in order to provide additional protection to marine mammals near the survey area by allowing them to vacate the area prior to the commencement of survey equipment operation at full power. Operators should ramp-up sources to half power for 5 minutes and then proceed to full power.

Ramp-up activities must be delayed if a marine mammal(s) enters its respective EZ. Ramp-up will resume if the animal has been observed exiting its respective EZ or until an additional time period has elapsed with no further sighting (*i.e.,* 15 minutes for small odontocetes and pinnipeds, 30 minutes for all other species).

Ramp-up may occur at times of poor visibility, including nighttime, if appropriate visual monitoring has occurred with no detections of marine mammals in the 30 minutes prior to beginning ramp-up. Acoustic source activation may only occur at night where operational planning cannot reasonably avoid such circumstances.

Shutdown Procedures

An immediate shutdown of the impulsive HRG survey equipment (*i.e.,* sparkers, boomers) will be required if a marine mammal is sighted entering or is within its respective EZ. The vessel operator must comply immediately with any call for shutdown by the Lead PSO. Any disagreement between the Lead PSO and vessel operator should be discussed only after shutdown has occurred. Subsequent restart of the survey equipment can be initiated if the animal has been observed exiting its respective EZ or until an additional time period has elapsed with no further sighting (*i.e.,* 15 minutes for small odontocetes and pinnipeds, 30 minutes for all other species).

If a species for which authorization has not been granted, or, a species for which authorization has been granted but the authorization number of takes have been met, approaches or is observed within the Level B harassment zone, shutdown must occur.

If the acoustic source is shut down for reasons other than mitigation (*e.g.,* mechanical difficulty) for less than 30 minutes, it may be activated again without ramp-up if PSOs have maintained constant observation and no detections of any marine mammal have occurred within the respective EZs. If the acoustic source is shut down for a period longer than 30 minutes, then pre-clearance and ramp-up procedures will be initiated as described in the previous section.

The shutdown requirement will be waived for pinnipeds and for small delphinids of the following genera: *Delphinus, Lagenorhynchus, Stenella,* and *Tursiops.* Specifically, if a delphinid from the specified genera or a pinniped is visually detected approaching the vessel (*i.e.,* to bow ride) or towed equipment, shutdown is not required. Furthermore, if there is uncertainty regarding identification of a marine mammal species (*i.e.,* whether the observed marine mammal(s) belongs to one of the delphinid genera for which shutdown is waived), PSOs must use best professional judgment in making the decision to call for a shutdown. Additionally, shutdown is required if a delphinid or pinniped is detected in the EZ and belongs to a genus other than those specified.

Shutdown, pre-start clearance, and ramp-up procedures are not required during HRG survey operations using only non-impulsive sources (*e.g.,* side-scan sonar, echosounders) other than non-parametric sub-bottom profilers (*e.g.,* CHIRPs).

Vessel Strike Avoidance

Orsted must adhere to the following measures except in the case where compliance will create an imminent and serious threat to a person or vessel or to the extent that a vessel is restricted in its ability to maneuver and, because of the restriction, cannot comply:

- Vessel operators and crews must maintain a vigilant watch for all marine mammals and slow down, stop their vessel, or alter course, as appropriate and regardless of vessel size, to avoid striking any marine mammal. A visual observer aboard the vessel must monitor a vessel strike avoidance zone based on the appropriate separation distance around the vessel. Visual observers monitoring the vessel strike avoidance zone may be third-party observers (*i.e.,* PSOs) or crew members, but crew members responsible for these duties must be provided sufficient training to (1) distinguish protected species from other phenomena, and (2) broadly identify a marine mammal as a right whale, other whale (defined in this context as sperm whales or baleen whales other than right whales), or other marine mammal;
- All survey vessels, regardless of size, must observe a 10 kn (18.5 km/hr) speed restriction in specified areas designated by NMFS for the protection of NARWs from vessel strikes. These specified areas include all seasonal management areas (SMA) established under 50 CFR 224.105 (when in effect), any dynamic management areas (DMA) (when in effect), and Slow Zones. See: *https://www.fisheries.noaa.gov/national/endangered-species-conservation/reducing-vessel-strikes-north-atlantic-right-whales* for specific detail regarding these areas;
- All vessels must reduce speed to 10 kn (18.5 km/hr) or less when mother/calf pairs, pods, or large assemblages of cetaceans are observed near a vessel;
- All vessels must maintain a minimum separation distance of 500 m from right whales and other ESA-listed large whales;
  - If an ESA-listed species is sighted within the relevant separation distance, the vessel must steer a course away at 10-kn (18.5 km/hr) or less until the 500-m separation distance has been established. If a whale is observed but cannot be confirmed as a species that is not ESA-listed, the vessel operator must assume that it is an ESA-listed species and take appropriate action;
- All vessels must maintain a minimum separation distance of 100 m from non-ESA-listed baleen whales;
- All vessels must, to the maximum extent practicable, attempt to maintain a minimum separation distance of 50 m from all other marine mammals, with an understanding that at times this may not be possible (*e.g.,* for animals that approach the vessel); and
- When marine mammals are sighted while a vessel is underway, the vessel shall take action as necessary to avoid violating the relevant separation distance (*e.g.,* attempt to remain parallel to the animal's course, avoid excessive speed or abrupt changes in direction until the animal has left the area);
  - If marine mammals are sighted within the relevant separation distance, the vessel must reduce speed and shift the engine to neutral, not engaging the engines until animals are clear of the area. This does not apply to any vessel towing gear or any vessel that is navigationally constrained.

Project-specific training must be conducted for all vessel crew prior to the start of a survey and during any changes in crew such that all survey personnel are fully aware and understand the mitigation, monitoring, and reporting requirements.

Based on our evaluation of the applicant's proposed measures, as well as other measures considered to by NMFS, NMFS has determined that the mitigation measures provide the means of effective the least practicable impact on marine mammal species or stocks

and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

Visual monitoring must be performed by qualified, NMFS-approved PSOs, the resumes of whom will be provided to NMFS for review and approval prior to the start of survey activities. Orsted must employ independent, dedicated, trained PSOs, meaning that the PSOs must (1) be employed by a third-party observer provider, (2) have no tasks other than to conduct observational effort, collect data, and communicate with and instruct relevant vessel crew with regard to the presence of marine mammals and mitigation requirements (including brief alerts regarding maritime hazards), and (3) have successfully completed an approved PSO training course appropriate for their designated task. On a case-by-case basis, trained crew members may be approved by NMFS for limited, specified duties in support of approved, independent PSOs on smaller vessels with limited crew operating in nearshore waters.

The PSOs will be responsible for monitoring the waters surrounding each survey vessel to the farthest extent permitted by sighting conditions, including EZs, during all HRG survey operations. PSOs will visually monitor and identify marine mammals, including those approaching or entering the established EZs during survey activities. It will be the responsibility of the Lead PSO on duty to communicate the presence of marine mammals as well as to communicate the action(s) that are necessary to ensure mitigation and monitoring requirements are implemented as appropriate.

During all HRG survey operations (*e.g.,* any day on which use of an HRG source is planned to occur), a minimum of one PSO must be on duty during daylight operations on each survey vessel, conducting visual observations at all times on all active survey vessels during daylight hours (*i.e.,* from 30 minutes prior to sunrise through 30 minutes following sunset). Two PSOs will be on watch during nighttime operations. The PSO(s) will ensure 360 degree visual coverage around the vessel from the most appropriate observation posts and will conduct visual observations using binoculars and/or night vision goggles and the naked eye while free from distractions and in a consistent, systematic, and diligent manner. PSOs may be on watch for a maximum of 4 consecutive hours followed by a break of at least 2 hours between watches and may conduct a maximum of 12 hours of observations per 24-hr period. In cases where multiple vessels are surveying concurrently, any observations of marine mammals will be communicated to PSOs on all nearby survey vessels.

PSOs must be equipped with binoculars and have the ability to estimate distance and bearing to detect marine mammals, particularly in proximity to EZs. Reticulated binoculars must also be available to PSOs for use as appropriate based on conditions and visibility to support the sighting and monitoring of marine mammals. During nighttime operations, night-vision goggles with thermal clip-ons and infrared technology will be used. Position data will be recorded using hand-held or vessel GPS units for each sighting.

During good conditions (*e.g.,* daylight hours; Beaufort sea state (BSS) 3 or less), to the maximum extent practicable, PSOs will also conduct observations when the acoustic source is not operating for comparison of sighting rates and behavior with and without use of the active acoustic sources. Any observations of marine mammals by crew members aboard any vessel associated with the survey will be relayed to the PSO team. Data on all PSO observations will be recorded based on standard PSO collection requirements. This will include dates, times, and locations of survey operations; dates and times of observations, location and weather, details of marine mammal sightings (*e.g.,* species, numbers, behaviors); and details of any observed marine mammal behavior that occurs (*e.g.,* notes behavioral disturbances).

Orsted must consult NMFS NARW reporting system and Whale Alert, daily and as able, for the presence of NARWs throughout survey operations, and for the establishment of a DMA. If NMFS should establish a DMA in the Lease Areas during the survey, the vessels must abide by speed restrictions in the DMA

Within 90 days after completion of survey activities or expiration of this IHA, whichever comes sooner, a draft comprehensive report will be provided to NMFS that fully documents the methods and monitoring protocols, summarizes the data recorded during monitoring, summarizes the number of marine mammals observed during survey activities (by species, when known), summarizes the mitigation actions taken during surveys including what type of mitigation and the species and number of animals that prompted the mitigation action, when known), and provides an interpretation of the results and effectiveness of all mitigation and monitoring. Any recommendations made by NMFS must be addressed in the final report prior to acceptance by NMFS. A final report must be submitted within 30 days following any comments on the draft report. All draft and final marine mammal and acoustic monitoring reports must be submitted to *PR.ITP.MonitoringReports@noaa.gov* and *ITP.clevenstine@noaa.gov.* The report must contain at minimum, the following:

- PSO names and affiliations;
- Dates of departures and returns to port with port names;
- Dates and times (Greenwich Mean Time (GMT)) of survey effort and times corresponding with PSO effort;
- Vessel location (latitude/longitude) when survey effort begins and ends; vessel location at beginning and end of visual PSO duty shifts;
- Vessel heading and speed at beginning and end of visual PSO duty shifts and upon any line change;
- Environmental conditions while on visual survey (at beginning and end of PSO shift and whenever conditions change significantly), including wind speed and direction, BSS, Beaufort wind force, swell height, weather conditions, cloud cover, sun glare, and overall visibility to the horizon;
- Factors that may be contributing to impaired observations during each PSO shift change or as needed as environmental conditions change (*e.g.,* vessel traffic, equipment malfunctions); and
- Survey activity information, such as type of survey equipment in operation, acoustic source power output while in operation, and any other notes of significance (*i.e.,* pre-clearance survey, ramp-up, shutdown, end of operations, *etc.*).

If a marine mammal is sighted, the following information should be recorded:

- Watch status (sighting made by PSO on/off effort, opportunistic, crew, alternate vessel/platform);
- PSO who sighted the animal;
- Time of sighting;
- Vessel location at time of sighting;
- Water depth;
- Direction of vessel's travel (compass direction);
- Direction of animal's travel relative to the vessel;
- Pace of the animal;
- Estimated distance to the animal and its heading relative to vessel at initial sighting;
- Identification of the animal (*e.g.,* genus/species, lowest possible taxonomic level, or unidentified); also

note the composition of the group if there is a mix of species;

- Estimated number of animals (high/low/best);
- Estimated number of animals by cohort (adults, yearlings, juveniles, calves, group composition, *etc.*);
- Description (as many distinguishing features as possible of each individual seen, including length, shape, color, pattern, scars or markings, shape and size of dorsal fin, shape of head, and blow characteristics);
- Detailed behavior observations (*e.g.,* number of blows, number of surfaces, breaching, spyhopping, diving, feeding, traveling; as explicit and detailed as possible; note any observed changes in behavior);
- Animal's closest point of approach and/or closest distance from the center point of the acoustic source;
- Platform activity at time of sighting (*e.g.,* deploying, recovering, testing, data acquisition, other); and
- Description of any actions implemented in response to the sighting (*e.g.,* delays, shutdown, ramp-up, speed or course alteration, etc.) and time and location of the action.

If a NARW is observed at any time by PSOs or personnel on any project vessels, during surveys or during vessel transit, Orsted must report the sighting information to the NMFS NARW Sighting Advisory System (866–755–6622) within 2 hours of occurrence, when practicable, or no later than 24 hours after occurrence. NARW sightings in any location may also be reported to the U.S. Coast Guard via channel 16 and through the WhaleAlert app (*http://www.whalealert.org/*).

In the event that Orsted personnel discover an injured or dead marine mammal, Orsted must report the incident to the NMFS Office of Protected Resources (OPR) and the NMFS New England/Mid-Atlantic Stranding Coordinator as soon as feasible. The report will include the following information:

- Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);
- Species identification (if known) or description of the animal(s) involved;
- Condition of the animal(s) (including carcass condition if the animal is dead);
- Observed behaviors of the animal(s), if alive;
- If available, photographs or video footage of the animal(s); and
- General circumstances under which the animal was discovered.

In the unanticipated event of a vessel strike of a marine mammal by any vessel involved in this activities covered by the IHA, Orsted will report the incident to NMFS by phone (866–755–6622) and by email (*nmfs.gar.incidental-take@noaa.gov* and *PR.ITP.MonitoringReports@noaa.gov*) as soon as feasible. The report will include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Species identification (if known) or description of the animal(s) involved;
- Vessel's speed during and leading up to the incident;
- Vessel's course/heading and what operations were being conducted (if applicable);
- Status of all sound sources in use;
- Description of avoidance measures/requirements that were in place at the time of the strike and what additional measures were taken, if any, to avoid strike;
- Environmental conditions (*e.g.,* wind speed and direction, BSS, cloud cover, visibility) immediately preceding the strike;
- Estimated size and length of animal that was struck;
- Description of the behavior of the marine mammal immediately preceding and following the strike;
- If available, description of the presence and behavior of any other marine mammals immediately preceding the strike;
- Estimated fate of the animal (*e.g.,* dead, injured but alive, injured and moving, blood or tissue observed in the water, status unknown, disappeared); and
- To the extent practicable, photographs or video footage of the animal(s).

Determinations

Orsted's HRG survey activities are unchanged from those analyzed in support of the 2022 IHA. When issuing the 2022 IHA (87 FR 30182, May 18, 2022) and 2023 reissuance of that IHA, NMFS found Orsted's proposed HRG surveys would have a negligible impact to species or stocks' annual rates of recruitment and survival, and the amount of taking would be small relative to the population size of such species or stocks. Additionally, the potential effects of the activities, taking into consideration the planned mitigation and related monitoring measures, are identical to those assumed when considering the 2022 IHA. NMFS expects that all potential takes would be short-term Level B behavioral harassment, predominantly in the form of avoidance of the sound sources that may cause a temporary abandonment of the location during active use of acoustic sources that may result in a temporary interruption of foraging activities for some species (if such activity was occurring), reactions that are considered to be of low severity and with no lasting biological consequences (*e.g.,* Southall *et al.,* 2007). NMFS does not expect that the planned activity will have long-term or permanent impacts as the acoustic sources would be mobile and would leave the area within a specific amount of time for which the animals could return to the area.

Feeding behavior is not likely to be significantly impacted as prey species are mobile and are broadly distributed throughout the survey area; therefore, marine mammals that may be temporarily displaced during survey activities are expected to be able to resume foraging once they have moved away from areas with disturbing levels of underwater noise. Because of the temporary nature of the disturbance and the availability of similar habitat and resources in the surrounding area, the impacts to marine mammals and the food sources that they utilize are not expected to cause significant or long-term consequences for individual marine mammals or their populations. Even considering the increased estimated take for some species, the impacts of these lower severity exposures are not expected to accrue to a degree that the fitness of any individuals would be impacted and, therefore, no impacts on the annual rates of recruitment or survival would result.

In addition to being temporary, the maximum expected harassment zone around a survey vessel is 141 m from use of sparkers. Although this distance is assumed for all survey activity evaluated here and in authorizing take numbers, in reality, much of the survey activity would involve use of acoustic sources with reduced acoustic harassment zones (see tables 1 and 4 in the previous **Federal Register** notices (87 FR 15922, March 21, 2022; 87 FR 30182, May 18, 2022)), producing expected effects of particularly low severity. The ensonified area surrounding each vessel is extremely small compared to the overall distribution of the animals in the area and the available habitat.

As previously discussed in the 2022 IHA (87 FR 15922, March 21, 2022; 87 FR 30182, May 18, 2022), impacts from the survey are expected to be localized to the specific area of activity and only during periods when Orsted's acoustic sources are active. There are no rookeries, mating or calving grounds known to be biologically important to

marine mammals within the survey area. The survey area lies significantly south (over 250 miles (402 km)) of where Biologically Important Areas are defined for fin and humpback whales. There is no designated critical habitat for any marine mammals listed under the ESA in the survey area.

There is a slight increase in estimated take for 5 species (humpback whale, minke whale, Atlantic spotted dolphin, gray seal, harbor seal) relative to those authorized under the 2022 IHA but the total amount of takes authorized are small (less than 1 percent) relative to estimated population size of each species or stock. Additionally, due to updated information in the draft 2023 SAR on the stock abundance of the WNA stock of common dolphins, there is a minor increase in the estimated take as a percentage of that stock, however, that also results in estimated take of less than 1 percent of the population. Even considering the increased estimated take for 5 species, the impacts of these lower severity exposures are not expected to accrue to a degree that the fitness of any individuals would be impacted, and therefore, no impacts on the annual rates of recruitment or survival are expected to result. Overall, the total amount of takes authorized are small (less than 1 percent) relative to estimated population size of each species or stock (less than 1 percent for 13 species; less than 2 percent for NARW; less than 7 percent for the WNA Offshore stock of bottlenose dolphin) except for the WNA Migratory Coastal stock of bottlenose dolphin (62 percent). The values presented in table 2 are likely conservative estimates as they assume all takes are of different individual animals which is likely not to be the case. Some individuals may return multiple times in a day, but PSOs will count them as separate takes if they cannot be individually identified. This is the particularly the case for bottlenose dolphins. Given the uncertainty regarding the number of days Orsted's survey may be within the 20 m isobath, the authorization of 4,118 instances of take by Level B harassment is not allocated to a specific stock but rather could be of either stock. However, based on the expansive ranges of both bottlenose dolphin stocks and the stocks' respective occurrence in the area, it is unlikely that large segments of either stock would consistently remain in the survey area. Considering this and various factors as described in the previous **Federal Register** notices (87 FR 15922, March 21, 2022; 87 FR 30182, May 18, 2022), we have determined that the number of individuals taken will comprise of less than one-third of the best available population abundance estimate of either stock.

Orsted's planned activities would occur in a small fraction of the migratory corridor for NARW and impacts are expected to be limited to low levels of behavioral harassment, resulting in temporary and minor behavioral changes during any brief period of exposure. The size of the Project Area (approximately 4,510 km^2) in comparison with the entire migratory habitat for the NARW (Biologically Important Area of 269,448 km^2) is small, representing 1.67 percent of the entire migratory corridor. Because of this, and in context of the minor, low-level nature of the impacts expected to result from the planned survey, such impacts are not expected to result in disruption to biologically important behaviors.

Given the transitory nature of NARW in this area and due to the lack of year-round ''core'' NARW foraging habitat (Oleson *et al.,* 2020) (such habitat is located further north in the southern area of Martha's Vineyard and Nantucket Islands where both visual and acoustic detections of NARW indicate a nearly year-round presence (Oleson *et al.,* 2020)), it is unlikely for any exposure to cause chronic effects as any exposure would be short and intermittent. Furthermore, given the small size of the Level B harassment zones (141 m) and the robust suite of mitigation and monitoring measures, with specific note on the mitigation zones for NARW (EZ; 500 m), NMFS does not expect adverse impacts on this species. Lastly, NMFS notes the reduction in requested take from the 2022 IHA (87 FR 15922, March 21, 2022; 87 FR 30182, May 18, 2022) due to the revised density data (Roberts *et al.,* 2023). Under the 2022 IHA, NMFS authorized 11 instances of take for NARW. Here, NMFS is proposing only 4 takes by Level B harassment representing less than 2 percent of the overall species abundance. Given the updates to the density for this species, in particular during the periods where project activities are expected to be ongoing, NMFS expects low-level impacts (*e.g.,* temporary avoidance of the area) from this project on NARW.

We also note that our findings for other species with active UMEs or species where biologically important areas or haul-outs have been previously described in the **Federal Register** notices associated with issuance of the 2022 IHA remain applicable to this project. In conclusion, there is no new information suggesting that our analysis or findings should change.

Based on the information contained here and in the referenced documents, NMFS has determined the following: (1) the required mitigation measures will effect the least practicable impact on marine mammal species or stocks and their habitat; (2) the authorized takes will have a negligible impact on the affected marine mammal species or stocks; (3) the authorized takes represent small numbers of marine mammals relative to the affected stock abundances; (4) Orsted's activities will not have an unmitigable adverse impact on taking for subsistence purposes as no relevant subsistence uses of marine mammals are implicated by this action, and (5) appropriate monitoring and reporting requirements are included.

Endangered Species Act

Section 7(a)(2) of the ESA of 1973 (16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species.

NMFS OPR is authorizing the incidental take of four species of marine mammals which are listed under the ESA, the North Atlantic right, fin, sei, and sperm whale, and has determined that this activity falls within the scope of activities analyzed in NMFS Greater Atlantic Regional Fisheries Office's programmatic consultation regarding geophysical surveys along the U.S. Atlantic coast in the 3 Atlantic Renewable Energy Regions (completed June 29, 2021; revised September 2021).

National Environmental Policy Act

To comply with NEPA of 1969 (42 U.S.C. 4321 *et seq.*) and NAO 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an IHA) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHAs with no anticipated serious injury or mortality) of the Companion Manual for NAO 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has determined that the issuance

of the IHA qualifies to be categorically excluded from further NEPA review.

Authorization

NMFS has issued an IHA to Orsted for the potential harassment of small numbers of 15 species (16 stocks) of marine mammals incidental to conducting marine site characterization surveys off the coast of Delaware for a period of 1 year, that includes the previously explained mitigation, monitoring, and reporting requirements.

Dated: July 25, 2024.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2024–16788 Filed 7–30–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE142]

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

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

ACTION: Notice of public meeting and webinar/conference call.

SUMMARY: NMFS will hold a 2-day Atlantic Highly Migratory Species (HMS) Advisory Panel (AP) meeting in September 2024. The intent of the meeting is to consider options for the conservation and management of Atlantic HMS. The meeting is open to the public.

DATES: The AP meeting and webinar will be held on Wednesday, September 4, from 9 a.m. to 5 p.m. ET; and Thursday, September 5, from 9 a.m. to 3 p.m. ET.

ADDRESSES: The meeting will be held at the DoubleTree by Hilton Silver Spring Hotel, 8777 Georgia Avenue, Silver Spring, MD 20910. The meeting will also be accessible via WebEx webinar/conference call. Conference call and webinar access information are available at: *https://www.fisheries.noaa.gov/event/september-2024-hms-advisory-panel-meeting.*

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

FOR FURTHER INFORMATION CONTACT: Peter Cooper, *peter.cooper@noaa.gov,* 301–427–8503.

SUPPLEMENTARY INFORMATION: Atlantic HMS fisheries (tunas, billfish, swordfish, and sharks) are managed under the 2006 Consolidated Atlantic HMS Fishery Management Plan (FMP) and its amendments pursuant to the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) and consistent with the Atlantic Tunas Convention Act (16 U.S.C. 971 *et seq.*). HMS implementing regulations are at 50 CFR part 635.

The Magnuson-Stevens Act requires the establishment of APs and requires NMFS to consult with and consider the comments and views of AP members during the preparation and implementation of FMPs or FMP amendments (16 U.S.C. 1854(g)(1)(A)–(B)). NMFS meets with the HMS AP approximately twice each year to consider potential alternatives for the conservation and management of Atlantic tunas, swordfish, billfish, and shark fisheries, consistent with the Magnuson-Stevens Act.

Some of the discussion topics are:

- Electronic reporting rulemaking update;
- HMS economic situation update; and
- General updates related to HMS.

We anticipate having other NMFS offices, other Federal agencies, and the U.S. Coast Guard to provide updates, if available, on their activities relevant to HMS fisheries. Additional information on the meetings and a copy of the draft agenda will be posted prior to the meeting (see **ADDRESSES**).

All members of the public will have virtual access to the meeting available via webinar and status updates of in-person public access to the meeting will be available on the NMFS website (see **ADDRESSES**). The meeting location is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Peter Cooper at 301–427–8503, at least 7 days prior to the meeting.

Dated: July 25, 2024.

Lindsay Fullenkamp,

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

[FR Doc. 2024–16764 Filed 7–30–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[AFD–2071]

Notice of Intent To Grant a Partially Exclusive Patent License

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Notice of intent.

SUMMARY: Pursuant to the Bayh-Dole Act and implementing regulations, the Department of the Air Force hereby gives notice of its intent to grant a partially exclusive (the field to include First Responder Market) patent license to The Science and Engineering Corps having a place of business at 9179 AA Highway, California, KY 41007.

DATES: Written objections must be filed no later than fifteen (15) calendar days after the date of publication of this Notice.

ADDRESSES: Submit written objections to Pamela Kallio, AFRL/SPT, 711 East Monument Avenue, Dayton, OH 45402; Phone: (937) 999–1621; or Email: *pamela.kallio.3.ctr@us.af.mil.* Include Docket No. AFD 2071 in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Pamela Kallio, AFRL/SPT, 711 East Monument Avenue, Dayton, OH 45402; Phone: (937) 999–1621; or Email: *pamela.kallio.3.ctr@us.af.mil.*

SUPPLEMENTARY INFORMATION:

Abstract of Patent

Personal hydration systems with cooling and/or warming capability, and the components thereof are disclosed. The personal hydration systems may include a liquid transport system for transporting cooling or heating fluid between a reservoir and a pad, which pad is configured for wearing adjacent to a wearer's body. A pump is provided for pumping the liquid through the system. A drinking tube is connected to the system for removing liquid from the system. Liquid can be removed from the system for drinking by sucking on the end of the drinking tube. A check valve is used to bypass the pump so the user will not have to suck the liquid through the pump. Alternatively, liquid can be removed by spraying the liquid out of the drinking tube using the power of the pump.

Intellectual Property

U.S. Patent No. 11,717,074, issued on August 8, 2023, and entitled, ''Personal Hydration System With Cooling or Warming Capability.''

The Department of the Air Force may grant the prospective license unless a

timely objection is received that sufficiently shows the grant of the license would be inconsistent with the Bayh-Dole Act or implementing regulations. A competing application for a patent license agreement, completed in compliance with 37 CFR 404.8 and received by the Air Force within the period for timely objections, will be treated as an objection and may be considered as an alternative to the proposed license.

Authority: 35 U.S.C. 209; 37 CFR part 404.

Tommy W. Lee,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2024–16810 Filed 7–30–24; 8:45 am]

BILLING CODE 3911–44–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

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

Filings Instituting Proceedings

Docket Numbers: RP24–917–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Negotiated Rates—Yankee Gas to Emera Energy eff 7–25–24 to be effective 7/25/2024.

Filed Date: 7/25/24.

Accession Number: 20240725–5030.

Comment Date: 5 p.m. ET 8/6/24.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP24–834–001.

Applicants: Gulf South Pipeline Company, LLC.

Description: Compliance filing: Compliance Filing in Docket No. RP24–834–000 to be effective 7/22/2024.

Filed Date: 7/24/24.

Accession Number: 20240724–5110.

Comment Date: 5 p.m. ET 8/5/24.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

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

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

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: July 25, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–16860 Filed 7–30–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CD24–3–000]

City of Tualatin, Oregon; Notice of Preliminary Determination of a Qualifying Conduit Hydropower Facility and Soliciting Comments and Motions To Intervene

On July 23, 2024, the City of Tualatin, Oregon, filed a notice of intent to construct a qualifying conduit hydropower facility, pursuant to section 30 of the Federal Power Act (FPA). The proposed Tualatin Service Center Hydroelectric Energy Recovery Project would have an installed capacity of 56 kilowatts (kW), and would be located along the applicant's existing water supply system in the City of Tualatin, Washington County, Oregon.

Applicant Contact: Gregg Semler, InPipe Energy, 830 NE Holladay St., Portland, OR 97232, 503–341–0004, *gregg@inpipeenergy.com.*

FERC Contact: Christopher Chaney, 202–502–6778, *christopher.chaney@ferc.gov.*

Qualifying Conduit Hydropower Facility Description: The project would consist of: (1) one 56-kW centrifugal pump as turbine generating unit and (2) appurtenant facilities. The proposed project would have an estimated annual generation of approximately 278 megawatt-hours.

A qualifying conduit hydropower facility is one that is determined or deemed to meet all the criteria shown in the table below.

TABLE 1—CRITERIA FOR QUALIFYING CONDUIT HYDROPOWER FACILITY

Statutory provision	Description	Satisfies (Y/N)
FPA 30(a)(3)(A)	The conduit the facility uses is a tunnel, canal, pipeline, aqueduct, flume, ditch, or similar manmade water conveyance that is operated for the distribution of water for agricultural, municipal, or industrial consumption and not primarily for the generation of electricity.	Y
FPA 30(a)(3)(C)(i)	The facility is constructed, operated, or maintained for the generation of electric power and uses for such generation only the hydroelectric potential of a non-federally owned conduit.	Y
FPA 30(a)(3)(C)(ii)	The facility has an installed capacity that does not exceed 40 megawatts	Y
FPA 30(a)(3)(C)(iii)	On or before August 9, 2013, the facility is not licensed, or exempted from the licensing requirements of Part I of the FPA.	Y

Preliminary Determination: The proposed Tualatin Service Center Hydroelectric Energy Recovery Project will not alter the primary purpose of the conduit, which is for municipal water supply. Therefore, based upon the above criteria, Commission staff preliminarily determines that the operation of the project described above satisfies the

requirements for a qualifying conduit hydropower facility, which is not required to be licensed or exempted from licensing.

Comments and Motions to Intervene: Deadline for filing comments contesting whether the facility meets the qualifying criteria is 30 days from the issuance date of this notice. Deadline for filing motions to intervene is 30 days from the issuance date of this notice. Anyone may submit comments or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210 and 385.214. Any motions to intervene must be received on or before the specified deadline date for the particular proceeding.

Filing and Service of Responsive Documents: All filings must (1) bear in all capital letters the ''COMMENTS CONTESTING QUALIFICATION FOR A CONDUIT HYDROPOWER FACILITY'' or ''MOTION TO INTERVENE,'' as applicable; (2) state in the heading the name of the applicant and the project number of the application to which the filing responds; (3) state the name, address, and telephone number of the person filing; and (4) otherwise comply with the requirements of sections 385.2001 through 385.2005 of the Commission's regulations.[1] All comments contesting Commission staff's preliminary determination that the facility meets the qualifying criteria must set forth their evidentiary basis.

The Commission strongly encourages electronic filing. Please file motions to intervene and comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may send a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Locations of Notice of Intent: The Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's website at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (*i.e.,* CD24–3) in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. Copies of the notice of intent can be obtained directly from the applicant. For assistance, call toll-free 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659.

Dated: July 25, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–16858 Filed 7–30–24; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 385.2001–2005 (2023).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP24–498–000]

Eastern Gas Transmission and Storage, Inc.; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on July 18, 2024, Eastern Gas Transmission and Storage, Inc. (EGTS), 10700 Energy Way, Glen Allen, VA 23060, filed in the above referenced docket, a prior notice request pursuant to sections 157.205(b) and 157.216(b) of the Commission's regulations under the Natural Gas Act (NGA), and EGTS's blanket certificate issued in Docket No. CP82–537–000, for authorization to abandon three storage wells, all associated facilities, and four-inch-diameter pipelines at each well. All of the facilities proposed to be abandoned are located in Harrison and Lewis Counties, West Virginia (Fink-Kennedy/Lost Creek Well Abandonment Project). The project will allow EGTS to abandon these storage wells that do not provide significant value through either flow performance or maintenance of current integrity standards. EGTS estimates the cost for the project to be $16 million, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*). From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

User assistance is available for eLibrary and the Commission's website during normal business hours from FERC Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

Any questions concerning this request should be directed to George W. Flugrad, Senior Counsel, Eastern Gas Transmission and Storage, Inc., 10700 Energy Way, Glen Allen, VA 23060, or via email at *George.Flugrad@bhegts.com.*

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on September 23, 2024. How to file protests, motions to intervene, and comments is explained below.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,[1] any person [2] or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,[3] and must be submitted by the protest deadline, which is September 23, 2024. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

Any person has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [4] and the regulations under the NGA [5] by the intervention deadline for the project, which is September 23, 2024. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Comments

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before September 20, 2024. The filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding.

How To File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP24–498–000 in your submission.

(1) You may file your protest, motion to intervene, and comments by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Protest'', ''Intervention'', or ''Comment on a Filing''; or [6]

(2) You can file a paper copy of your submission by mailing it to the address below. Your submission must reference the Project docket number CP24–498–000.

To file via USPS: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other method: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of submissions (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Protests and motions to intervene must be served on the applicant either by mail or email (with a link to the document) at George W. Flugrad, Senior Counsel, Eastern Gas Transmission and Storage, Inc., 10700 Energy Way, Glen Allen, VA 23060, or via email at *George.Flugrad@bhegts.com.* Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Dated: July 25, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–16862 Filed 7–30–24; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 157.205.

[2] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[3] 18 CFR 157.205(e).

[4] 18 CFR 385.214.

[5] 18 CFR 157.10.

[6] Additionally, you may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

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

Docket Numbers: ER20–391–010; ER21–2557–005; ER22–2662–005; ER22–2663–005; ER22–2664–005; ER23–1275–003; ER23–1276–003; ER23–1277–003; ER24–1276–001.

Applicants: Aron Energy Prepay 35 LLC, Aron Energy Prepay 23 LLC, Aron Energy Prepay 22 LLC, Aron Energy Prepay 21 LLC, Aron Energy Prepay 16 LLC, Aron Energy Prepay 15 LLC, Aron Energy Prepay 14 LLC, Aron Energy Prepay 5 LLC, J. Aron & Company LLC.

Description: Notice of Change in Status of J. Aron & Company LLC, et al.

Filed Date: 7/25/24.

Accession Number: 20240725–5112.

Comment Date: 5 p.m. ET 8/15/24.

Docket Numbers: ER24–1929–001.

Applicants: Willowbrook Solar I, LLC.

Description: Tariff Amendment: Response to Deficiency Letter in Docket ER24–1929–000 to be effective 5/24/2024.

Filed Date: 7/25/24.

Accession Number: 20240725–5093.

Comment Date: 5 p.m. ET 8/15/24.

Docket Numbers: ER24–2079–000.

Applicants: Basin Electric Power Cooperative.

Description: Refund Report: Refund Report to be effective N/A.

Filed Date: 7/25/24.

Accession Number: 20240725–5027.

Comment Date: 5 p.m. ET 8/15/24.

Docket Numbers: ER24–2587–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original WMPA, SA No. 7305; Project Identifier No. AF2–380 to be effective 6/24/2024.

Filed Date: 7/24/24.

Accession Number: 20240724–5123.

Comment Date: 5 p.m. ET 8/14/24.

Docket Numbers: ER24–2588–000.

Applicants: NextEra Energy Seabrook, LLC.

Description: § 205(d) Rate Filing: NextEra Energy Seabrook, LLC 3rd Amendment to A&R EP Agreement with NECEC to be effective 7/3/2024.

Filed Date: 7/25/24.

Accession Number: 20240725–5070.

Comment Date: 5 p.m. ET 8/15/24.

Docket Numbers: ER24–2589–000.

Applicants: Castleton Commodities Energy Services LLC.

Description: Baseline eTariff Filing: Baseline new to be effective 7/26/2024.

Filed Date: 7/25/24.

Accession Number: 20240725–5096.

Comment Date: 5 p.m. ET 8/15/24.

Docket Numbers: ER24–2590–000.

Applicants: Castleton Commodities Energy Trading LLC.

Description: Baseline eTariff Filing: Baseline new to be effective 7/26/2024.

Filed Date: 7/25/24.

Accession Number: 20240725–5097.

Comment Date: 5 p.m. ET 8/15/24.

Docket Numbers: ER24–2591–000.

Applicants: PacifiCorp.

Description: Tariff Amendment: Termination of Powerex LTF PTP Conditional Firm Agreement (SA 1016 and SA 1017) to be effective 9/24/2024.

Filed Date: 7/25/24.

Accession Number: 20240725–5102.

Comment Date: 5 p.m. ET 8/15/24.

Docket Numbers: ER24–2592–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2024–07–25_SA 4313 NSP-Summit Lake Solar GIA (J1581) to be effective 7/18/2024.

Filed Date: 7/25/24.

Accession Number: 20240725–5113.

Comment Date: 5 p.m. ET 8/15/24.

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

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

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

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: July 25, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–16859 Filed 7–30–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP24–497–000]

MountainWest Pipeline, LLC; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on July 18, 2024, MountainWest Pipeline, LLC (MWP) filed a prior notice request for authorization, in accordance with sections 157.205 and 157.214, of the Federal Energy Regulatory Commission's (Commission) regulations under the Natural Gas Act and MWP's blanket certificate issued in Docket No. CP82–491–000,[1] to increase: (1) the maximum certificated shut-in pressure, (2) the maximum certificated volume of natural gas to be stored, and (3) the working gas inventory at its Clay Basin underground gas storage reservoir (Clay Basin Storage Reservoir) in Daggett County, Utah. MWP proposes to increase the maximum certificated shut-in pressure from 2,536 pounds per square inch absolute (psia) to 2,700 psia, the maximum certificated storage capacity from 120.2 billion standard cubic feet (Bscf) to 128.0 Bscf and the working gas inventory from 54.0 Bscf to 61.8 Bscf at its existing Clay Basin Storage Reservoir, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*). From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

User assistance is available for eLibrary and the Commission's website during normal business hours from FERC Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the

[1] *Mountain Fuel Resources, Inc.,* 20 FERC ¶ 62,580 (1982).

Public Reference Room at *public.referenceroom@ferc.gov.*

Any questions concerning this request should be directed to Greg Williams, Regulatory Analyst Lead, MountainWest Pipeline, LLC, 333 South State Street, Salt Lake City, Utah 84111, or call (801) 209–6764, or via email to *greg.williams@williams.com.*

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on September 23, 2024. How to file protests, motions to intervene, and comments is explained below.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,[2] any person [3] or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,[4] and must be submitted by the protest deadline, which is September 23, 2024. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

Any person has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [5] and the regulations under the NGA [6] by the intervention deadline for the project, which is September 23, 2024. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Comments

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before September 23, 2024. The filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding.

How To File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP24–497–000 in your submission.

(1) You may file your protest, motion to intervene, and comments by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Protest'', ''Intervention'', or ''Comment on a Filing''; or [7]

(2) You can file a paper copy of your submission by mailing it to the address below. Your submission must reference the Project docket number CP24–497–000.

To file via USPS: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426

To file via any other method: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852

The Commission encourages electronic filing of submissions (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Protests and motions to intervene must be served on the applicant either by mail or email (with a link to the document) at: Greg Williams, Regulatory Analyst Lead, MountainWest Pipeline, LLC, 333 South State Street, Salt Lake City, Utah 84111, or via email to *greg.williams@williams.com.* Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–

[2] 18 CFR 157.205.

[3] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[4] 18 CFR 157.205(e).

[5] 18 CFR 385.214.

[6] 18 CFR 157.10.

[7] Additionally, you may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project.

FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Dated: July 25, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–16861 Filed 7–30–24; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL HOUSING FINANCE AGENCY

[No. 2024–N–9]

Privacy Act of 1974; System of Records

AGENCY: Federal Housing Finance Agency.

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, (Privacy Act), the Federal Housing Finance Agency (FHFA or Agency) is proposing to modify the current FHFA system of records titled, ''FHFA–14, Emergency Notification System'' (System). The system of records allows FHFA to maintain emergency contact information for current and former employees and contractors. This modification is to correct the Agency's address and change the location of the system in accordance with OMB Circular A–108. These changes are administrative and non-significant in nature.

DATES: This modified system of records will go into effect without further notice on July 31, 2024, unless otherwise revised pursuant to comments received.

Comments must be received on or before August 30, 2024. FHFA will publish a new notice if the effective date is delayed in order for the Agency to review the comments or if changes are made based on comments received.

ADDRESSES: Submit comments to FHFA, identified by ''No. 2024–N–9,'' using any one of the following methods:

- *Agency Website: www.fhfa.gov/open-for-comment-or-input.*
- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. If you submit your comments to the Federal eRulemaking Portal, please also send it by email to FHFA at *RegComments@fhfa.gov* to ensure timely receipt by FHFA. Please include ''Comments/No. 2024–N–9'' in the subject line of the message.
- *Hand Delivered/Courier:* The hand delivery address is: Clinton Jones, General Counsel, Attention: Comments/No. 2024–N–9, Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219. The package should be delivered to the Seventh Street entrance Guard Desk, First Floor, on business days between 9 a.m. and 5 p.m., EST.
- *U.S. Mail, United Parcel Service, Federal Express, or Other Mail Service:* The mailing address for comments is: Clinton Jones, General Counsel, Attention: Comments/No. 2024–N–9, Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219. *Please note that all mail sent to FHFA via the U.S. Postal Service is routed through a national irradiation facility, a process that may delay delivery by approximately two weeks. For any time-sensitive correspondence, please plan accordingly.*

See **SUPPLEMENTARY INFORMATION** for additional information on submission and posting of comments.

FOR FURTHER INFORMATION CONTACT: Stacy Easter, Privacy Act Officer, *privacy@fhfa.gov* or (202) 649–3803; or Tasha Cooper, Senior Agency Official for Privacy, *privacy@fhfa.gov* or (202) 649–3091 (not toll-free numbers), Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219. For TTY/TRS users with hearing and speech disabilities, dial 711 and ask to be connected to any of the contact numbers above.

SUPPLEMENTARY INFORMATION:

I. Comments

FHFA seeks public comments on the revision to the system of records and will take all comments into consideration. In addition to referencing ''Comments/No. 2024–N–9,'' please reference ''FHFA–14, Emergency Notification System.''

FHFA will post all public comments on the FHFA public website at *http://www.fhfa.gov,* except as described below. Commenters should submit only information that the commenter wishes to make available publicly. FHFA may post only a single representative example of identical or substantially identical comments, and in such cases will generally identify the number of identical or substantially identical comments represented by the posted example. FHFA may, in its discretion, redact or refrain from posting all or any portion of any comment that contains content that is obscene, vulgar, profane, or threatens harm. All comments, including those that are redacted or not posted, will be retained in their original form in FHFA's internal file and considered as required by all applicable laws. Commenters that would like FHFA to consider any portion of their comment exempt from disclosure on the basis that it contains trade secrets, or financial, confidential or proprietary data or information, should follow the procedures in section IV.D. of FHFA's Policy on Communications with Outside Parties in Connection with FHFA Rulemakings, *see https://www.fhfa.gov/sites/default/files/documents/Ex-Parte-Communications-Public-Policy_3-5-19.pdf.* FHFA cannot guarantee that such data or information, or the identity of the commenter, will remain confidential if disclosure is sought pursuant to an applicable statute or regulation. *See* 12 CFR 1202.8, 12 CFR 1214.2, and *https://www.fhfa.gov/about/foia-reference-guide* for additional information.

II. Introduction

This notice informs the public of FHFA's proposed revision to an existing system of records. This notice satisfies the Privacy Act requirement that an agency publishes a system of records notice in the **Federal Register** when there is an addition or change to an agency's system of records. Congress has recognized that application of all requirements of the Privacy Act to certain categories of records may have an undesirable and often unacceptable effect upon agencies in the conduct of necessary public business. Consequently, Congress established general exemptions and specific exemptions that could be used to exempt records from provisions of the Privacy Act. Congress also required that exempting records from provisions of the Privacy Act would require the head of an agency to publish a determination to exempt a record from the Privacy Act as a rule in accordance with the Administrative Procedure Act. Records and information in this system of records are not exempt from the requirements of the Privacy Act.

Pursuant to OMB Circular A–108, FHFA has not submitted a report describing the modified system of records covered by this notice to OMB

and Congress because the changes to the system are minor and administrative, and changes of this nature are not required to be reported.

III. Revised System of Records

The revised system of records notice is set out in its entirety and described in detail below. The proposed modification to the System makes the following non-substantive changes:

(1) Update the Agency's address to spell out the street name; and

(2) Change the location of the system, in accordance with OMB Circular A–108.

SYSTEM NAME AND NUMBER:

Emergency Notification System, FHFA–14.

SECURITY CLASSIFICATION:

Sensitive but unclassified.

SYSTEM LOCATION:

Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219; OnSolve, LLC, 6240 Avalon Blvd., Alpharetta, GA 30009; and any alternate work site utilized by FHFA employees or by individuals assisting such employees.

SYSTEM MANAGER(S):

Office of the Chief Operating Officer, Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 552a; 12 U.S.C. 4515; and Executive Orders 12656, 12148, and 10995.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system of records is to maintain emergency contact information for current and former FHFA employees and contractor personnel. The system provides for high-speed message delivery that reaches all agency and contractor personnel in response to threat alerts issued by the Department of Homeland Security, weather related emergencies, or other critical situations that disrupt the operations of and accessibility to an FHFA worksite. The system also provides for personnel accountability during an emergency, through personnel sign-in and rapid alert and notification.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former FHFA employees and contractor personnel, and emergency contacts for these individuals.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name and contact information such as addresses (home, mailing and/or business), telephone numbers (personal and/or business), electronic mail addresses (personal and/or business), photographs, and geospatial and/or geological data.

RECORD SOURCE CATEGORIES:

Information is provided by FHFA employees and FHFA contractor personnel.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside FHFA as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

(1) When (a) it is suspected or confirmed that the security or confidentiality of information in the system of records has been compromised; (b) FHFA has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by FHFA or another agency or entity) that rely upon the compromised information; and (c) the disclosure is made to such agencies, entities, and persons who are reasonably necessary to assist in connection with FHFA's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

(2) Records in this system may be disclosed to any individual during the course of any inquiry or investigation conducted by FHFA, or in connection with civil or administrative litigation, if FHFA has reason to believe that the individual to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

(3) A record or information in the system may be disclosed to any individual with whom FHFA contracts to reproduce, by typing, photocopy or other means, any record within this system for use by FHFA and its employees in connection with their official duties or to any individual who is utilized by FHFA to perform clerical or stenographic functions relating to the official business of FHFA.

(4) To appropriate federal, state, and local authorities responsible for investigating or prosecuting a violation of, or for enforcing or implementing a statute, rule, regulation, or order issued, when the information indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule, or order issued pursuant thereto.

(5) To a court, magistrate, or other administrative body in the course of presenting evidence, including disclosures to counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations or in connection with criminal proceedings, when FHFA is a party to the proceeding or has a significant interest in the proceeding, to the extent that the information is determined to be relevant and necessary.

(6) To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

(7) To contractor personnel, interns, and others performing or working on a contract, service, grant, cooperative agreement, or project for FHFA.

(8) To any Federal government authority for the purpose of coordinating with or reviewing FHFA's continuity of operations plans or emergency contingency plans.

(9) To any Federal, State or Local government authority for the purpose of coordinating a response to threat alerts issued by the Department of Homeland Security, weather related emergencies, or other critical situations that disrupt the operations of and accessibility to an FHFA worksite.

(10) To the National Archives and Records Administration, Office of Government Information Services (OGIS), to the extent necessary to fulfill its responsibilities in 5 U.S.C. 552(b), to review administrative agency policies, procedures and compliance with the Freedom of Information Act (FOIA), and to facilitate OGIS' offering of mediation services to resolve disputes between persons making FOIA requests and administrative agencies.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic format, paper form, and magnetic disk or tape. Electronic records are stored in computerized databases. Paper and magnetic disk, or tape records are stored in locked file rooms, locked file cabinets and/or safes.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by any of the following: Name, email address,

telephone number, or an assigned file number for the purpose of responding to the requester. Information may additionally be retrieved by other personal identifiers.

POLICIES AND PRACTICIES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are periodically purged and disposed of for individuals who are no longer employees or contractors of FHFA. Otherwise, records are retained and disposed of in accordance with the appropriate National Archives and Records Administration General Records Schedules and FHFA Retention Schedules.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records are safeguarded in a secured environment. Buildings where records are stored have security cameras and 24-hour security guard service. Computerized records are safeguarded through use of access codes and other information technology security measures. Paper records are safeguarded by locked file rooms, locked file cabinets, and/or safes. Access to the records is restricted to those who require the records in the performance of official duties related to the purposes for which the system is maintained.

RECORD ACCESS PROCEDURES:

Direct requests for access to a record to the Privacy Act Officer. Requests may be mailed to the Privacy Act Officer, Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219, or can be submitted electronically at *http://www.fhfa.gov/AboutUs/FOIAPrivacy/Pages/Privacy.aspx* in accordance with the procedures set forth in 12 CFR part 1204.

CONTESTING RECORD PROCEDURES:

Direct requests to contest or appeal an adverse decision for a record to the Privacy Act Appeals Officer. Requests may be mailed to the Privacy Act Appeals Officer, Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219, or can be submitted electronically at *http://www.fhfa.gov/AboutUs/FOIAPrivacy/Pages/Privacy.aspx* in accordance with the procedures set forth in 12 CFR part 1204.

NOTIFICATION PROCEDURES:

Direct inquiries as to whether this system contains a record pertaining to an individual to the Privacy Act Officer. Inquiries may be mailed to the Privacy Act Officer, Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219, or can be submitted electronically at *http://www.fhfa.gov/AboutUs/FOIAPrivacy/Pages/Privacy.aspx* in accordance with the procedures set forth in 12 CFR part 1204.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

The system of records was last published in full in the **Federal Register** at 81 FR 22268 (April 15, 2016).

Clinton Jones,

General Counsel, Federal Housing Finance Agency.

[FR Doc. 2024–16856 Filed 7–30–24; 8:45 am]

BILLING CODE 8070–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments, relevant information, or documents regarding the agreements to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, 800 North Capitol Street, Washington, DC 20573. Comments will be most helpful to the Commission if received within 12 days of the date this notice appears in the **Federal Register**, and the Commission requests that comments be submitted within 7 days on agreements that request expedited review. Copies of agreements are available through the Commission's website (*www.fmc.gov*) or by contacting the Office of Agreements at (202) 523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 201434.

Agreement Name: The AWC Vessel Sharing Agreement.

Parties: Sea Lead Pte. Ltd.; T.S. Lines Limited.

Filing Party: Wayne Rohde; Cozen O'Connor.

Synopsis: The agreement authorizes the parties to share vessels in the trade between ports in China and South Korea on the one hand and Los Angeles/Long Beach on the other hand.

Proposed Effective Date: 07/19/2024.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/362.

Dated: July 26, 2024.

Alanna Beck,

Federal Register Alternate Liaison Officer.

[FR Doc. 2024–16840 Filed 7–30–24; 8:45 am]

BILLING CODE 6730–02–P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, without revision, the Disclosure Requirements of Subpart H of Regulation H (Consumer Protection in Sales of Insurance) (FR H–7; OMB No. 7100–0298).

DATES: Comments must be submitted on or before September 30, 2024.

ADDRESSES: You may submit comments, identified by FR H–7, by any of the following methods:

- *Agency Website: https://www.federalreserve.gov/.* Follow the instructions for submitting comments at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx.*
- *Email: regs.comments@federalreserve.gov.* Include the OMB number or FR number in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Federal Reserve Board of Governors, Attn: Ann E. Misback, Secretary of the Board, Mailstop M–4775, 2001 C St. NW, Washington, DC 20551.

All public comments are available from the Board's website at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any confidential business information, identifying information, or contact information. Public comments may also be viewed electronically or in paper in Room M–4365A, 2001 C St. NW, Washington, DC 20551, between 9:00 a.m. and 5:00 p.m. on weekdays, except for Federal holidays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452–3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory

Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, *nuha.elmaghrabi@frb.gov,* (202) 452–3884.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

During the comment period for this proposal, a copy of the proposed PRA OMB submission, including the draft reporting form and instructions, supporting statement (which contains more detail about the information collection and burden estimates than this notice), and other documentation, will be made available on the Board's public website at *https://www.federalreserve.gov/apps/reportingforms/home/review* or may be requested from the agency clearance officer, whose name appears above. On the page displayed at the link above, you can find the supporting information by referencing the collection identifier, FR H–7. Final versions of these documents will be made available at *https://www.reginfo.gov/public/do/PRAMain,* if approved.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal under OMB Delegated Authority To Extend for Three Years, Without Revision, the Following Information Collection

Collection title: Disclosure Requirements of Subpart H of Regulation H (Consumer Protection in Sales of Insurance).

Collection identifier: FR H–7.

OMB control number: 7100–0298.

General description of collection: Subpart H of Regulation H—Membership of State Banking Institutions in the Federal Reserve System (12 CFR part 208) was adopted by the Board in 2000 (65 FR 75822 (December 4, 2000) pursuant to section 305 of the Gramm-Leach-Bliley Act of 1999 (GLBA), which required the Board, the Office of the Comptroller of the Currency, and the Federal Deposit Insurance Corporation to issue joint regulations governing retail sales practices, solicitations, advertising, and offers of insurance by, on behalf of, or at the offices of depository institutions. Respondents are required to prepare and provide to consumers certain disclosures in insurance product advertisements before a consumer buys the insurance product and at the time a consumer applies for an extension of credit in connection with the solicitation, offer, or sale of an insurance product or annuity.

Frequency: Event-generated.

Respondents: State member banks or any other person who sells, solicits, advertises, or offers an insurance product or annuity to a consumer at an office of a bank or on behalf of a bank.

Total estimated number of respondents: 339.

Total estimated annual burden hours: 8,685.

Board of Governors of the Federal Reserve System, July 25, 2024.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024–16763 Filed 7–30–24; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision, the Survey of Consumer Finances (FR 3059; OMB No. 7100–0287).

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, *nuha.elmaghrabi@frb.gov,* (202) 452–3884.

Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements (which contain more detailed information about the information collections and burden estimates than this notice), and approved collection of information instrument(s) are available at *https://www.reginfo.gov/public/do/PRAMain.* These documents are also available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportingforms/home/review* or may be requested from the agency clearance officer, whose name appears above. On the page displayed at the link above, you can find the supporting information by referencing the collection identifier, FR 3059.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection

Collection title: Survey of Consumer Finances.

Collection identifier: FR 3059.

OMB control number: 7100–0287.

General description of collection: This triennial survey is the only source of representative information on the structure of U.S. families' finances. The survey collects data on the assets, debts, income, work history, pension rights, use of financial services, and attitudes of a sample of U.S. families. Because the ownership of some assets is relatively concentrated in a small number of families, the survey makes a special effort to ensure proper representation of such assets by systematically oversampling wealthier families. For the 2025 survey, the Board will conduct: (1) up to 150 interviews averaging about 110 minutes as a test or series of tests of the survey procedures in 2025, and (2) up to 7,000 interviews averaging about 110 minutes (main survey) between April 2025 and March 2026.

Frequency: Triennial.

Respondents: U.S. families.

Total estimated number of respondents: 7,150.

Total estimated annual burden hours: 4,410.

Current actions: On March 7, 2024, the Board published a notice in the **Federal Register** (89 FR 16571) requesting public comment for 60 days on the extension, without revision, of the FR 3059. The comment period for this notice expired on May 6, 2024. The Board did not receive any comments.

Board of Governors of the Federal Reserve System, July 25, 2024.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024–16768 Filed 7–30–24; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than August 14, 2024.

A. Federal Reserve Bank of St. Louis (Holly A. Rieser, Senior Manager) P.O. Box 442, St. Louis, Missouri 63166–2034. Comments can also be sent electronically to *Comments.applications@stls.frb.org:*

1. *Gary D. Misselhorn, individually, and the Gary D. Misselhorn and Barbara A. Misselhorn, as co-trustees, all of Campbell Hill, Illinois; Hilary Sternberg, Redbud, Illinois; and Clint E. Misselhorn, Carterville, Illinois;* to establish the Misselhorn Family Control Group, a group acting in concert, to retain voting shares of Campbell Hill Bancshares, Inc., and thereby indirectly retain voting shares of First State Bank of Campbell Hill, both of Campbell Hill, Illinois.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024–16789 Filed 7–30–24; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than August 29, 2024.

A. Federal Reserve Bank of Minneapolis (Mark Rauzi, Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291. Comments can also be sent electronically to *MA@mpls.frb.org:*

1. *Bank Forward Employee Stock Ownership Plan and Trust;* to acquire up to 43.11 percent of the voting shares of Security State Bank Holding Company, and thereby indirectly acquire voting shares of Bank Forward, all of Fargo, North Dakota.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024–16791 Filed 7–30–24; 8:45 am]

BILLING CODE P

GENERAL SERVICES ADMINISTRATION

[Notice–IE–2024–04; Docket No. 2024–0002; Sequence No. 33]

Privacy Act of 1974; System of Records

AGENCY: General Services Administration (GSA).

ACTION: Notice of a new system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, notice is given that the General Services Administration (GSA) proposes to establish a new system of records, entitled Events Management System, GSA/PBS–9. This system of records manages registration and attendance for virtual events and in-person events on GSA-managed properties.

DATES: Submit comments on or before August 30, 2024.

ADDRESSES: Comments may be submitted to the Federal eRulemaking Portal, *http://www.regulations.gov.* Submit comments by searching for GSA/PBS–9, Events Management System.

FOR FURTHER INFORMATION CONTACT: Call or email Richard Speidel, Chief Privacy Officer at 202–969–5830 and *gsa.privacyact@gsa.gov.*

SUPPLEMENTARY INFORMATION: GSA proposes to establish a system of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, to manage the personal information provided by visitors to GSA properties in connection with scheduled events.

SYSTEM NAME AND NUMBER:

Events Management System, GSA/PBS–9.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records are maintained in an electronic form on a Software as a Service (SaaS) platform under contract to GSA.

SYSTEM MANAGER(S):

Regional Fine Arts Officer, National Capital Region, Public Buildings Service, General Services Administration, 1800 F Street NW, Washington, DC 20405.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The E-Government Act of 2002 (Pub. L. 107–347, 44 U.S.C. 3601 n.); The Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. 3501).

PURPOSE(S) OF THE SYSTEM:

The purpose of the system is to collect information about event attendees that can be used to access virtual events or federal government properties for in-person events. This information is only used for a single event and then archived in accordance with the appropriate records retention schedule.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The system of records includes members of the public who register to attend an event held by GSA (in-person or virtual). The system also includes federal employees of other agencies, federal contractors, or others who may register for an event.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, email address, affiliation, minor status, and country of citizenship. After registration, individuals may be asked if accommodations are necessary and individuals may disclose additional information in order to obtain such accommodations. As this is a free response, individuals provide what information they believe is necessary to obtain accommodations.

RECORD SOURCE CATEGORIES:

The source for information in the system is the individuals who provide this information or their representative.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed to authorized entities, as is determined to be relevant and necessary, outside GSA as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

a. In any legal proceeding, where pertinent, to which GSA, a GSA employee, or the United States is a party before a court or administrative body.

b. To a Federal, State, local, or foreign agency responsible for investigating, prosecuting, enforcing, or carrying out a statute, rule, regulation, or order when GSA becomes aware of a violation or potential violation of civil or criminal law or regulation.

c. To an appeal, grievance, hearing, or complaints examiner; an equal employment opportunity investigator, arbitrator, or mediator; and an exclusive representative or other person authorized to investigate or settle a grievance, complaint, or appeal filed by an individual who is the subject of the record.

d. To the Office of Personnel Management (OPM), the Office of Management and Budget (OMB), and the Government Accountability Office (GAO) in accordance with their responsibilities for evaluating Federal programs.

e. To a Member of Congress or his or her staff on behalf of and at the request of the individual who is the subject of the record.

f. To an expert, consultant, or contractor of GSA in the performance of a Federal duty to which the information is relevant.

g. To the National Archives and Records Administration (NARA) for records management purposes.

h. In connection with any litigation or settlement discussions regarding claims by or against the GSA, including public filing with a court, to the extent that GSA determines the disclosure of the information is relevant and necessary to the litigation or discussions.

i. To appropriate agencies, entities, and persons when (1) GSA suspects or has confirmed that there has been a breach of the system of records, (2) GSA has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, GSA (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with GSA's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

j. To another Federal agency or Federal entity, when GSA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

k. To compare such records to other agencies' systems of records or to non-Federal records, in coordination with an OIG in conducting an audit, investigation, inspection, evaluation, or some other review as authorized by the IG Act.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

All records are stored electronically in a database. Information is encrypted in transit and at rest.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records can be retrieved by name or other personal identifier.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records relating to events management will be retained for 6 years from the end of the fiscal year of the event in accordance with the NARA-approved GSA Records Schedule DAA–0269–2016–0007–0003—''Events Records''.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records in the system are protected from unauthorized access and misuse through a combination of administrative, technical and physical security measures. Administrative measures include but are not limited to policies that limit system access to individuals within an agency with a legitimate business need, and regular review of security procedures and best practices to enhance security. Technical measures include but are not limited to system design that allows authorized system users access only to data for which they are responsible; and use of encryption for certain data transfers. Physical security measures include but are not limited to the use of data centers which meet government requirements for storage of sensitive data.

RECORD ACCESS PROCEDURES:

If an individual wishes to access any data or record pertaining to him or her in the system after it has been submitted, that individual should consult the GSA's Privacy Act implementation rules available at 41 CFR part 105–64.2.

CONTESTING RECORD PROCEDURES:

If an individual wishes to contest the content of any record pertaining to him or her in the system after it has been submitted, that individual should consult the GSA's Privacy Act implementation rules available at 41 CFR part 105–64.4.

NOTIFICATION PROCEDURES:

If an individual wishes to be notified at his or her request if the system contains a record pertaining to him or her after it has been submitted, that individual should consult the GSA's Privacy Act implementation rules available at 41 CFR part 105–64.4.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Richard Speidel,

Chief Privacy Officer, Office of Enterprise Data & Privacy Management, General Services Administration.

[FR Doc. 2024–16845 Filed 7–30–24; 8:45 am]

BILLING CODE 6820–AB–P

GENERAL SERVICES ADMINISTRATION

[Notice—PBS–2024–07; Docket No. 2024–0002; Sequence No. 32]

Notice of Availability for the Final Environmental Impact Statement for the Buildings 202, 214 and 220 South State Street, Chicago, Illinois.

AGENCY: U.S. General Services Administration (GSA).

ACTION: Notice of availability (NOA).

SUMMARY: The GSA, in cooperation with the U.S. Federal Protective Service and in accordance with the National Environmental Policy Act (NEPA), announces the availability of the Final Environmental Impact Statement (EIS) for the future of 202, 214, and 220 South State Street, Chicago, Illinois. The Final EIS analyzed the potential environmental impacts of GSA's Proposed Action to address the future of the vacant buildings GSA owns at 202, 214, and 220 South State Street between Adams Street and Jackson Boulevard, adjacent to the Everett McKinley Dirksen U.S. Courthouse (Dirksen Courthouse) in downtown Chicago, Illinois. GSA considered two action alternatives (Alternative A, Demolition, and Alternative B, Viable Adaptive Reuse) and a No Action Alternative. The Final EIS states the purpose and need for the Proposed Action, analyzes alternatives considered, and assesses environmental impacts of each alternative, including avoidance, minimization, and mitigation measures. GSA has selected Viable Adaptive Reuse (Alternative B) as its Preferred Alternative.

DATES: Publication Period: The Final EIS is published with this notice of availability (NOA) in the **Federal Register** until Monday September 2, 2024. Written comments must be received by the last day of this publishing period (see **ADDRESSES** section of this NOA on how to submit comments). After this period, GSA will issue the Record of Decision (ROD).

ADDRESSES: Comments concerning the Final EIS should be directed to:

- *Email: statestreet@gsa.gov.* Please include 'Final EIS Publication' in the subject line of the message.
- *Mail:* ATTN: Joseph Mulligan, U.S. General Services Administration, 230 S Dearborn St., Suite 3600, Chicago, IL 60604.

Further information, including an electronic copy of the Final EIS, may be found online at this website: *https://www.gsa.gov/about-us/gsa-regions/region-5-great-lakes/buildings-and-facilities/illinois/chicago-202220-s-state-st-fps.*

SUPPLEMENTARY INFORMATION:

Proposed Action

The Proposed Action is to address the future of the three vacant buildings at 202, 214 and 220 South State Street, east of the Dirksen Courthouse. The purpose of the Proposed Action is to address the security needs of the Dirksen Courthouse, respond to the Congressional intent and funding authorization provided in the 2022 Consolidated Appropriations Act, and manage Federal assets.

Preferred Alternative

GSA's Preferred Alternative is Viable Adaptive Reuse (Alternative B). GSA will pursue viable adaptive reuse under the NHPA section 111 outlease authority. GSA will issue a Request for Lease Proposals (RLP) to seek a reuse that meets the purpose and need for the proposed action.

The Viable Adaptive Reuse Alternative meets the purpose and need for the Proposed Action upon satisfying the security needs of the Dirksen Courthouse. Therefore, GSA will request market-driven redevelopment proposals with the following considerations. First, GSA shall consider and prioritize proposals that align with the viable adaptive reuse security criteria established for this proposed action and demonstrate the financial capability of the offeror to successfully execute. Second, GSA shall consider proposals with proposed deviations from the viable adaptive reuse security criteria that demonstrate the financial capability of the offeror to successfully execute. Any proposed deviation must be agreed to by GSA. There are no federal funds available for reuse or proposed deviations from the security criteria. The RLP will allow for redevelopment of all buildings and parcels at 202 through 220 South State Street or one, two, or all three buildings in a manner that addresses the purpose and need.

Summary of Potential Impacts

The Final EIS identifies, describes, and analyzes the potential effects of

both the Action and No Action alternatives, including direct, indirect, and cumulative effects. GSA analyzed beneficial and adverse potential impacts of the following resources: cultural resources; aesthetic and visual resources; land use and zoning; community facilities; socioeconomics and environmental justice; greenhouse gas emissions; hazardous materials and solid waste; air quality; noise; health and safety; and transportation and traffic. The Final EIS considers measures that would avoid, minimize, or mitigate identified adverse impacts. The Final EIS identifies Viable Adaptive Reuse as the Environmentally Preferred Alternative.

National Historic Preservation Act

Consultation under section 106 of the NHPA is ongoing concurrently with the NEPA process. The Century Building (202 South State Street) and the Consumers Building (220 South State Street) are historic resources contributing to the Loop Retail Historic District, which are listed in the National Register of Historic Places (NRHP). In this Proposed Action, 214 South State Street is being treated as eligible for listing in the NRHP as a contributing resource to the Loop Retail Historic District. A draft Programmatic Agreement is included in the Final EIS. GSA will execute the Programmatic Agreement with the Illinois State Historic Preservation Officer and Advisory Council on Historic Preservation before issuing the Record of Decision.

William Renner,

Director, Facilities Management and Services Programs Division, Great Lakes Region 5, U.S. General Services Administration.

[FR Doc. 2024–16837 Filed 7–30–24; 8:45 am]

BILLING CODE 6820–CF–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve an extension of the currently approved information collection project: ''*Medical Office Survey on Patient Safety Culture Database.*'' In accordance with the Paperwork Reduction Act of 1995, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by September 30, 2024.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *REPORTSCLEARANCEOFFICER@ahrq.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *REPORTSCLEARANCEOFFICER@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Medical Office Survey on Patient Safety Culture Database

In 1999, the Institute of Medicine called for health care organizations to develop a ''culture of safety'' such that their workforce and processes focus on improving the reliability and safety of care for patients (IOM, 1999; *To Err is Human: Building a Safer Health System*). To respond to the need for tools to assess patient safety culture in health care, AHRQ developed and pilot tested the Surveys on Patient Safety Culture® (SOPS®) Medical Office Survey with OMB approval (OMB NO.0935–0131; Approved July 5, 2007).

The survey is designed to enable medical offices to assess provider and staff perspectives about patient safety issues, medical error, and error reporting. The survey includes 38 items that measure 10 composites of patient safety culture. In addition to the composite items, 14 items measure staff perceptions of how often medical offices have problems exchanging information with other settings as well as other patient safety and quality issues. AHRQ made the survey publicly available along with a Survey User's Guide and other toolkit materials in January 2009, on the AHRQ website.

The AHRQ SOPS Medical Office Database consists of data from the AHRQ Medical Office Survey on Patient Safety Culture and may include reportable, non-required supplemental items. Medical offices in the U.S. can voluntarily submit data from the survey to AHRQ, through its contractor, Westat. The SOPS Medical Office Database (OMB NO. 0935–0196, last approved on September 24, 2021) was developed by AHRQ in 2011 in response to requests from medical offices interested in tracking their own survey results. Those organizations submitting data receive a feedback report, as well as a report of the aggregated, de-identified findings of the other medical offices submitting data. These reports are used to assist medical office staff in their efforts to improve patient safety culture in their organizations.

The goal of the Medical Office Survey on Patient Safety Culture Database is to promote improvements in the quality and safety of healthcare in medical office settings. The survey, toolkit materials, and database results are all made publicly available on AHRQ's website. Technical assistance is provided by AHRQ through its contractor at no charge to medical offices, to facilitate the use of these materials for medical office patient safety and quality improvement.

This database:

(1) Presents results from medical offices that voluntarily submit their data,

(2) Provides data to medical offices to facilitate internal assessment and learning in the patient safety improvement process, and

(3) Provides supplemental information to help medical offices identify their strengths and areas with potential for improvement in patient safety culture.

To achieve the goal of this project the following activities and data collections will be implemented:

(1) Eligibility and Registration Form—The medical office point-of-contact (POC) completes several data submission steps and forms, beginning with the completion of an online Eligibility and Registration Form. The purpose of this form is to collect basic demographic information about the medical office and initiate the registration process.

(2) Medical Office Site Information Form—The purpose of the site information form, also completed by the medical office POC, is to collect background characteristics of the medical office. This information will be used to analyze data collected with SOPS Medical Office Survey.

(3) Data Use Agreement—The purpose of the data use agreement, completed by the medical office POC, is to state how data submitted by medical offices will be used and provides privacy assurances.

(4) Data File(s) Submission—POCs upload their data file(s), using the medical office data file specifications, to ensure that users submit their data in a standardized way (*e.g.,* variable names, order, coding, formatting).The number

of submissions to the database is likely to vary from submission period to submission period because medical offices do not administer the survey and submit data every year. Data submission is typically handled by one POC who is either an office manager or a survey vendor who contracts with a medical office to collect their data. POCs submit data on behalf of 20 medical offices, on average, because many medical offices are part of a health system that includes many medical office sites, or the POC is a vendor that is submitting data for multiple medical offices.

This study is being conducted by AHRQ through its contractor, Westat, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to: the quality, effectiveness, efficiency, appropriateness and value of healthcare services; quality measurement and improvement; and database development. 42 U.S.C. 299a(a)(1), (2), and (8).

Method of Collection

All information collection for the SOPS Medical Office Database is done electronically, except the Data Use Agreement (DUA) that medical offices print, sign and return (either via fax, by scanning and emailing or uploading to a secure website, or by mailing back). Registration, submission of medical office information, and data upload is handled online through a secure website. Customized feedback reports are delivered electronically (the person submitting the data will enter a username and password for access to a secure website from which to download their reports).

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in the database. An estimated 85 POCs, each representing an average of 30 individual medical offices each, will complete the database submission steps and forms. Each POC will submit the following:

1. Eligibility and Registration Form—Estimated to take 3 minutes to complete.

2. Medical Office Site Information Form—Estimated to take 5 minutes to complete.

3. Data Use Agreement—Estimated to take 3 minutes to complete.

4. Survey Data File(s) Submission—Estimated to take 1 hour to complete.

The total burden is estimated to be 308 hours.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to submit their data. The cost burden is estimated to be $19,891 annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per POC	Hours per response	Total burden hours
1. Eligibility/Registration Form	85	1	3/60	5
2. Medical Office Site Information Form	85	30	5/60	213
3. Data Use Agreement	85	1	3/60	5
4. Data File(s) Submission	85	1	1	85
Total	NA	NA	NA	308

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Total burden hours	Average hourly wage rate *	Total cost burden
1. Eligibility/Registration Form	5	$ 64.58	$323
2. Medical Office Site Information Form	213	64.58	13,756
3. Data Use Agreement	5	64.58	323
4. Data File(s) Submission	85	64.58	5,489
Total	308	NA	19,891

* Mean hourly wage rate of $64.58 for Medical and Health Services Managers (SOC code 11–9111) was obtained from the May 2023 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 621100—Offices of Physicians located at *https://www.bls.gov/oes/current/naics4_621100.htm.*

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: July 25, 2024.

Marquita Cullom,

Associate Director.

[FR Doc. 2024–16792 Filed 7–30–24; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2019]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Class II Special Controls: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Principle

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by August 30, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0594. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Class II Special Controls: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle

OMB Control Number 0910–0594—Extension

This information collection helps to support Agency regulations and guidance. Under Section 513(a)(1)(B) of the Federal Food, Drug and Cosmetics Act (FD&C Act) (21 U.S.C. 360c(a)(1)(B)), FDA may establish special controls, including performance standards, postmarket surveillance, patient registries, guidelines, and other appropriate actions it believes necessary to provide reasonable assurance of the safety and effectiveness of the device. The guidance entitled ''Guidance for Industry and FDA Staff—Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle'' (March 2011) is available at *https://www.fda.gov/media/124263/download.* The special control guidance serves as the special control for the automated blood cell separator device operating by centrifugal or filtration separation principle intended for the routine collection of blood and blood components (§ 864.9245 (21 CFR 864.9245)).

For currently marketed products not approved under the premarket approval process, the manufacturer should file with FDA for 3 consecutive years an annual report on the anniversary date of the device reclassification from class III to class II or on the anniversary date of the 510(k) of the FD&C Act (21 U.S.C. 360(k)) clearance. These annual reports are submitted as supplements to the original 510(k) via the electronic submission gateway at *https://www.fda.gov/electronic-submissions-gateway.* The reports can also be submitted in paper format and sent to the CBER Document Control Center at *https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/regulatory-submissions-electronic-and-paper.*

Any subsequent change to the device requiring the submission of a premarket notification in accordance with section 510(k) of the FD&C Act should be included in the annual report. Also, a manufacturer of a device determined to be substantially equivalent to the centrifugal or filtration-based automated cell separator device intended for the routine collection of blood and blood components should comply with the same general and special controls.

Reclassification of this device from class III to class II relieves manufacturers of the burden of complying with the premarket approval requirements of section 515 of the FD&C Act (21 U.S.C. 360e) and may permit small potential competitors to enter the marketplace by reducing the burden. Although the special control guidance recommends that manufacturers of these devices file with FDA an annual report for 3 consecutive years, this would be less burdensome than the current postapproval requirements under 21 CFR part 814, subpart E, including the submission of periodic reports under 21 CFR 814.84.

In the special control guidance document, FDA recommends that manufacturers include in their annual reports a summary of adverse reactions maintained by the blood collection establishment or transfusion service or similar reports of adverse events collected.

In the **Federal Register** of May 22, 2024, (89 FR 44991), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Recommended activity; guidance section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Annual Report; Section VI, Special Controls	3	1	3	5	15

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on submissions to FDA over the last few years, there are three manufacturers of automated blood cell separator devices. We estimate that the manufacturers will spend approximately 5 hours preparing and submitting the annual report.

The annual report should include, at a minimum, a summary of anticipated and unanticipated adverse events that have occurred and that are not required to be reported by manufacturers under Medical Device Reporting (MDR) (part 803 (21 CFR part 803)). The reporting of adverse device events summarized in an annual report will alert FDA to trends or clusters of events that might be a

safety issue otherwise unreported under the MDR regulation. The report should also include any subsequent change to the preamendments class III device requiring a 30-day notice in accordance with 21 CFR 814.39(f).

Blood collection establishments and transfusion services, the intended users of the device, and the device manufacturers have certain responsibilities under the Federal regulations. For example, collection establishments and or transfusion services are required to maintain records of any reports of complaints of adverse reactions (21 CFR 606.170), while the device manufacturer is responsible for conducting an investigation of each event that is reasonably known to the manufacturer and evaluating the cause of the event (§ 803.50(b) (21 CFR 803.50(b))). In addition, manufacturers of medical devices are required to submit to FDA individual adverse event reports of death, serious injury, and malfunctions (§ 803.50).

Other burden hours required for § 864.9245 are reported and approved under OMB control number 0910–0120 (premarket notification submission 510(k), 21 CFR part 807, subpart E), and OMB control number 0910–0437 (MDR, part 803).

Based on a review of the information collection from our last request for OMB approval, we estimate that the number of manufacturers of automated blood cell separator devices remains unchanged. As a result, we have made no adjustments to our burden estimates.

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16831 Filed 7–30–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3382]

Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the fiscal year (FY) 2025 fee rates for certain domestic and foreign facility reinspections, failures to comply with a recall order, and importer reinspections that are authorized by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA).

DATES: These fees apply to the period from October 1, 2024, and will remain in effect through September 30, 2025.

FOR FURTHER INFORMATION CONTACT:

For questions related to FSMA program fees: FSMAFeeStaff@fda.hhs.gov.

For questions related to this notice: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 240–402–4989; or the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 107 of the FSMA (Pub. L. 111–353) added section 743 to the FD&C Act (21 U.S.C. 379j–31) to provide FDA with the authority to assess and collect fees from, in part: (1) the responsible party for each domestic facility and the U.S. agent for each foreign facility subject to a reinspection to cover reinspection-related costs; (2) the responsible party for a domestic facility and an importer who does not comply with a recall order to cover food [1] recall activities associated with such order; and (3) each importer subject to a reinspection to cover reinspection-related costs (sections 743(a)(1)(A), (B), and (D) of the FD&C Act). Section 743 of the FD&C Act directs FDA to establish fees for each of these activities based on an estimate of 100 percent of the costs of each activity for each year (sections 743(b)(2)(A)(i), (ii), and (iv)), and these fees must be made available solely to pay for the costs of each activity for which the fee was incurred (section 743(b)(3)). These fees are effective on October 1, 2024, and will remain in effect through September 30, 2025. Section 743(b)(2)(B)(iii) of the FD&C Act directs FDA to develop a proposed set of guidelines in consideration of the burden of fee amounts on small businesses. As a first step in developing these guidelines, FDA invited public comment on the potential impact of the fees authorized by section 743 of the FD&C Act on small businesses (76 FR 45818, August 1, 2011). The comment period for this request ended November 30, 2011. As stated in FDA's October 2011 ''Guidance for Industry: Implementation of the Fee Provisions of Section 107 of the FDA Food Safety Modernization Act'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-implementation-fee-provisions-section-107-fda-food-safety-modernization-act*), because FDA recognizes that for small businesses the full cost recovery of FDA reinspection or recall oversight could impose severe economic hardship, FDA intends to consider reducing certain fees for those firms. FDA does not intend to issue invoices for reinspection or recall order fees until FDA publishes a guidance document outlining the process through which firms may request a reduction in fees.

In addition, as stated in the October 2011 Guidance, FDA is in the process of considering various issues associated with the assessment and collection of importer reinspection fees. The fee rates set forth in this notice will be used to determine any importer reinspection fees assessed in FY 2025.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2025

FDA is required to estimate 100 percent of its costs for each activity in order to establish fee rates for FY 2025. In each year, the costs of salary (or personnel compensation) and benefits for FDA employees account for between 50 and 60 percent of the funds available to, and used by, FDA. Almost all the remaining funds (operating funds) available to FDA are used to support FDA employees by paying for rent, travel, utility, information technology (IT), and other operating costs.

A. Estimating the Full Cost per Direct Work Hour in FY 2025

Full-time Equivalent (FTE) reflects the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered ''hours worked'' for purposes of defining FTE employment.

In general, the starting point for estimating the full cost per direct work hour is to estimate the cost of an FTE or paid staff year. Calculating an Agency-wide total cost per FTE requires three primary cost elements: payroll, nonpayroll, and rent.

We have used an average of past year cost elements to predict the FY 2025 cost. The FY 2025 FDA-wide average cost for payroll (salaries and benefits) is

[1] The term ''food'' for purposes of this document has the same meaning as such term in section 201(f) of the FD&C Act (21 U.S.C. 321(f)).

$213,556; non-payroll (including equipment, supplies, IT, general and administrative overhead) is $131,739; and rent (including cost allocation analysis and adjustments for other rent and rent-related costs) is $23,750 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, nonpayroll, and rent, brings the FY 2025 average fully supported cost to $369,046 [2] per FTE, excluding travel costs. FDA will use this base unit fee in determining the hourly fee rate for reinspection and recall order fees for FY 2025 prior to including domestic or foreign travel costs as applicable for the activity.

To calculate an hourly rate, FDA must divide the FY 2025 average fully supported cost of $369,046 per FTE by the average number of supported direct FDA work hours in FY 2023 (the last fiscal year for which data are available). See table 1.

TABLE 1—SUPPORTED DIRECT FDA WORK HOURS IN A PAID STAFF YEAR IN FY 2023

Total number of hours in a paid staff year	2,080
Less:	
11 paid holidays	−88
20 days of annual leave	−160
10 days of sick leave	−80
12.5 days of training	−100
22 days of general administration	−176
26.5 days of travel	−212
2 hours of meetings per week	−104
Net Supported Direct FDA Work Hours Available for Assignments	1,160

Dividing the average fully supported FTE cost in FY 2025 ($369,046) by the total number of supported direct work hours available for assignment in FY 2023 (1,160) results in an average fully supported cost of $318 (rounded to the nearest dollar), excluding inspection travel costs, per supported direct work hour in FY 2025.

B. Adjusting FY 2023 Travel Costs for Inflation To Estimate FY 2025 Travel Costs

To adjust the hourly rate for FY 2025, FDA must estimate the cost of inflation in each year for FY 2024 and FY 2025. FDA uses the method prescribed for estimating inflationary costs under the Prescription Drug User Fee Act (PDUFA) provisions of the FD&C Act (section 736(c)(1) (21 U.S.C. 379h(c)(1))), the statutory method for inflation adjustment in the FD&C Act that FDA has used consistently. FDA previously determined the FY 2024 inflation rate to be 3.8896 percent; this rate was published in the FY 2024 PDUFA user fee rates notice in the **Federal Register** (88 FR 48881, July 28, 2023). Utilizing the method set forth in section 736(c)(1) of the FD&C Act, FDA has calculated an inflation rate of 3.8896 percent for FY 2024 and 4.1167 percent for FY 2025, and FDA intends to use these inflation rates to make inflation adjustments for FY 2025 for several of its user fee programs; the derivation of this rate will be published in the **Federal Register** in the FY 2025 notice for the PDUFA user fee rates.

The average fully supported cost per supported direct FDA work hour, excluding travel costs, of $318 already takes into account inflation as the calculation above is based on FY 2025 predicted costs. FDA will use this base unit fee in determining the hourly fee rate for reinspection and recall order fees for FY 2025 prior to including domestic or foreign travel costs as applicable for the activity. In FY 2023, FDA's Office of Regulatory Affairs (ORA) spent a total of $7,463,679 for domestic regulatory inspection travel costs and General Services Administration Vehicle costs related to FDA's Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM) field activities programs. The total ORA domestic travel costs spent is then divided by the 8,811 CFSAN and CVM domestic inspections, which averages a total of $847 per inspection. These inspections average 41.35 hours per inspection. Dividing $847 per inspection by 41.35 hours per inspection results in a total and an additional cost of $20 (rounded to the nearest dollar) per hour spent for domestic inspection travel costs in FY 2023. To adjust for the $20 per hour additional domestic cost inflation increases for FY 2024 and FY 2025, FDA must multiply the FY 2024 PDUFA inflation rate adjustor (1.038896) times the FY 2025 PDUFA inflation rate adjustor (1.041167) times the $20 additional domestic cost, which results in an estimated cost of $22 (rounded to the nearest dollar) per paid hour in addition to $318 for a total of $340 per paid hour ($318 plus $22) for each direct hour of work requiring domestic inspection travel. FDA will use these rates in charging fees in FY 2025 when domestic travel is required.

In FY 2023, ORA spent a total of $2,629,906 on 431 foreign inspection trips related to FDA's CFSAN and CVM field activities programs, which averaged a total of $6,102 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $6,102 per trip by 120 hours per trip results in a total and an additional cost of $51 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2023. To adjust $51 for inflationary increases in FY 2024, and FY 2025, FDA must multiply it by the same inflation factors mentioned previously in this document (1.038896 and 1.041167), which results in an estimated cost of $55 (rounded to the nearest dollar) per paid hour in addition to $318 for a total of $373 per paid hour ($318 plus $55) for each direct hour of work requiring foreign inspection travel. FDA will use these rates in charging fees in FY 2025 when foreign travel is required.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2025

Fee category	Fee rates for FY 2025
Hourly rate if domestic travel is required	$340
Hourly rate if foreign travel is required	373

III. Fees for Reinspections of Domestic or Foreign Facilities Under Section 743(a)(1)(A)

A. What will cause this fee to be assessed?

The fee will be assessed for a reinspection conducted under section 704 of the FD&C Act (21 U.S.C. 374) to determine whether corrective actions have been implemented and are effective and compliance has been achieved to the Secretary of Health and Human Services' (the Secretary) (and, by delegation, FDA's) satisfaction at a facility that manufactures, processes, packs, or holds food for consumption necessitated as a result of a previous inspection (also conducted under section 704) of this facility, which had a final classification of Official Action Indicated (OAI) conducted by or on behalf of FDA, when FDA determined the noncompliance was materially related to food safety requirements of the FD&C Act. FDA considers such noncompliance to include noncompliance with a statutory or regulatory requirement under section 402 of the FD&C Act (21 U.S.C. 342) and section 403(w) of the FD&C Act (21 U.S.C. 343(w)). However, FDA does not consider noncompliance that is materially related to a food safety requirement to include circumstances where the noncompliance is of a

[2] Total includes rounding.

technical nature and not food safety related (*e.g.,* failure to comply with a food standard or incorrect font size on a food label). Determining when noncompliance, other than under sections 402 and 403(w) of the FD&C Act, is materially related to a food safety requirement of the FD&C Act may depend on the facts of a particular situation. FDA intends to issue guidance to provide additional information about the circumstances under which FDA would consider noncompliance to be materially related to a food safety requirement of the FD&C Act.

Under section 743(a)(1)(A) of the FD&C Act, FDA is directed to assess and collect fees from ''the responsible party for each domestic facility (as defined in section 415(b) (21 U.S.C. 350d(b))) and the U.S. agent for each foreign facility subject to a reinspection'' to cover reinspection-related costs.

Section 743(a)(2)(A)(i) of the FD&C Act defines the term ''reinspection'' with respect to domestic facilities as ''1 or more inspections conducted under section 704 subsequent to an inspection conducted under such provision which identified noncompliance materially related to a food safety requirement of this Act, specifically to determine whether compliance has been achieved to the Secretary's satisfaction.''

The FD&C Act does not contain a definition of ''reinspection'' specific to foreign facilities. In order to give meaning to the language in section 743(a)(1)(A) of the FD&C Act to collect fees from the U.S. agent of a foreign facility subject to a reinspection, the Agency is using the following definition of ''reinspection'' for purposes of assessing and collecting fees under section 743(a)(1)(A), with respect to a foreign facility: ''1 or more inspections conducted by officers or employees duly designated by the Secretary subsequent to such an inspection which identified noncompliance materially related to a food safety requirement of the FD&C Act, specifically to determine whether compliance has been achieved to the Secretary's (and, by delegation, FDA's) satisfaction.''

This definition allows FDA to fulfill the mandate to assess and collect fees from the U.S. agent of a foreign facility in the event that an inspection reveals noncompliance materially related to a food safety requirement of the FD&C Act, causing one or more subsequent inspections to determine whether compliance has been achieved to the Secretary's (and, by delegation, FDA's) satisfaction. By requiring the initial inspection to be conducted by officers or employees duly designated by the Secretary, the definition ensures that a foreign facility would be subject to fees only in the event that FDA, or an entity designated to act on its behalf, has made the requisite identification at an initial inspection of noncompliance materially related to a food safety requirement of the FD&C Act. The definition of ''reinspection-related costs'' in section 743(a)(2)(B) of the FD&C Act relates to both a domestic facility reinspection and a foreign facility reinspection, as described in section 743(a)(1)(A).

B. Who will be responsible for paying this fee?

The FD&C Act states that this fee is to be paid by the responsible party for each domestic facility (as defined in section 415(b) of the FD&C Act) and by the U.S. agent for each foreign facility (section 743(a)(1)(A) of the FD&C Act). This is the party to whom FDA will send the invoice for any fees that are assessed under this section.

C. How much will this fee be?

The fee is based on the number of direct hours spent on such reinspections, including time spent conducting the physical surveillance and/or compliance reinspection at the facility, or whatever components of such an inspection are deemed necessary, making preparations and arrangements for the reinspection, traveling to and from the facility, preparing any reports, analyzing any samples or examining any labels if required, and performing other activities as part of the OAI reinspection until the facility is again determined to be in compliance. The direct hours spent on each such reinspection will be billed at the appropriate hourly rate shown in table 2 of this document.

IV. Fees for Noncompliance With a Recall Order Under Section 743(a)(1)(B)

A. What will cause this fee to be assessed?

The fee will be assessed for not complying with a recall order under section 423(d) (21 U.S.C. 350l(d)) or section 412(f) of the FD&C Act (21 U.S.C. 350a(f)) to cover food recall activities associated with such order performed by the Secretary (and by delegation, FDA) (section 743(a)(1)(B) of the FD&C Act). Noncompliance may include the following: (1) not initiating a recall as ordered by FDA; (2) not conducting the recall in the manner specified by FDA in the recall order; or (3) not providing FDA with requested information regarding the recall, as ordered by FDA.

B. Who will be responsible for paying this fee?

Section 743(a)(1)(B) of the FD&C Act states that the fee is to be paid by the responsible party for a domestic facility (as defined in section 415(b) of the FD&C Act) and an importer who does not comply with a recall order under section 423 or under section 412(f) of the FD&C Act. In other words, the party paying the fee would be the party that received the recall order.

C. How much will this fee be?

The fee is based on the number of direct hours spent taking action in response to the firm's failure to comply with a recall order. Types of activities could include conducting recall audit checks, reviewing periodic status reports, analyzing the status reports and the results of the audit checks, conducting inspections, traveling to and from locations, and monitoring product disposition. The direct hours spent on each such recall will be billed at the appropriate hourly rate shown in table 2 of this document.

D. How must the fees be paid?

An invoice will be sent to the responsible party for paying the fee after FDA completes the work on which the invoice is based. Payment must be made within 30 days of the invoice date in U.S. currency by electronic check, credit card, check, bank draft, U.S. postal money order, or wire transfer payable to the order of the Food and Drug Administration. Detailed payment information will be included with the invoice when it is issued.

V. What are the consequences of not paying these fees?

Under section 743(e)(2) of the FD&C Act, any fee that is not paid within 30 days after it is due shall be treated as a claim of the U.S. Government subject to provisions of subchapter II of chapter 37 of title 31, United States Code.

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3453]

Medical Device User Fee Rates for Fiscal Year 2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fee rates and payment procedures for medical device user fees for fiscal year (FY) 2025. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Medical Device User Fee Amendments of 2022 (MDUFA V), authorizes FDA to collect user fees for certain medical device submissions and annual fees both for certain periodic reports and for establishments subject to registration. This notice establishes the fee rates for FY 2025, which apply from October 1, 2024, through September 30, 2025, and provides information on how the fees for FY 2025 were determined, the payment procedures you should follow, and how you may qualify for reduced small business fees.

FOR FURTHER INFORMATION CONTACT:

For information on Medical Device User Fees: https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa.

For questions relating to the MDUFA Small Business Program, please visit the Center for Devices and Radiological Health's website: https://www.fda.gov/medical-devices/premarket-submissions/reduced-medical-device-user-fees-small-business-determination-sbd-program.

For questions relating to this notice: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 240–402–4989; or the User Fee Support Staff at *OO-OFBAP-OFM-UFFS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The FD&C Act, as amended by MDUFA V, authorizes FDA to collect user fees for certain medical device submissions and annual fees both for certain periodic reports and for establishments subject to registration. Section 738 of the FD&C Act (21 U.S.C. 379j) establishes fees for certain medical device applications, submissions, supplements, notices, and requests (for simplicity, this document refers to these collectively as ''submissions'' or ''applications''); for periodic reporting on class III devices; and for the registration of certain establishments.

Under the FD&C Act, the fee rate for each type of submission is set at a specified percentage of the standard fee for a premarket application (a premarket application is a premarket approval application (PMA), a product development protocol (PDP), or a biologics license application (BLA)). The FD&C Act specifies the base fee for a premarket application for each year from FY 2023 through FY 2027; the base fee for a premarket application received by FDA during FY 2025 is $445,000. From this starting point, this document establishes FY 2025 fee rates for certain types of submissions, and for periodic reporting, by applying criteria specified in the FD&C Act. Under statutorily defined conditions, a qualified applicant may receive a fee waiver or may pay a lower small business fee (see sections 738(a)(3)(B), 738(d) and 738(e) of the FD&C Act). For more information on fee waivers, please see Section IX. Small Business Fee Reductions and Fee Waivers.

The FD&C Act specifies the base fee for establishment registration for each year from FY 2023 through FY 2027; the base fee for an establishment registration in FY 2025 is $7,100. Each establishment that is registered (or is required to register) with the Secretary of Health and Human Services under section 510 of the FD&C Act (21 U.S.C. 360), because such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of a device, is required to pay the annual fee for establishment registration.

II. Total Revenue Amount for FY 2025

The total revenue amount for FY 2025 is $350,746,400, as set forth in the statute prior to the inflation adjustment (see section 738(b)(3) of the FD&C Act). MDUFA V directs FDA to use the yearly total revenue amount as a starting point to set the standard fee rates for each fee type. The fee calculations for FY 2025 are described in this document.

Inflation Adjustment

MDUFA specifies that the $350,746,400 is to be adjusted for inflation increases for FY 2025 using two separate adjustments: one for payroll costs and one for non-payroll costs (see section 738(c)(2) of the FD&C Act). The base inflation adjustment for FY 2025 is the sum of one plus the two separate adjustments and is compounded as specified in the statute (see section 738(c)(2)(C) and 738(c)(2)(B) of the FD&C Act).

The component of the inflation adjustment for payroll costs is the average annual percent change in the cost of all personnel compensation and benefits (PC&B) paid per full-time equivalent (FTE) position at FDA for the first 3 of the 4 preceding FYs, multiplied by 0.60, or 60 percent (see section 738(c)(2)(C)(i)(I) of the FD&C Act).

Table 1 summarizes the actual cost and FTE data for the specified FYs, provides the percent change from the previous fiscal year, and provides the average percent change over the first 3 of the 4 fiscal years preceding FY 2025. The 3-year average is 3.8539 percent (rounded).

TABLE 1—FDA PC&BS EACH YEAR AND PERCENT CHANGE

	FY 2021	FY 2022	FY 2023	3-Year average
Total PC&B	$3,039,513,000	$3,165,477,000	$3,436,513,000	.....
Total FTE	18,501	18,474	18,729	.....
PC&B per FTE	$164,289	$171,348	$183,486	.....
Percent change from previous year	0.1811%	4.2967%	7.0838%	3.8539%

The payroll adjustment is 3.8539 percent multiplied by 60 percent, or 2.3123 percent. The statute specifies that the component of the inflation adjustment for non-payroll costs for FY 2025 is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Arlington-Alexandria, DC-VA-MD-WV; Not Seasonally Adjusted; All Items; Annual Index) for the first 3 of the preceding 4 years of available

data multiplied by 0.40, or 40 percent (see section 738(c)(2)(C)(i)(II) of the FD&C Act).

Table 2 provides the summary data and the 3-year average percent change in the specified CPI for the Washington-Arlington-Alexandria area. These data are published by the Bureau of Labor Statistics and can be found on their website under series Id CUURS35ASA0 at: *https://data.bls.gov/pdq/SurveyOutputServlet?data_tool=dropmap&series_id=CUURS35ASA0,CUUSS35ASA0.*

TABLE 2—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN WASHINGTON-ARLINGTON-ALEXANDRIA AREA CPI

	2021	2022	2023	3-Year average
Annual CPI	277.728	296.117	305.317	.....
Annual Percent Change	3.9568%	6.6212%	3.1069%	.....
3-Year Average Percent Change in CPI	.....	.....	.....	4.5616%

The non-payroll adjustment is 4.5616 percent multiplied by 40 percent, or 1.8246 percent. Next, the payroll adjustment (2.3123 percent or 0.023123) is added to the non-payroll adjustment (1.8246 percent or 0.018246), for a total of 4.1369 percent (or 0.041369). To complete the inflation adjustment, 1 (100 percent or 1.0) is added for a total base inflation adjustment of 1.041369 for FY 2025. If the base inflation adjustment for a fiscal year is greater than 1.04, such adjustment shall be considered to be equal to 1.04 (see section 738(c)(2)(C)(ii)(II) of the FD&C Act). The total base inflation adjustment for FY 2025 is 1.04.

MDUFA V provides for this inflation adjustment to be compounded for FY 2023 and each subsequent fiscal year (see section 738(c)(2)(B) of the FD&C Act). To complete the compounded inflation adjustment for FY 2025, the FY 2024 compounded adjustment (1.079318) is multiplied by the FY 2025 base inflation adjustment (1.040000) to reach the applicable inflation adjustment of 1.122491 (rounded) for FY 2025. We then multiply the total revenue amount for FY 2025 ($350,746,400) by 1.122491, yielding an inflation adjusted total revenue amount of $393,710,000 (rounded to the nearest thousand dollars).

III. Adjustments to Base Fee Amounts for FY 2025

Under the FD&C Act, all submission fees and the periodic reporting fee are set as a percent of the standard (full) fee for a premarket application (see section 738(a)(2)(A) and (b)(1) of the FD&C Act).

A. Inflation Adjustment

MDUFA specifies that the base fees of $445,000 (premarket application) and $7,100 (establishment registration) are to be adjusted for FY 2025 using the same methodology as that for the total revenue inflation adjustment in section II (see section 738I(2)(D)(i) of the FD&C Act). Multiplying the base fees by the compounded inflation adjustment of 1.122491 yields inflation adjusted base fees of $499,508 (premarket application) and $7,970 (establishment registration).

B. Further Adjustments To Generate the Inflation-Adjusted Total Revenue Amount

After the applicable inflation adjustment to fees is done, FDA may increase, if necessary to achieve the inflation adjusted total revenue amount, the base fee amounts on a uniform proportionate basis (see section 738(c)(2)(D)(ii) of the FD&C Act). After this adjustment, if necessary, FDA may further increase the base establishment registration fees to generate the inflation-adjusted total revenue amount (see section 738(c)(3) of the FD&C Act).

For FY 2025, further adjustments were required to meet the inflation adjusted total revenue amount of $393,710,000. After increasing base fees, on a uniform proportionate basis, and further increasing establishment registration fees, this yields inflation adjusted base fees of $540,783 (premarket application) and $8,716 (establishment registration).

C. MDUFA V Adjustments Solely to Registration Fees

MDUFA V has three new potential adjustments that will not change the total revenue amount but may impact collections by increasing or decreasing establishment registration base fees only. These adjustments are the performance improvement adjustment, the hiring adjustment, and the operating reserve adjustment.

1. Performance Improvement Adjustment

Beginning with FY 2025, this adjustment allows FDA to collect fees in addition to the total revenue amount in FYs 2025, 2026, and 2027, if the Agency meets certain performance goals in FYs 2023, 2024, and 2025. If applicable, this provision further increases base establishment registration fee amounts to achieve an increase in total fee collections equal to the applicable performance improvement adjustment, which is set forth in the statute (see section 738(c)(4) of the FD& C Act). FDA met the FY 2023 Pre-Submission Written Feedback goal, which triggers the performance improvement adjustment for FY 2025.

For FY 2025, the performance improvement adjustment is equal to the product of the pre-submission amount in section 738(c)(4)(B)(i)(I) of the FD&C Act, $15,396,600, and the inflation adjustment under section 738(c)(2)(B) of the FD&C Act, 1.122491. See section 738(c)(4)(A)(i) of the FD&C Act. For FY 2025, the performance improvement adjustment is $17,282,545.

2. Hiring Adjustment

Beginning with FY 2025, this adjustment provides for the reduction of base establishment registration fees in FYs 2025, 2026, and 2027, if specified hiring goals for FYs 2023, 2024, and 2025 are not met by a certain threshold. The hiring adjustment would serve to decrease the base establishment registration fee amounts, as necessary, to achieve a reduction in total fee collections equal to the hiring adjustment amount, which is set forth in the statute (see section 738(c)(5) of the FD&C Act).

FDA met the FY 2023 statutory hiring threshold of 123 hires, so establishment registration fees will not need to be lowered by the hiring adjustment amount in FY 2025. Since FDA met the FY 2023 Pre-Submission Written Feedback goal, the FY 2027 statutory hiring goal will be 83 hires for fiscal year 2025 (see section 738(c)(5)(D)(iii)(II) of the FD&C Act) and the threshold will be 75 hires for fiscal year 2025 (see section 738(c)(5)(B)(iii)(II) of the FD&C Act).

3. Operating Reserve Adjustment

For FYs 2023 to 2027, the operating reserve adjustment requires FDA to decrease base establishment registration fees if the amount of operating reserves

of carryover user fees exceeds the ''designated amount'', and such reduction is necessary to provide for not more than such designated amount of operating reserves of carryover user fees (see section 738(c)(6)(A) of the FD&C Act). In making this calculation for FYs 2023 to 2026, a certain amount is excluded from the designated amount and is not subject to the decrease (see section 738(c)(6)(C) of the FD&C Act). For FY 2025, this excluded amount is $77,496,161.

The designated amount is equal to the sum of 13 weeks of operating reserves of carryover user fees plus 1 month of operating reserves, as described in 738(c)(8) (see 738(c)(6)(B) of the FD&C Act).

To determine the 13-week operating reserves of carryover user fees amount, the FY 2025 inflation-adjusted total revenue amount (from section II), $393,710,000, is added to the inflation-adjusted performance improvement adjustment amount (from section III.C.1), $17,282,545, resulting in $410,992,545. This amount is then divided by 52, and then multiplied by 13. The 13-week operating reserve amount for FY 2025 is $102,748,136.

To determine the 1 month of operating reserves described in section 738(c)(8) of the FD&C Act, the FY 2025 inflation-adjusted total revenue amount of $393,710,000 is added to the inflation-adjusted performance improvement adjustment amount of $17,282,545, resulting in $410,992,545. This amount is then divided by 12. The 1 month of operating reserves for FY 2025 is $34,249,379.

For FY 2025, the designated amount is equal to the 13-week operating reserve of $102,748,136 plus the 1 month of operating reserves of $34,249,379, totaling $136,997,515.

To determine the FY 2024 end-of-year operating reserves of carryover user fees amount, FDA combined the actual collections and obligations at the end of the third quarter (June 2024) and added the forecasted collections and obligations for the fourth quarter of FY 2024 to generate a full year estimate for FY 2024. The estimated end-of-year FY 2024 operating reserves of carryover user fees is $50,394,972 (Note, this amount includes the 1-month reserve).

Note that under MDUFA V, for the purposes of calculating the operating reserve adjustment, this amount does not include user fee funds considered unappropriated ($26,680,243) or unearned revenue ($62,498,454). In addition, as noted above, for purposes of the operating reserve adjustment, operating reserves of carryover user fees do not include the estimated $77,496,161 remaining to spend at the end of FY 2024 from the total of $118,000,000 intended to support the Total Product Life Cycle Advisory Program Pilot and Third-Party Review programs.

Because the estimated end-of-year FY 2024 MDUFA operating reserves of carryover user fees amount totaling $50,394,972 does not exceed the FY 2025 designated amount of $136,997,515, FDA will not decrease the base establishment registration fee amounts for FY 2025 to provide for not more than such designated amount.

As there is a performance improvement adjustment for FY 2025, but no hiring adjustment or operating reserve adjustment, establishment registration fees are increased to achieve an increase in total fee collections for FY 2025 equal to the performance improvement adjustment amount of $17,282,545. After so increasing establishment registration fees only, this yields fees of $540,783 (premarket application) and $9,280 (establishment registration).

IV. Calculation of Fee Rates

As noted in section II, the total revenue amount after the applicable inflation adjustment is $393,710,000 (rounded to the nearest thousand dollar). As noted in section III, the performance improvement adjustment solely to registration fees for FY 2025 is $17,282,545. There is no hiring adjustment or operating reserve adjustment for FY 2025.

Table 3A provides fee-paying submission counts, excluding establishment registration, for the last 3 years and the 3-year average. Table 3B provides establishment registration fee-paying submission counts for the most recently completed fiscal year (FY 2023). Historically, FDA has estimated the total number of fee-paying submission counts it expects to receive during the next fiscal year by averaging the number of fee-paying submission counts received in the 3 most recently completed fiscal years; for FY 2025 fee-setting, this would be an average of FY 2021 through FY 2023. FDA received an abnormally high volume of fee-paying establishment registrations due to the COVID–19 pandemic in FY 2020 and FY 2021. The surge in fee-paying establishment registrations has been declining starting in FY 2022, trending back toward pre-pandemic levels. In an effort to normalize the projected volume of establishment registration submissions for the FY 2025 fee-setting calculation, and more accurately project the associated establishment registration revenue, FDA decided to utilize the number of establishment registration fee-paying submission counts from FY 2023.

TABLE 3A—THREE-YEAR AVERAGE OF FEE-PAYING SUBMISSIONS

[Excluding establishment registration]

Application type	FY 2021 actual	FY 2022 actual	FY 2023 actual	3 Yr average
Full Fee applications	25	18	31	25
Small Business	5	3	3	4
Panel-Track Supplements	31	21	22	25
Small Business	6	1	5	4
De Novo Classifications	16	23	26	22
Small Business	42	53	68	54
180-Day Supplements	98	93	113	101
Small Business	34	31	12	26
Real-Time Supplements	150	140	138	143
Small Business	20	12	28	20
510(k)s	2,133	2,012	1,943	2,029
Small Business	1,846	1,757	2,031	1,878
30-Day Notice (Note also includes counts for 135 Day Supplements)	843	782	825	817
Small Business	77	67	53	66
513(g)(21 U.S.C. 360c(g)) Request for Classification Information	83	93	82	86
Small Business	53	58	59	57

TABLE 3A—THREE-YEAR AVERAGE OF FEE-PAYING SUBMISSIONS—Continued

[Excluding establishment registration]

Application type	FY 2021 actual	FY 2022 actual	FY 2023 actual	3 Yr average
Annual Fee for Periodic Reporting	613	620	657	630
Small Business	84	87	22	64

TABLE 3B—FISCAL YEAR 2023 ACTUAL FEE-PAYING ESTABLISHMENT REGISTRATION SUBMISSIONS

Application type	FY 2023	FY 2025 estimate for registrations
Establishment Registrations	30,645	30,645

The information in tables 3A and 3B is necessary to estimate the amount of revenue that will be collected based on the fee amounts. Tables 4A and 4B display the FY 2025 base fees set in statute (column one) and the inflation adjusted base fees (per calculations in section III.A.) (column two). Using the inflation adjusted fees, the 3-year average of fee-paying submissions (excluding establishment registration), and the fee-paying establishment registration submissions from FY 2023, collections are projected to total $361,177,583 which is $32,532,417 lower than the inflation adjusted total revenue amount (in section II). Accordingly, the next step in the fee setting process is to increase the base fee amounts on a uniform proportionate basis to generate the inflation adjusted total revenue amounts (see 738(c)(2)(D)(ii) of the FD&C Act and table 4A, column three).

Applying these further adjusted fee rates to the 3-year average of fee-paying submissions, and the fee-paying establishment registration submissions from FY 2023 results in estimated total fee collections of $391,014,947 which is still $2,695,053 lower than the inflation adjusted total revenue amount (in Section II). The next step in the fee setting process, after the adjustment in (2)(D) is done, is to increase the base establishment registration fee amount as necessary for total fee collections to generate the inflation adjusted total revenue amount, as adjusted under paragraph (2) (see 738(c)(3) of the FD&C Act). Accordingly, the base establishment registration fee was increased by $88 for an establishment registration fee rate of $8,716 (see 738(c)(3) of the FD& C Act and table 4B, column three). The performance improvement adjustment amount is $17,282,544. Per statute, the establishment registration fee is further adjusted to account for the performance improvement adjustment amount. The inflation adjusted establishment registration fee is increased by $564 for an establishment registration fee of $9,280. The fees in column three in table 4A and column four in table 4B are those we are establishing for FY 2025, which are the standard fees.

TABLE 4A—FEES NEEDED TO ACHIEVE NEW FY 2025 REVENUE TARGET

Application type	FY 2025 statutory fees (base fees)	FY 2025 inflation adjusted statutory base fees	Adjusted FY 2025 fees to meet revenue target (uniform proportionate increase)	3-Year average of fee-paying submissions	FY 2025 revenue from adjusted fees
Full Fee Applications	$445,000	$499,508	$540,783	25	$13,519,575
Small Business	111,250	124,877	135,196	4	540,784
Panel-Track Supplement	356,000	399,607	432,626	25	10,815,650
Small Business	89,000	99,902	108,157	4	432,628
De Novo Classification Request	133,500	149,583	162,235	22	3,569,170
Small Business	33,375	37,463	40,559	54	2,190,186
180-Day Supplements	66,750	74,926	81,117	101	8,192,817
Small Business	16,688	18,732	20,279	26	527,254
Real-Time Supplements	31,150	34,966	37,855	143	5,413,265
Small Business	7,788	8,741	9,464	20	189,280
510(k)s	20,025	22,478	24,335	2,029	49,375,715
Small Business	5,006	5,619	6,084	1,878	11,425,752
30-Day Notice	7,120	7,992	8,653	817	7,069,501
Small Business	3,560	3,996	4,326	66	285,516
513(g) Request for Classification Information	6,008	6,743	7,301	86	627,886
Small Business	3,004	3,372	3,650	57	208,050
Annual Fee for Periodic Reporting	15,575	17,483	18,927	630	11,924,010
Small Business	3,894	4,371	4,732	64	302,848
Total					126,609,887

TABLE 4B—FEES NEEDED TO ACHIEVE NEW FY 2025 REVENUE TARGET PLUS/MINUS ADJUSTMENTS

Application type	FY 2025 statutory fees (base fees)	FY 2025 inflation adjusted statutory base fees	Adjusted FY 2025 fees to meet inflation adjusted total revenue amount (uniform proportionate increase + further adjustment to establishment registrations)	Adjusted FY 2025 fees to meet inflation adjusted total revenue +/− adjustments	FY 2023 fee-paying submissions	FY 2025 revenue from adjusted fees
Establishment Registrations	$7,100	$7,970	$8,716	$9,280	30,645	$267,101,820

The standard fee (adjusted base amount) for a premarket application, including a BLA, and for a premarket report and a BLA efficacy supplement, is $540,783 for FY 2025. The fees set by reference to the standard fee for a premarket application are:

- For a panel-track supplement, 80 percent of the standard fee
- For a de novo classification request, 30 percent of the standard fee
- For a 180-day supplement, 15 percent of the standard fee
- For a real-time supplement, 7 percent of the standard fee
- For an annual fee for periodic reporting concerning a class III device, 3.5 percent of the standard fee
- For a 510(k) premarket notification, 4.5 percent of the standard fee
- For a 30-day notice, 1.6 percent of the standard fee
- For a 513(g) request for classification information, 1.35 percent of the standard fee

For all submissions other than a 30-day notice and a 513(g) request for classification information, the small business fee is 25 percent of the standard (full) fee for the submission (see section 738(d)(2)(C) and (e)(2)(C) of the FD&C Act). For a 30-day notice and a 513(g) request for classification information, the small business fee is 50 percent of the standard (full) fee for the submission (see section 738(d)(2)(C) of the FD&C Act).

The annual fee for establishment registration, after adjustments, is set at $9,280 for FY 2025. For FY 2025, there is no small business waiver for the annual establishment registration fee; all establishments pay the same fee.

For more information on reduced fees and waivers for small businesses, please see Section IX. Small Business Fee Reductions and Fee Waivers.

Table 5 summarizes the FY 2025 rates for all medical device fees.

TABLE 5—MEDICAL DEVICE FEES FOR FY 2025

Application fee type	Standard fee (as a percent of the standard fee for a premarket application)	FY 2025 standard fee	FY 2025 small business fee
Premarket application (a PMA submitted under section 515(c)(1) of the FD&C Act (21 U.S.C. 360e(c)(1)), a PDP submitted under section 515(f) of the FD&C Act, or a BLA submitted under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262)).	Base fee specified in statute	$540,783	$135,196
Premarket report (submitted under section 515(c)(2) of the FD&C Act)	100%	540,783	135,196
Efficacy supplement (to an approved BLA under section 351 of the PHS Act)	100%	540,783	135,196
Panel-track supplement	80%	432,626	108,157
De novo classification request	30%	162,235	40,559
180-day supplement	15%	81,117	20,279
Real-time supplement	7%	37,855	9,464
510(k) premarket notification submission	4.5%	24,335	6,084
30-day notice	1.60%	8,653	4,326
513(g) request for classification information	1.35%	7,301	3,650
Annual Fee Type			
Annual fee for periodic reporting on a class III device	3.50%	18,927	4,732
Annual establishment registration fee (to be paid by the establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device, as defined by 21 U.S.C. 379i(14)).	Base fee specified in statute	9,280	9,280

V. How To Qualify as a Small Business for Purposes of Medical Device Fees

If your business, including your affiliates, has gross receipts or sales of no more than $100 million for the most recent tax year, you may qualify for reduced small business fees. If your business, including your affiliates, has gross sales or receipts of no more than $30 million, you may also qualify for a waiver of the fee for your first premarket application (*i.e.,* PMA, PDP, or BLA) or premarket report. If you want to pay the small business fee rate for a submission or you want to receive a waiver of the fee for your first premarket application or premarket report, you must submit the materials showing you qualify as a small business at least 60 days before you send your submission to FDA. For more information on fee waivers or reductions, please see Section IX. Small Business Fee Reductions and Fee Waivers.

Please note that the establishment registration fee is not eligible for a reduced small business fee. For FY 2025, there is no small business waiver for the annual establishment registration fee. As a result, if the establishment registration fee is the only medical device user fee that you will pay in FY 2025, you should not submit a Small Business Certification Request. FDA will review your information and determine whether you qualify as a small business eligible for the reduced fee and/or fee waiver. If you make a submission before FDA finds that you qualify as a small business, you must pay the standard (full) fee for that submission.

If your business qualified as a small business for FY 2024, your status as a small business will expire at the close of business on September 30, 2024. You must re-qualify for FY 2025 in order to pay small business fees during FY 2025.

A. Domestic (U.S.) Businesses

If you are a domestic (U.S.) business and wish to qualify as a small business for FY 2025, submit the following to FDA:

1. A completed MDUFA Small Business Certification Request for a Business Headquartered in the United States (Form FDA 3602). Form FDA 3602 is provided in the FDA Forms database: *https://www.fda.gov/about-fda/reports-manuals-forms/forms.*

2. A signed copy of your Federal (U.S.) Income Tax Return for the most recent tax year. The most recent tax year will be 2024, except:

- If you submit your MDUFA Small Business Certification Request for FY 2025 before April 15, 2025, and you have not yet filed your return for 2024, you may use tax year 2023.
- If you submit your MDUFA Small Business Certification Request for FY 2025 on or after April 15, 2025, and have not yet filed your 2024 return because you obtained an extension, you may submit your most recent return filed prior to the extension.

3. For each of your affiliates, either:

- If the affiliate is a domestic (U.S.) business, a signed copy of the affiliate's Federal (U.S.) Income Tax Return for the most recent tax year, or
- If the affiliate is a foreign business and cannot submit a Federal (U.S.) Income Tax Return, a National Taxing Authority Certification completed by, and bearing the official seal of, the National Taxing Authority, if extant, of the country in which the firm is headquartered. The National Taxing Authority is the foreign equivalent of the U.S. Internal Revenue Service. This certification must show the amount of gross receipts or sales for the most recent tax year, in both U.S. dollars and the local currency of the country, the exchange rate used in converting the local currency to U.S. dollars, and the dates of the gross receipts or sales collected. The business must also submit a statement signed by the head of the business's firm or by its chief financial officer that the business has submitted certifications for all of its affiliates, identifying the name of each affiliate, or that the business has no affiliates.
- If your affiliate is headquartered in a country without a National Taxing Authority, please contact the Division of Industry and Consumer Education at 800–638–2041 or 301–796–7100 or email at *DICE@fda.hhs.gov.*

4. Once you have completed and signed your Form FDA 3602, submit your form and your supporting documentation (copies of the Federal (U.S.) income tax returns), using the instructions which are available at the following website: *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm577696.htm.*

If you need assistance, please contact the Division of Industry and Consumer Education at 800–638–2041 or 301–796–7100 or email at *DICE@fda.hhs.gov.*

B. Foreign Businesses

If you are a foreign business, and wish to qualify as a small business for FY 2025, submit the following:

1. A completed MDUFA Foreign Small Business Certification Request for a Business Headquartered Outside the United States (Form FDA 3602A). Form FDA 3602A is provided in the FDA Forms database: *https://www.fda.gov/about-fda/reports-manuals-forms/forms.*

2. A National Taxing Authority Certification, completed by, and bearing the official seal of, the National Taxing Authority, if extant, of the country in which the firm is headquartered. This certification must show the amount of gross receipts or sales for the most recent tax year, in both U.S. dollars and the local currency of the country, the exchange rate used in converting the local currency to U.S. dollars, and the dates of the gross receipts or sales collected.

If your firm is headquartered in a country without a National Taxing Authority, please contact the Division of Industry and Consumer Education at 800–638–2041 or 301–796–7100 or email at *DICE@fda.hhs.gov.*

3. For each of your affiliates, either:

- If the affiliate is a domestic (U.S.) business, a signed copy of the affiliate's Federal (U.S.) Income Tax Return for the most recent tax year (2023 or later), or
- If the affiliate is a foreign business and cannot submit a Federal (U.S.) Income Tax Return, a National Taxing Authority Certification completed by, and bearing the official seal of, the National Taxing Authority, if extant, of the country in which the firm is headquartered. The National Taxing Authority is the foreign equivalent of the U.S. Internal Revenue Service. This certification must show the amount of gross receipts or sales for the most recent tax year, in both U.S. dollars and the local currency of the country, the exchange rate used in converting the local currency to U.S. dollars, and the dates for the gross receipts or sales collected. The business must also submit a statement signed by the head of the business's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, identifying the name of each affiliate, or that the business has no affiliates.
- If your affiliate is headquartered in a country without a National Taxing Authority, please contact the Division of Industry and Consumer Education at 800–638–2041 or 301–796–7100 or email at *DICE@fda.hhs.gov.*

4. Once you have completed and signed your Form FDA 3602A, submit your form and your supporting documentation, including the following, using the instructions which are available at the following website: *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm577696.htm.*

- A copy of the most recent Federal (U.S.) income tax return for each of your affiliates headquartered in the U.S. and
- A copy of an MDUFA Foreign Small Business Certification Request for each of your foreign affiliates.

If you need assistance, please contact the Division of Industry and Consumer Education at 800–638–2041 or 301–796–7100 or email at *DICE@fda.hhs.gov.*

VI. Procedures for Paying Application Fees

If your application or submission is subject to a fee and your payment is received by FDA between October 1, 2024, and September 30, 2025, you must pay the fee in effect for FY 2025. To avoid delay in the review of your application, you should pay the application fee at the time you submit your application to FDA. The later of the date that the application is received in the reviewing center's document room or the date the U.S. Treasury recognizes the payment determines whether the fee rates for FY 2024 or FY 2025 apply. FDA must receive the correct fee at the time that an application is submitted, or the application will not be accepted for filing or review.

FDA requests that you follow the steps below before submitting a medical device application subject to a fee to ensure that FDA links the fee with the correct application. (*Note:* Do not send your user fee check to FDA with the application.)

A. Secure a Payment Identification Number (PIN) and Medical Device User Fee Cover Sheet From FDA Before Submitting Either the Application or the Payment

Log into the User Fee System at: *https://userfees.fda.gov/OA_HTML/mdufmaCAcdLogin.jsp.* Complete the Medical Device User Fee cover sheet. Be sure you choose the correct application

submission date range. (Two choices will be offered until October 1, 2024. One choice is for applications and fees that will be received on or before September 30, 2024, which are subject to FY 2024 fee rates. A second choice is for applications and fees received on or after October 1, 2024, which are subject to FY 2025 fee rates.) After completing data entry, print a copy of the Medical Device User Fee cover sheet and note the unique PIN located in the upper right-hand corner of the printed cover sheet.

B. Electronically Transmit a Copy of the Printed Cover Sheet With the PIN

When you are satisfied that the data on the cover sheet is accurate, electronically transmit that data to FDA according to instructions on the screen. Applicants are required to set up a user account and password to assure data security in the creation and electronic submission of cover sheets.

C. Submit Payment for the Completed Medical Device User Fee Cover Sheet

1. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). FDA has partnered with the U.S. Department of the Treasury to utilize *Pay.gov*, a web-based payment system, for online electronic payment. You may make a payment via electronic check or credit card after submitting your cover sheet. Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay. Note:* Only full payments are accepted. No partial payments can be made online. Once you search for your invoice, select ''Pay Now'' to be redirected to *Pay.gov.* Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S bank accounts as well as U.S. credit cards.

2. If paying with a paper check:

- All paper checks must be in U.S. currency from a U.S. bank and made payable to the Food and Drug Administration. If needed, FDA's tax identification number is 53–0196965.
- Please write your application's unique PIN (from the upper right-hand corner of your completed Medical Device User Fee cover sheet) on your check.
- *Mail the paper check and a copy of the completed cover sheet to:* Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000.

If you prefer to send a check by a courier, the courier may deliver the check to: U.S. Bank, Attn: Government Lockbox 979033, 3180 Rider Trail S, Earth City, MO 63045. (*Note:* This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery contact U.S. Bank at 800–495–4981. This telephone number is only for questions about courier delivery).

3. If paying with a wire transfer:

- Please include your application's unique PIN (from the upper right-hand corner of your completed Medical Device User Fee cover sheet) in your wire transfer. Without the PIN, your payment may not be applied to your cover sheet and review of your application may be delayed.
- The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee it is required that you add that amount to the payment to ensure that the invoice is paid in full.

Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33.

FDA records the official application receipt date as the later of the following: (1) the date the application was received by the FDA Document Control Center for the reviewing Center or (2) the date the U.S. Treasury recognizes the payment.

D. Submit Your Application to FDA With a Copy of the Completed Medical Device User Fee Cover Sheet

Please submit your application and a copy of the completed Medical Device User Fee cover sheet to the address located at *https://www.fda.gov/cdrhsubmissionaddress.*

VII. Procedures for Paying the Annual Fee for Periodic Reporting

You will be invoiced at the end of the quarter in which your PMA Periodic Report is due. Invoices will be sent based on the details included on your PMA file. You are responsible for ensuring FDA has your current billing information, and you may update your contact information for the PMA by submitting an amendment to the pending PMA or a supplement to the approved PMA.

1. The preferred payment method is online using electronic check (ACH also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* (*Note:* Only full payments are accepted. No partial payments can be made online). Once you search for your invoice, select ''Pay Now'' to be redirected to *Pay.gov.* Note that electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

2. *If paying with a paper check:* The check must be in U.S. currency from a U.S. bank and made payable to the Food and Drug Administration. If needed, FDA's tax identification number is 53–0196965.

- Please write your invoice number on the check.
- *Mail the paper check and a copy of the invoice to:* Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000.

To send a check by a courier, the courier must deliver the check and printed copy of the cover sheet to U.S. Bank, Attn: Government Lockbox 979033, 3180 Rider Trail S, Earth City, MO 63045. (*Note:* This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 800–495–4981. This telephone number is only for questions about courier delivery).

3. When paying by a wire transfer, it is required that the invoice number is included; without the invoice number the payment may not be applied. If the payment amount is not applied, the invoice amount would be referred to collections. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required that you add that amount to the payment to ensure that the invoice is paid in full.

Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33.

VIII. Procedures for Paying Annual Establishment Registration Fees

To pay the annual establishment registration fee, firms must access the Device Facility User Fee (DFUF) website at *https://userfees.fda.gov/OA_HTML/furls.jsp.* (FDA has verified the website address, but FDA is not responsible for any subsequent changes to the website

address after this document publishes in the **Federal Register**.) Create a DFUF order and you will be issued a PIN when you place your order. After payment has been processed, you will be issued a payment confirmation number (PCN). You will not be able to register your establishment if you do not have a PIN and a PCN. An establishment required to pay an annual establishment registration fee is not legally registered in FY 2025 until it has completed the steps below to register and pay any applicable fee (see section 738(f)(2) of the FD&C Act).

Companies that do not manufacture any product other than a licensed biologic are required to register in the Blood Establishment Registration (BER) system. FDA's Center for Biologics Evaluation and Research (CBER) will send establishment registration fee invoices annually to these companies.

A. Submit a DFUF Order With a PIN From FDA Before Registering or Submitting Payment

To submit a DFUF Order, you must create or have previously created a user account and password for the user fee website listed previously in this section. After creating a username and password, log into the Establishment Registration User Fee FY 2025 store. Complete the DFUF order by entering the number of establishments you are registering that require payment. When you are satisfied that the information in the order is accurate, electronically transmit that data to FDA according to instructions on the screen. Print a copy of the final DFUF order and note the unique PIN located in the upper right-hand corner of the printed order.

B. Pay for Your DFUF Order

Unless paying by U.S. credit card, all payments must be in U.S. currency and drawn on a U.S. bank.

1. *If paying by credit card or electronic check (ACH or eCheck):* The DFUF order will include payment information, including details on how you can pay online using a credit card or electronic check. Follow the instructions provided to make an electronic payment.

2. *If paying with a paper check:* The check must be in U.S. currency and drawn on a U.S. bank, and mailed to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000.

If a check is sent by a courier that requests a street address, the courier can deliver the check to: U.S. Bank, Attn: Government Lockbox 979033, 3180 Rider Trail S, Earth City, MO 63045. (*Note:* This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 800–495–4981. This telephone number is only for questions about courier delivery.)

Please make sure that both of the following are written on your check: (1) the FDA post office box number (P.O. Box 979033) and (2) the PIN that is printed on your order. Include a copy of your printed order when you mail your check.

3. *If paying with a wire transfer:* Wire transfers may also be used to pay annual establishment registration fees. To send a wire transfer, please read and comply with the following information:

Include your order's unique PIN (in the upper right-hand corner of your completed DFUF order) in your wire transfer. Without the PIN, your payment may not be applied to your facility and your registration may be delayed.

The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required that you add that amount to the payment to ensure that the invoice is paid in full. Use the following account information when sending a wire transfer: U.S. Dept. of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

C. Complete the Information Online To Update Your Establishment's Annual Registration for FY 2025, or To Register a New Establishment for FY 2025

Go to the Center for Devices and Radiological Health's website at *https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing* and click the ''Access Electronic Registration'' link on the left side of the page. This opens a new page with important information about the FDA Unified Registration and Listing System (FURLS). After reading this information, click on the ''Access Electronic Registration'' link in the middle of the page. This link takes you to an FDA Industry Systems page with tutorials that demonstrate how to create a new FURLS user account if your establishment did not create an account in FY 2024. Manufacturers of licensed biologics should register in the electronic Blood Establishment Registration (eBER) system at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-establishment-registration.*

Enter your existing account ID and password to log into FURLS. From the FURLS/FDA Industry Systems menu, click on the Device Registration and Listing Module (DRLM) of FURLS button. New establishments will need to register, and existing establishments will update their annual registration using choices on the DRLM menu. When you choose to register or update your annual registration, the system will prompt you through the entry of information about your establishment and your devices. If you have any problems with this process, email: *reglist@cdrh.fda.gov* or call 301–796–7400 for assistance. (*Note:* This email address and this telephone number are for assistance with establishment registration only; they are not to be used for questions related to other aspects of medical device user fees.) Problems with the eBER system should be directed to *https://www.accessdata.fda.gov/scripts/email/cber/bldregcontact.cfm* or call 240–402–8360.

D. Enter Your DFUF Order PIN and PCN

After completing your annual or initial registration and device listing, you will be prompted to enter your DFUF order PIN and PCN, when applicable. This process does not apply to establishments engaged only in the manufacture, preparation, propagation, compounding, or processing of licensed biologic devices. CBER will send invoices for payment of the establishment registration fee to such establishments.

IX. Small Business Fee Reductions and Fee Waivers

To qualify for reduced fees for small businesses or a small business fee waiver, please see the requirements for qualification provided in Section V. How To Qualify as a Small Business for Purposes of Medical Device Fees. The applicant should submit a Small Business Certification Request and the supporting materials showing you qualify as a small business at least 60 days before you send your submission to FDA. FDA will review your information and determine whether you qualify as a small business eligible for the reduced fee and/or fee waiver. If you make a submission before FDA finds that you qualify as a small business, you must pay the standard (full) fee for that submission.

If you need assistance, please contact the Division of Industry and Consumer Education at 800–638–2041 or 301–796–7100 or email at *DICE@fda.hhs.gov.*

A. Premarket Approval Fee Reduction or Waiver

A small business applicant may request to pay a reduced rate for

premarket approval fees. An applicant may also request a fee waiver for their first premarket application or premarket report (section 738(d) of the FD&C Act).

B. Premarket Notification Submission Fee Reduction

A small business applicant may request to pay a reduced rate for a premarket notification submission.

C. Annual Establishment Registration Fee Waiver

For FY 2025, there is no small business waiver for the annual establishment registration fee; all establishments pay the same fee.

X. Refunds

To qualify for consideration for a refund, a person shall submit to FDA a written request for a refund not later than 180 days after such fee is due. FDA has discretion to refund a fee or a portion of the fee. A determination by FDA concerning a refund shall not be reviewable. For more information on qualifying and submitting a refund, see section 738(a)(2)(D) of the FD&C Act.

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16883 Filed 7–30–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3423]

Biosimilar User Fee Rates for Fiscal Year 2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the rates for biosimilar user fees for fiscal year (FY) 2025. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Biosimilar User Fee Amendments of 2022 (BsUFA III), authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development; review of certain applications for approval of biosimilar biological products; and each biosimilar biological product approved in a biosimilar biological product application. BsUFA III directs FDA to establish, before the beginning of each fiscal year, the amount of initial and annual biosimilar biological product development (BPD) fees, the reactivation fee, and the biosimilar biological product application and program fees for such year. These fees apply to the period from October 1, 2024, through September 30, 2025.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–4989, and the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744G, 744H, and 744I of the FD&C Act (21 U.S.C. 379j–51, 379j–52, and 379j–53), as amended by BsUFA III, authorize the collection of fees for biosimilar biological products. Under section 744H(a)(1)(A) of the FD&C Act, the initial BPD fee for a product is due when the sponsor submits an investigational new drug (IND) application that FDA determines is intended to support a biosimilar biological product application or within 7 calendar days after FDA grants the first BPD meeting, whichever occurs first. A sponsor who has paid the initial BPD fee is considered to be participating in FDA's BPD program for that product.

Under section 744H(a)(1)(B) of the FD&C Act, once a sponsor has paid the initial BPD fee for a product, the annual BPD fee is assessed beginning with the next fiscal year. The annual BPD fee is assessed for the product each fiscal year until the sponsor submits a marketing application for the product that is accepted for filing, the sponsor discontinues participation in FDA's BPD program for the product, or the sponsor has been administratively removed from the BPD program for the product.

Under section 744H(a)(1)(D) of the FD&C Act, if a sponsor has discontinued participation in FDA's BPD program or has been administratively removed from the BPD program for a product and wants to reengage with FDA on development of the product, the sponsor must pay all annual BPD fees previously assessed for such product and still owed, and a reactivation fee to resume participation in the program. The sponsor must pay the reactivation fee by the earlier of the following dates: (1) no later than 7 calendar days after FDA grants the sponsor's request for a BPD meeting for that product or (2) upon the date of submission by the sponsor of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application for that product. The sponsor will be assessed an annual BPD fee beginning in the next fiscal year after payment of the reactivation fee.

BsUFA III also authorizes fees for certain biosimilar biological product applications and for each biosimilar biological product identified in an approved biosimilar biological product application (section 744H(a)(2) and (3) of the FD&C Act). Under certain conditions, FDA will grant a small business a waiver of the biosimilar biological product application fee (section 744H(d)(1) of the FD&C Act).

For FY 2023 through FY 2027, the base revenue amounts for the total revenues from all BsUFA fees are established by BsUFA III. For FY 2025, the base revenue amount is the FY 2024 total revenue amount excluding any operating reserve adjustment, which equates to the amount of $51,058,823. The FY 2025 base revenue amount is to be adjusted by the inflation adjustment, strategic hiring and retention adjustment, capacity planning adjustment (CPA), operating reserve adjustment, and the additional dollar amount. Each of these adjustments will be discussed in the sections below.

This document provides fee rates for FY 2025 for the initial and annual BPD fee ($10,000), for the reactivation fee ($20,000), for an application requiring clinical data ($1,471,118) for an application not requiring clinical data ($735,559) and for the program fee ($256,168). These fees are effective on October 1, 2024, and will remain in effect through September 30, 2025. For applications that are submitted on or after October 1, 2024, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2025

The base revenue amount for FY 2025 is $51,058,823 prior to adjustments for inflation, strategic hiring and retention, capacity planning, operating reserves, and the additional dollar amount (see section 744H(b) and (c) of the FD&C Act).

A. FY 2025 Statutory Fee Revenue Adjustments for Inflation

BsUFA III specifies that the $51,058,823 is to be adjusted for inflation increases for FY 2025 using two separate adjustments: one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 744H(c)(1) of the FD&C Act).

The component of the inflation adjustment for payroll costs shall be the average annual percent change in the cost of all PC&B paid per full-time

equivalent (FTE [1]) positions at FDA for the first 3 of the preceding 4 fiscal years, multiplied by the proportion of PC&B costs to total FDA costs of the process for the review of biosimilar biological product applications for the first 3 of the preceding 4 fiscal years (see section 744H(c)(1)(B) of the FD&C Act).

Table 1 summarizes the actual cost and FTE data for the specified fiscal years and provides the percent changes from the previous fiscal years and the average percent changes over the first 3 of the 4 fiscal years preceding FY 2025. The 3-year average is 3.8539 percent.

TABLE 1—FDA PC&B EACH YEAR AND PERCENT CHANGES

	FY 2021	FY 2022	FY 2023	3-Year average
Total PC&B	$3,039,513,000	$3,165,477,000	$3,436,513,000	3.8539%
Total FTE	18,501	18,474	18,729	
PC&B per FTE	$164,289	$171,348	$183,486	
Percent Change from Previous Year	0.1811%	4.2967%	7.0838%	

The statute specifies that this 3.8539 percent be multiplied by the proportion of PC&B costs to the total FDA costs of the process for the review of biosimilar biological product applications. Table 2 shows the PC&B and the total obligations for the process for the review of biosimilar biological product applications for the first 3 of the preceding 4 fiscal years.

TABLE 2—PC&B AS A PERCENT OF TOTAL COST OF THE PROCESS FOR THE REVIEW OF BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS

	2021	2022	2023	3-Year average
Total PC&B (proportion of costs)	$30,932,267	$34,065,826	$45,893,774	
Total Costs	$55,928,075	$68,521,689	$86,101,288	
PC&B percent	55.3072%	49.7154%	53.3021%	52.7749%

The payroll adjustment is 3.8539 percent from table 1 multiplied by 52.7749 percent (or 2.0339 percent).

The statute specifies that the portion of the inflation adjustment for nonpayroll costs is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Arlington-Alexandria, DC-VA-MD-WV; not seasonally adjusted; all items; annual index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than PC&B costs to total costs of the process for the review of biosimilar biological product applications for the first 3 years of the preceding 4 fiscal years (see section 744H(c)(1)(B) of the FD&C Act). Table 3 provides the summary data for the percent changes in the specified CPI for the Washington-Arlington-Alexandria area.[2]

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN CPI FOR WASHINGTON-ARLINGTON-ALEXANDRIA AREA

Fiscal year	2021	2022	2023	3-Year average
Annual CPI	277.728	296.117	305.317	
Annual Percent Change	3.9568%	6.6212%	3.1069%	4.5616%

The statute specifies that this 4.5616 percent be multiplied by the proportion of all costs other than PC&B to total costs of the process for the review of biosimilar biological product applications obligated. Since 52.7749 percent was obligated for PC&B (as shown in table 2), 47.2251 percent is the portion of costs other than PC&B (100 percent minus 52.7749 percent equals 47.2251 percent). The non-payroll adjustment is 4.5616 percent times 47.2251 percent, 2.1542 percent.

Next, we add the payroll adjustment (2.0339 percent) to the nonpayroll adjustment (2.1542 percent), for a total inflation adjustment of 4.1881 percent (rounded) for FY 2025.

We then multiply the base revenue amount for FY 2025 ($51,058,823) by the inflation adjustment percentage (4.1881 percent), yielding an inflation adjustment of $2,138,395. Adding this amount yields an inflation-adjusted amount of $53,197,218.

B. Strategic Hiring and Retention Adjustment

The statute specifies that for each fiscal year, after the annual base revenue is adjusted for inflation, FDA shall further increase the fee revenue and fees by the strategic hiring and retention adjustment, which is $150,000 for FY 2025 (see section 744H(c)(2) of the FD&C Act).

C. FY 2025 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that the fee revenue and fees shall be further adjusted to reflect changes in the resource capacity needs for the process for the review of biosimilar biological product applications (see section 744H(c)(3) of the FD&C Act). Following a process agreed upon by FDA and

[1] Full-time equivalents refer to a paid staff year, rather than a count of individual employees.

[2] The data are published by the Bureau of Labor Statistics and can be found on its website at: *https://data.bls.gov/pdq/SurveyOutputServlet?data_tool=dropmap&series_id=CUURS35ASA0,CUUSS35ASA0.*

industry during BsUFA II reauthorization discussions and subsequently required in statute, FDA established the capacity planning adjustment methodology and first applied it in the setting of FY 2021 fees. The establishment of this methodology is described in the **Federal Register** at 85 FR 47220. This methodology includes a continuous, iterative improvement approach, under which the Agency intends to refine its data and estimates for the core review activities to improve their accuracy over time.

Improvements adopted for the FY 2025 CPA include the incorporation of hiring plans and attrition estimates within the capacity calculation. In prior years, the impacts of expected hiring on the review capacity of the program were considered a step within the managerial adjustment process. The FY 2025 resource capacity number includes an estimate of the onboard capacity for direct review-related work, as well as an estimate of the additional capacity that would be provided from any additional positions expected to be added through the course of FY 2024. No additional deduction for positions planned to be added prior to the end of FY 2024 then needs to be deducted within the managerial adjustment moving forward. Because of this change, the resource capacity numbers presented in this **Federal Register** Notice cannot be directly compared to those provided in prior years' fee-setting notices.

The CPA methodology consists of four steps:

1. *Forecast workload volumes:* predictive models estimate the volume of workload for the upcoming fiscal year.

2. *Forecast the resource needs:* forecast algorithms are generated utilizing time reporting data. These algorithms estimate the required demand in FTEs for direct review-related effort. This is then compared to current available resources for the direct review-related workload.

The current available resources for the direct review-related workload (presented as current resource capacity below) is a measure of the percentage of time onboard staff report to direct review-related workload activities, plus a percentage of the additional positions that are targeted to be hired within the remainder of FY 2024. Of note, the current resource capacity is not directly a function of the change in submission volume from one year to the next, but rather a summation of the percent of total staff time plus vacancies estimated to be available for direct review work. As time reporting is a direct input into the current review capacity calculations, the current review capacity may be impacted by factors such as shifts in the level of effort required for review work, staff reporting time exceeding their tour of duty, or other shifts impacting the workload of the program.

3. A managerial adjustment to assess the resource forecast in the context of additional internal factors: program leadership examines operational, financial, and resourcing data to assess whether FDA will be able to utilize additional funds during the fiscal year and whether the funds are required to support additional review capacity. FTE amounts are adjusted, if needed. The managerial adjustment process includes consideration of prior years' forecast performance, future year considerations, hiring capacity considerations, and other relevant considerations.

4. Convert the FTE need to dollars: utilizing FDA's fully loaded FTE cost model, the final feasible FTEs are converted to an equivalent dollar amount. The fully loaded FTE cost model is higher in FY 2025 than in prior years primarily due to the impact of inflation.

The following section outlines the major components of the FY 2025 BsUFA III CPA. Table 4 summarizes the forecasted workload volumes for BsUFA III in FY 2025 based on predictive models, as well as historical actuals from FY 2023 for comparison.

TABLE 4—BSUFA III ACTUAL FY 2023 WORKLOAD VOLUMES & PREDICTED FY 2025 WORKLOAD VOLUMES

Workload category	FY 2023 actuals	FY 2025 predictions
Original Biosimilar Supplements [1]	40	48
Manufacturing Supplements	92	95
Biosimilar Biological Product Applications	19	17
BsUFA Industry Meetings (BIA, BPD Type 1–4)	130	150
Participating BPD Programs [2]	114	111
Annual Reports [3]	48	52
PMR/PMC-Related Documents [3]	23	31
Active REMS Programs [2 3]	0	1

[1] Includes Supplements with Clinical Data and Labeling Supplements.
[2] Represents activities related to the review of materials submitted to the application file after approval.
[3] Represents the number of Active REMS Programs proportional to Center and User Fee by total number of qualifying products with the exclusion of the Opioid Shared System.

Utilizing the resource forecast algorithms, the forecasted workload volumes for FY 2025 were then converted into estimated FTE needs for FDA's BsUFA III direct review-related work. The resulting expected FY 2025 FTE need for BsUFA III was compared to current onboard capacity for BsUFA III direct review-related work to determine the FY 2025 resource delta, as summarized in table 5.

TABLE 5—FY 2025 BSUFA III RESOURCE DELTA

Current resource capacity	FY 2025 resource forecast	Predicted FY 2025 FTE delta
84	96	12

The projected 12 FTE delta was then assessed by FDA in the context of additional operational and internal factors to ensure that a fee adjustment is only made for resources which can be utilized in the fiscal year and for which

funds are required to support additional review capacity. In prior years, FDA adjusted the BsUFA FTE delta to 0 FTEs as there were additional funds available to support the needed FTEs. Due to large downward operating reserve adjustments in prior years, additional funds are needed to sustain additional FTE positions. BsUFA has also experienced sustained growth in review workload over recent years which is expected to continue. As such, FDA is adjusting the FTE delta to 7 FTE to provide a modest adjustment to support the sustained increases in review workload.

TABLE 6—FY 2025 BSUFA III CPA

Additional FTEs for FY 2025	Cost for each additional FTE	FY 2024 BsUFA III CPA
7	$380,675	$2,664,725

D. FY 2025 Additional Dollar Amount

For FY 2023 and FY 2024, BsUFA III provided an additional dollar amount for additional FTE for the biosimilar biological product review program to support enhancements outlined in the BsUFA III Commitment Letter. For FY 2024, the statute directed FDA to further increase the fee revenue and fees by the additional dollar amount, which was $320,569 for FY 2024 (see section 744H(b)(1)(G) of the FD&C Act). For FY 2025 no additional amount is specified in statute.

TABLE 7—BASE REVENUE AMOUNT AND ADJUSTMENTS PRIOR TO OPERATIVE RESERVE ADJUSTMENT

Fee	Amount
Base Revenue Amount (Section 744H(b)–(c) of the FD&C Act)	$51,058,823
Inflation Adjustment (Section 744H(c)(1) of the FD&C Act)	2,138,395
Strategic Hiring and Retention Adjustment (Section 744H(c)(2) of the FD&C Act)	150,000
Capacity Planning Adjustment (Section 744H(c)(3) of the FD&C Act)	2,664,725
Additional Dollar Amount	.....
Cumulative Revenue Amount Prior to Operative Reserve Adjustment	56,011,943

E. FY 2025 Statutory Fee Revenue Adjustments for Operating Reserve

BsUFA III sets forth an operating reserve adjustment to the fee revenue and fees. Specifically, for FY 2025, the statute directs FDA: (1) to increase the fee revenue and fees if such an adjustment is necessary to provide for at least 10 weeks of operating reserves of carryover user fees for the process for the review of biosimilar biological product applications and (2) if FDA has carryover balances for such process in excess of 21 weeks of such operating reserves, to decrease such fee revenue and fees to provide for not more than 21 weeks of such operating reserves (see section 744H(c)(4) of the FD&C Act).

To calculate the 10-week and 21-week threshold amounts for the FY 2025 operating reserve adjustment, the estimated adjusted revenue amount (*i.e.,* the base revenue amount and adjustments prior to the operating reserve adjustment), $56,011,943 is divided by 52, resulting in a $1,077,153 cost of operation for 1 week (rounded to the nearest dollar). The 1-week value ($1,077,153) is then multiplied by 10 weeks to generate the 10-week operating reserve threshold amount for FY 2025 of $10,771,528. The 1-week value is multiplied by 21 to generate the 21-week operating reserve threshold amount for FY 2025 of $22,620,208.

To calculate the estimated operating reserve of carryover user fees at the end of FY 2024, FDA estimated the operating reserves of carryover fees at the end of June 2024. The balance of operating reserves of carryover fees at the end of June 2024 is combined with the forecasted collections and obligations for the remainder of FY 2024 to generate a full year estimate for FY 2024. The estimated operating reserve of carryover user fees at the end of FY 2024 is $14,245,046.

The estimated operating reserve of carryover user fees at the end of FY 2024 of $14,245,046 is below the 21-week threshold allowable operating reserve of carryover user fees for FY 2025 of $22,620,208 and above the 10-week minimum operating reserve carryover user fees for FY 2025 of $10,771,528. As such, FDA is not applying a downward or upward operating reserve adjustment at the start of FY 2025, summarized below.

TABLE 8—TOTAL ESTIMATED ADJUSTED REVENUE AMOUNT

Fee	Amount
Base Revenue Amount (Section 744H(b)–(c) of the FD&C Act)	$51,058,823
Inflation Adjustment (Section 744H(c)(1) of the FD&C Act)	2,138,395
Strategic Hiring and Retention Adjustment (Section 744H(c)(2) of the FD&C Act)	150,000
Capacity Planning Adjustment (Section 744H(c)(3) of the FD&C Act)	2,664,725
Additional Dollar Amount	.....
Operating Reserve Adjustment	.....
Total Revenue Amount in sections 744H(b)–(c), 744H(c)(1), (2), (3) of the FD&C Act	56,011,943
Total Revenue Amount in sections 744H(b)–(c), 744H(c)(1), (2), (3) of the FD&C Act (rounded to the nearest thousand dollars)	56,012,000

III. Fee Amounts for FY 2025

Under section 744H(b)(2)(A) of the FD&C Act, FDA must determine the percentage of the total revenue amount for a fiscal year to be derived from: (1) initial and annual BPD fees, and reactivation fees; (2) biosimilar biological product application fees; and (3) biosimilar biological product program fees. As described above, an operating reserve adjustment is not required for FY 2025.

A. Application Fees

In establishing the biosimilar biological product application fee amount for FY 2025, FDA assessed multiple modeling options. Considering available factors, FDA selected a model that forecasts 17 biosimilar biological product applications requiring clinical data submitted for approval in FY 2025 and zero applications that do not require clinical data. Given recent years' data regarding biosimilar biological product applications that are refused to file and withdrawals before filing, the 17 submissions will be assumed to equate to 16.25 full application equivalents.

For FY 2025 the biosimilar biological product application fee for applications requiring clinical data is $1,471,118. Applications not requiring clinical data pay half that fee, or $735,559. This is estimated to provide a total of $23,905,668 representing 43 percent (rounded to the nearest whole number) of the FY 2025 target revenue amount.

B. Biosimilar Biological Product Program Fee

Under BsUFA III, FDA assesses biosimilar biological product program fees (''program fees''). An applicant in a biosimilar biological product application shall not be assessed more than five program fees for a fiscal year for biosimilar biological products identified in a single biosimilar biological product application (see section 744H(a)(3)(D) of the FD&C Act). Applicants are assessed a program fee for a fiscal year for biosimilar biological products that are identified in a biosimilar biological product application approved as of October 1 of such fiscal year; that may be dispensed only under prescription pursuant to section 503(b) of the FD&C Act; and that, as of October 1 of such fiscal year, do not appear on a list developed and maintained by FDA of discontinued biosimilar biological products. An approved biosimilar biological product that appears on the list of discontinued biosimilar biological products as of October 1 of a fiscal year would also be assessed the program fee if it is removed from the discontinued list during the fiscal year and the other statutory criteria for fee assessment are satisfied (see section 744H(a)(3)(E)(iii) of the FD&C Act).

Based on available information, FDA estimates that 121 program fees will be invoiced for FY 2025. For products invoiced in the FY 2025 regular billing cycle, FDA anticipates that zero program fees will be refunded.

For FY 2025, the biosimilar biological product program fee is $256,168. This is estimated to provide a total of $30,996,328, representing 55 percent (rounded to the nearest whole number) of the FY 2025 target revenue amount.

C. Initial and Annual BPD Fees, and Reactivation Fees

To estimate the number of BPD fees to be paid in FY 2025, FDA must consider the number of new BPD programs, the number of current BPD programs, and the number of BPD programs that will be reactivated. These estimates provide information that, when aggregated, allows FDA to set BPD fees (initial BPD fees, annual BPD fees, reactivation fees).

FDA analyzed available data to estimate the total number of BPD programs for FY 2025. In FY 2025, FDA estimates approximately 23 new BPD programs, no reactivations (a single reactivation is weighted as two BPD fees), and approximately 88 BPD programs to pay the annual BPD fee, yielding a rounded total estimated equivalent of 111 BPD fees to be collected in FY 2025. The remainder of the target revenue of $1,110,000 or 2 percent is to be collected from the BPD fees. Dividing this amount by the estimated 111 BPD fees to be paid equals an initial BPD and annual BPD fee amount of $10,000 (rounded to the nearest dollar). The reactivation fee is set at twice the initial/annual BPD amount at $20,000 (rounded to the nearest dollar).

IV. Fee Schedule for FY 2025

The fee rates for FY 2025 are displayed in table 9.

TABLE 9—FEE SCHEDULE FOR FY 2025

Fee category	Fee rates for FY 2025
Initial BPD	$10,000
Annual BPD	10,000
Reactivation	20,000
Applications:	
Requiring Clinical Data	1,471,118
Not Requiring Clinical Data	735,559
Program Fee	256,168

V. Fee Payment Options and Procedures

A. Initial BPD, Reactivation, and Application Fees

The fees established in the new fee schedule apply to FY 2025, *i.e.,* the period from October 1, 2024, through September 30, 2025. The initial BPD fee for a product is due when the sponsor submits an IND that FDA determines is intended to support a biosimilar biological product application for the product or within 7 calendar days after FDA grants the first BPD meeting for the product, whichever occurs first. Sponsors who have discontinued participation in the BPD program for a product or have been administratively removed from the BPD program for a product, and seek to resume participation in the BPD program for the product must pay all annual BPD fees previously assessed for such product and still owed and the reactivation fee by the earlier of the following dates: no later than 7 calendar days after FDA grants the sponsor's request for a BPD meeting for that product, or upon the date of submission by the sponsor of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application for that product.

The application fee for a biosimilar biological product is due upon submission of the application (see section 744H(a)(2)(C) of the FD&C Act).

To make a payment of the initial BPD, reactivation, or application fee, complete the Biosimilar User Fee Cover Sheet, available on FDA's website (*https://www.fda.gov/bsufa*) and generate a user fee identification (ID) number. Payment must be made in U.S. currency by electronic check, check, bank draft, U.S. postal money order, or wire transfer. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). FDA has partnered with the U.S. Department of the Treasury to use *www.pay.gov,* a web-based payment application, for online electronic payment. The *www.pay.gov* feature is available on the FDA website after the user fee ID number is generated. Secure electronic payments can be submitted using the User Fees Payment Portal at

https://userfees.fda.gov/pay (*Note:* only full payments are accepted. No partial payments can be made online). Once you search for your invoice, click ''Pay Now'' to be redirected to *www.pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

If a check, bank draft, or postal money order is submitted, make it payable to the order of the Food and Drug Administration and include the user fee ID number to ensure that the payment is applied to the correct fee(s). Payments can be mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000. If a check, bank draft, or money order is to be sent by a courier that requests a street address, the courier should deliver your payment to U.S. Bank, Attention: Government Lockbox 979108, 3180 Rider Trail South, Earth City, MO 63045. (Note: this U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 800–495–4981 (this telephone number is only for questions about courier delivery). Please make sure that the FDA post office box number (P.O. Box 979108) and ID number is written on the check, bank draft, or postal money order.

For payments made by wire transfer, include the unique user fee ID number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID number, the payment may not be applied. The originating financial institution may charge a wire transfer fee. Include applicable wire transfer fees with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should be used to send payments by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No: 75060099, Routing No: 021030004, SWIFT: FRNYUS33. FDA's tax identification number is 53–0196965.

B. Annual BPD and Program Fees

FDA will issue invoices with payment instructions for FY 2025 annual BPD and program fees under the new fee schedule in August 2024. Under sections 744H(a)(1)(B)(ii) and 744H(a)(3)(B) of the FD&C Act, annual BPD and program fees will be due on October 1, 2024.

If sponsors join the BPD program after the annual BPD invoices have been issued in August 2024 FDA will issue invoices in December 2024 to sponsors subject to fees for FY 2025 that qualify for the annual BPD fee after the August 2024 billing. FDA will issue invoices in December 2025 for any products that qualify for the annual program fee after the August 2024 billing.

C. Waivers and Returns

To qualify for consideration for a small business waiver under section 744H(d) of the FD&C Act, or the return of any fee paid under section 744H of the FD&C Act, including if the fee is claimed to have been paid in error, a person shall submit to FDA a written request justifying such waiver or return and, except as otherwise specified in section 744H of the FD&C Act, such written request shall be submitted to FDA not later than 180 days after such fee is due. Such written request shall include any legal authorities under which the request is made. See section 744H(h) of the FD&C Act.

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3404]

Generic Drug User Fee Rates for Fiscal Year 2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Federal Food, Drug, and Cosmetic Act (FD&C Act or statute), as amended by the Generic Drug User Fee Amendments of 2022 (GDUFA III), authorizes the Food and Drug Administration (FDA, Agency, or we) to assess and collect fees for abbreviated new drug applications (ANDAs); drug master files (DMFs); generic drug active pharmaceutical ingredient (API) facilities, finished dosage form (FDF) facilities, and contract manufacturing organization (CMO) facilities; and generic drug applicant program user fees. In this document, FDA is announcing fiscal year (FY) 2025 rates for GDUFA III fees. These fees are effective on October 1, 2024, and will remain in effect through September 30, 2025.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave, Silver Spring, MD 20903, 240–402–4989; or the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744A and 744B of the FD&C Act (21 U.S.C. 379j–41 and 379j–42), as amended by GDUFA III, authorize FDA to assess and collect fees associated with human generic drug products. Fees are assessed on: (1) certain types of applications for human generic drug products; (2) certain facilities where APIs and FDFs are produced; (3) certain DMFs associated with human generic drug products; and (4) generic drug applicants who own one or more approved ANDAs (the program fee) (see section 744B(a)(2) through (5) of the FD&C Act). For more information about GDUFA III, please refer to the FDA website (*https://www.fda.gov/gdufa*).

For FY 2025, the generic drug user fee rates are ANDA ($321,920), DMF ($95,084), domestic API facility ($41,580), foreign API facility ($56,580), domestic FDF facility ($231,952), foreign FDF facility ($246,952), domestic CMO facility ($55,668), foreign CMO facility ($70,668), large size operation generic drug applicant program ($1,891,664), medium size operation generic drug applicant program ($756,666), and small business generic drug applicant program ($189,166). These fees are effective on October 1, 2024, and will remain in effect through September 30, 2025. The fee rates for FY 2025 are set out in table 1.

TABLE 1—FEE SCHEDULE FOR FY 2025

Generic drug fee category	Fees rates for FY 2025
Applications:	
Abbreviated New Drug Application (ANDA)	$321,920
Drug Master File (DMF)	95,084
Facilities:	
Active Pharmaceutical Ingredient (API)—Domestic	41,580
API—Foreign	56,580
Finished Dosage Form (FDF)—Domestic	231,952
FDF—Foreign	246,952
Contract Manufacturing Organization (CMO)—Domestic	55,668
CMO—Foreign	70,668
GDUFA Program:	
Large size operation generic drug applicant	1,891,664
Medium size operation generic drug applicant	756,666
Small business generic drug applicant	189,166

II. Fee Revenue Amount for FY 2025

Under section 744B(b)(1)(B)(ii) of the FD&C Act, the base revenue amount for FY 2025 for GDUFA III is $613,538,015. Under section 744B(c)(1) of the FD&C Act, applicable inflation adjustments to base revenue shall be made beginning with FY 2024.

Under section 744B(c)(2) of the FD&C Act, for FY 2025, FDA shall, in addition to the inflation adjustment, apply a capacity planning adjustment to further adjust, as needed, the fee revenue and fees to reflect changes in the resource capacity needs of FDA for human generic drug activities.

Under section 744B(c)(3) of the FD&C Act, for FY 2025, FDA may, in addition to the inflation and capacity planning adjustments, apply an operating reserve adjustment to further increase the fee revenue and fees if necessary to provide operating reserves of carryover user fees for human generic drug activities for not more than the number of weeks specified in such section (or as applicable, shall apply such adjustment to decrease the fee revenues and fees to provide for not more than 12 weeks of such operating reserves).

A. Inflation Adjustment

As noted above, the base revenue amount for FY 2025 is $613,538,015. This is the total revenue amount specified for the prior fiscal year, FY 2024, pursuant to the statute (see section 744B(b)(1)(A) of the FD&C Act).[1] GDUFA III specifies that the $613,538,015 is to be adjusted for inflation for FY 2025 using two separate adjustments: one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see sections 744B(c)(1)(B) and (C) of the FD&C Act).

The component of the inflation adjustment for PC&B costs shall be the average annual percent change in the cost of all PC&B paid per full-time equivalent (FTE) positions at FDA for the first 3 of the 4 preceding fiscal years, multiplied by the proportion of PC&B costs to total FDA costs of human generic drug activities for the first 3 of the preceding 4 fiscal years (see section 744B(c)(1)(B) of the FD&C Act).

Table 2 summarizes the actual cost and total FTEs for the specified fiscal years and provides the percent change from the previous fiscal year and the average percent change over the first 3 of the 4 fiscal years preceding FY 2025. The 3-year average is 3.8539 percent.

TABLE 2—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGE

Fiscal year	2021	2022	2023	3-Year average
Total PC&B	$3,039,513,000	$3,165,477,000	$3,436,513,000	.....
Total FTEs	18,501	18,474	18,729	.....
PC&B per FTE	$164,289	$171,348	$183,486	.....
Percent Change from Previous Year	0.1811%	4.2967%	7.0838%	3.8539%

The statute specifies that this 3.8539 percent should be multiplied by the proportion of PC&B expended for human generic drug activities for the first 3 of the preceding 4 fiscal years. Table 3 shows the amount of PC&B and the total amount obligated for human generic drug activities from FY 2021 through FY 2023.

TABLE 3—PC&B AS A PERCENT OF FEE REVENUES SPENT ON HUMAN GENERIC DRUG ACTIVITIES OVER THE LAST 3 YEARS

Fiscal year	2021	2022	2023	3-Year average
PC&B	$410,587,565	$391,922,747	$441,930,068	.....
Non-PC&B	$271,328,560	$289,479,265	$301,930,017	.....
Total Costs	$681,916,125	$681,402,012	$743,860,085	.....
PC&B Percent	60.2109%	57.5171%	59.4104%	59.0461%

[1] Under section 744B(b)(1)(B)(ii) of the FD&C Act, the base revenue amount for a fiscal year is equal to the total revenue amount established for the previous fiscal year, not including any adjustments for such previous fiscal year under section 744B(c)(3).

TABLE 3—PC&B AS A PERCENT OF FEE REVENUES SPENT ON HUMAN GENERIC DRUG ACTIVITIES OVER THE LAST 3 YEARS—Continued

Fiscal year	2021	2022	2023	3-Year average
Non-PC&B Percent	39.7891%	42.4829%	40.5896%	40.9539%

The payroll adjustment is 3.8539 percent multiplied by 59.0461 percent (or 2.2756 percent).

The statute specifies that the portion of the inflation adjustment for non-PC&B costs for FY 2025 is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Arlington-Alexandria Area, DC-VA-MD-WV; not seasonally adjusted; all items; annual index) for the first 3 of the preceding 4 years of available data multiplied by the proportion of all costs other than PC&B costs to total costs of human generic drug activities for the first 3 years of the preceding 4 fiscal years (see section 744B(c)(1)(C) of the FD&C Act). Table 4 provides the summary data for the percent change in the specified CPI. The data are published by the Bureau of Labor Statistics and can be found on its website at: *https://data.bls.gov/pdq/SurveyOutputServlet?data_tool=dropmap&series_id=CUURS35ASA0,CUUSS35ASA0.*

TABLE 4—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN CPI FOR WASHINGTON-ARLINGTON-ALEXANDRIA AREA

Year	2021	2022	2023	3-Year average
Annual CPI	277.73	296.12	305.32	.....
Annual Percent Change	3.9568%	6.6212%	3.1069%	4.5616%

To calculate the inflation adjustment for non-pay costs, we multiply the 3-year average percent change in the CPI (4.5616 percent) by the proportion of all costs other than PC&B to total costs of human generic drug activities obligated. Because 59.0461 percent was obligated for PC&B as shown in table 3, 40.9539 percent is the portion of costs other than PC&B. The non-pay adjustment is 4.5616 percent times 40.9539 percent, or 1.8682 percent.

To complete the inflation adjustment for FY 2025, we add the PC&B component (2.2756 percent) to the non-PC&B component (1.8682 percent) for a total inflation adjustment of 4.1438 percent (rounded), and then add 1, making an inflation adjustment multiple of 1.041438. We then multiply the base revenue amount for FY 2025 ($613,538,015) by 1.041438, yielding an inflation-adjusted amount of $638,961,803.

B. FY 2025 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that after the base revenue amount for FY 2025 of $613,538,015 has been adjusted for inflation as described in section A above, the resulting amount shall be further adjusted to reflect changes in the resource capacity needs for human generic drug activities (see section 744B(c)(2) of the FD&C Act). Following a process required in the statute, FDA established the capacity planning adjustment (CPA) methodology that is derived from the methodology and recommendations made in the report titled ''Independent Evaluation of the GDUFA Resource Capacity Planning Adjustment Methodology: Evaluation and Recommendations'' as announced in the **Federal Register** of August 3, 2020, and incorporating approaches and attributes determined appropriate by the Agency, except that the workload drivers are limited to those specified in the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023–2027 (GDUFA III Commitment Letter).[2] This methodology includes a continuous, iterative improvement approach, under which the Agency intends to refine its data and estimates for the core review activities to improve the accuracy of its data and estimates over time.[3] Improvements adopted for the FY2025 CPA include the incorporation of hiring plans and attrition estimates within the capacity calculation. In calculation of GDUFA fees for the prior fiscal year (FY 2024), the impacts of expected hiring on the review capacity of the program were considered within the managerial adjustment process (described below).

The CPA methodology consists of four steps:

1. *Forecast workload volumes:* Predictive models estimate the volume of workload for the upcoming FY.

2. *Forecast the resource needs:* Forecast algorithms are generated utilizing time reporting data. These algorithms estimate the required demand in FTEs[4] for direct review-related effort. This is then compared to current available resources for the direct review-related workload. The current available resources for the direct review related workload are a measure of the percentage of time onboard staff report to direct review workload activities, plus a percentage of the additional positions that are targeted to be hired within the remainder of FY 2024.

3. *A managerial adjustment to assess the resource forecast in the context of additional internal factors:* Program leadership examines operational, financial, and resourcing data to assess whether FDA will be able to utilize additional funds during the fiscal year, and whether the additional funds are required to support additional review capacity. FTE amounts are adjusted, if needed.

4. *Convert the FTE need to dollars:* Utilizing FDA's fully loaded FTE cost model, the final feasible FTEs are converted to an equivalent dollar amount.

Table 5 summarizes the forecasted workload volumes for the Center for Drug Evaluation and Research (CDER)

[2] Section 744B(c)(2)(B) of the FD&C Act; see also section VIII.B.2.e. of the GDUFA III Commitment Letter available at *https://www.fda.gov/media/153631/download.*

[3] For example, FDA will aim to refine the CPA methodology to reflect a more comprehensive assessment of the applicable workload drivers across the Agency.

[4] Full-time equivalents refer to a paid staff year, rather than a count of individual employees.

for FY 2025 based on predictive models, as well as historical actuals from FY 2023 for comparison.

TABLE 5—CDER ACTUAL FY 2023 WORKLOAD VOLUMES AND PREDICTED FY 2025 WORKLOAD VOLUMES

Workload driver category	FY 2023 actuals	FY 2025 predictions
ANDA Originals [1]	685	651
ANDA Supplements [2]	10,237	12,045
Pre-ANDA Meetings	114	106
Controlled Correspondences [3]	3,580	3,156
Suitability Petitions	14	32
ANDA Annual Reports [4]	12,162	13,230
Active REMS Programs [4 5]	49	49

[1] Excludes response to refused to receive (RTR) and Orig-2+. ANDA Original and Resubmissions/Amendments captured in time reporting data.
[2] Includes changes being effected (CBE) and prior approval supplement (PAS) Manufacturing and Labeling Supplements. PAS exclude response to RTRs, risk evaluation and mitigation strategies (REMS) and Bioequivalence Supplements. ANDA Supplement and Resubmissions/Amendments captured in time reporting data.
[3] Includes all requesting controlled correspondences.
[4] Data represents workload related to resource needs for post-marketing safety activities (developed in alignment with the methodology used in fee-setting under PDUFA (section 736 of the FD&C Act) (21 U.S.C. 379h) and BsUFA (section 744H of the FD&C Act) (21 U.S.C. 379j–52)), as applicable.
[5] Represents the percentage of Active REMS Programs proportional to Center and User Fee by total number of qualifying products with the exclusion of the Opioid Shared System.

Utilizing the resource forecast algorithms, the forecasted workload volumes for FY 2025 were then converted into estimated FTE needs for FDA's GDUFA direct review-related work. The resulting expected FY 2025 FTE need for GDUFA was compared to current onboard capacity for GDUFA direct review-related work. Based on this comparison, FDA determined that the GDUFA program had sufficient resources to perform expected workload. Therefore, no CPA is applicable for FY 2025 fee setting.

TABLE 6—BASE REVENUE AMOUNT AND SECTION 744B(c)(1) AND (2) ADJUSTMENT AMOUNTS

Fee	Amount
Statutory Fee Revenue Base Amount (section 744B(b)(1) of the FD&C Act)	$613,538,015
Inflation Adjustment (section 744B(c)(1) of the FD&C Act)	25,423,788
Capacity Planning Adjustment (section 744B(c)(2) of the FD&C Act)	0
Revenue Amount after Adjustments in sections 744B(b)(1), 744B(c)(1), and 744B(c)(2) of the FD&C Act	638,961,803

C. FY 2025 Statutory Fee Revenue Adjustments for Operating Reserve

Under section 744B(c)(3) of the FD&C Act, for FY 2025, FDA may, in addition to the inflation and capacity planning adjustments, apply an operating reserve adjustment to further increase the fee revenue and fees if necessary to provide operating reserves of carryover user fees for human generic drug activities for not more than the number of weeks specified in such section (or as applicable, shall apply such adjustment to decrease the fee revenues and fees to provide for not more than 12 weeks of such operating reserves).

The upward operating reserve adjustment is discretionary. For FY 2025, FDA may take an adjustment to provide for not more than 9 weeks of operating reserve. If carryover is more than 12 weeks of operating reserve, FDA must decrease the fee revenues and fees to provide for not more than 12 weeks of operating reserve. To calculate the 9-week and 12-week threshold amounts for the FY 2025 operating reserve adjustment, the FY 2025 adjusted revenue amount, $638,961,803 is divided by 52, resulting in a $12,287,727 cost of operation for 1 week. The 1-week value is then multiplied by 9 weeks to generate the 9-week operating reserve threshold amount for FY 2025 of $110,589,543. The 1-week value is multiplied by 12 to generate the 12-week operating reserve threshold amount for FY 2025 of $147,452,724.

To determine the FY 2024 end-of-year operating reserves of carryover user fees, the Agency assessed the operating reserve of carryover fees at the end of June 2024 and forecast collections and obligations in the fourth quarter of FY 2024 combined. This provides an estimated end-of-year FY 2024 operating reserve of carryover user fees of $110,920,103 which equates to 9.03 weeks of operations. As the estimated end-of-year FY 2024 operating reserve is within the thresholds, there will not be an operating reserve adjustment.

Table 7 below summarizes FY 2025 fee revenue.

TABLE 7—TOTAL ESTIMATED ADJUSTED REVENUE AMOUNT

Fee	Amount
Statutory Fee Revenue Base Amount (section 744B(b)(1) of the FD&C Act)	$613,538,015
Inflation Adjustment (section 744B(c)(1) of the FD&C Act)	25,423,788
Capacity Planning Adjustment (section 744B(c)(2) of the FD&C Act)	0
Operating Reserve Adjustment (section (744B(c)(3) of the FD&C Act)	0
Total Revenue Amount (sections 744B(b)(1), 744B(c)(1), 744B(c)(2) and 744B(c)(3) of the FD&C Act)	638,961,803

TABLE 7—TOTAL ESTIMATED ADJUSTED REVENUE AMOUNT—Continued

Fee	Amount
Total Revenue Amount (rounded to the nearest thousand dollars) (sections 744B(b)(1), 744B(c)(1), 744B(c)(2) and 744B(c)(3) of the FD&C Act) (rounded to the nearest thousand)	638,962,000

III. ANDA Filing Fee

Under GDUFA III, the FY 2025 ANDA filing fee is owed by each applicant that submits an ANDA on or after October 1, 2024.[5] This fee is due on the submission date of the ANDA. Section 744B(b)(2)(B) of the FD&C Act specifies that the ANDA fee will make up 33 percent of the $638,962,000, which is $210,857,460.

To calculate the ANDA fee, FDA estimated the number of full application equivalents (FAEs) that will be submitted in FY 2025. The submissions are broken down into three categories: new originals (submissions that have not been received by FDA previously), submissions that FDA RTR for reasons other than failure to pay fees, and applications that are resubmitted after an RTR decision for reasons other than failure to pay fees. An ANDA counts as one FAE; however, 75 percent of the fee paid for an ANDA that has been RTR shall be refunded according to GDUFA III if: (1) the ANDA is refused for a cause other than failure to pay fees or (2) the ANDA has been withdrawn prior to receipt (section 744B(a)(3)(D)(i) of the FD&C Act). Therefore, an ANDA that is considered not to have been received by FDA due to reasons other than failure to pay fees or withdrawn prior to receipt counts as one-fourth of an FAE. After an ANDA has been RTR, the applicant has the option of resubmitting. For user fee purposes, these resubmissions are equivalent to new original submissions: ANDA resubmissions are charged the full amount for an application (one FAE).

As shown in table 5, FDA estimates that 651 new original ANDAs will be submitted and incur filing fees in FY 2025. Not all the new original ANDAs will be received by FDA and some of those not received will be resubmitted in the same fiscal year. Therefore, FDA expects that the FAE count for ANDAs will be 655 for FY 2025.

The FY 2025 ANDA filing fee is estimated by dividing the number of FAEs that will incur the fee in FY 2025 (655) into the fee revenue amount to be derived from ANDA filing fees in FY 2025 ($210,857,460). The result, rounded to the nearest dollar, is a fee of $321,920 per ANDA.

[5] Section 744B(a)(3) of the FD&C Act.

The statute provides that those ANDAs that include information about the production of APIs other than by reference to a DMF will pay an additional fee that is based on the number of such APIs and the number of facilities proposed to produce those ingredients (see section 744B(a)(3)(F) of the FD&C Act). FDA anticipates that this additional fee is unlikely to be assessed often; therefore, FDA has not included projections concerning the amount of this fee in calculating the fees for ANDAs.

IV. DMF Fee

Under GDUFA III, the DMF fee is owed by each person that owns a type II API DMF that is referenced, on or after October 1, 2012, in a generic drug submission by an initial letter of authorization.[6] This is a one-time fee for each DMF. This fee is due on the earlier of the date on which the first generic drug submission is submitted that references the associated DMF or the date on which the DMF holder requests the initial completeness assessment. Under section 744B(a)(2)(D)(iii) of the FD&C Act, if a DMF has successfully undergone an initial completeness assessment and the fee is paid, the DMF will be placed on a publicly available list documenting DMFs available for reference.

To calculate the DMF fee, FDA assessed the volume of DMF submissions over time. FDA assessed DMFs from October 1, 2022, to April 30, 2024, and concluded that averaging the number of fee-paying DMFs provided the most accurate model for predicting fee-paying DMFs for FY 2025. The monthly average of paid DMF submissions FDA received during FY 2023 and FY 2024 is 28. To determine the FY 2025 projected number of fee-paying DMFs, the average of 28 DMF submissions is multiplied by 12 months, which results in 336 estimated FY 2025 fee-paying DMFs. FDA is estimating 336 fee-paying DMFs for FY 2025.

The FY 2025 DMF fee is determined by dividing the DMF target revenue by the estimated number of fee-paying DMFs in FY 2025. Section 744B(b)(2)(A) of the FD&C Act specifies that the DMF fees will make up 5 percent of the $638,962,000, which is $31,948,100. Dividing the DMF revenue amount ($31,948,100) by the estimated fee-paying DMFs (336), and rounding to the nearest dollar, yields a DMF fee of $95,084 for FY 2025.

[6] Section 744B(a)(2) of the FD&C Act.

V. Foreign Facility Fee Differential

Under GDUFA III, the fee for a facility located outside the United States and its territories and possessions shall be $15,000 higher than the amount of the fee for a facility located in the United States and its territories and possessions.[7] The basis for this differential is the extra cost incurred by conducting an inspection outside the United States and its territories and possessions.

VI. FDF and CMO Facility Fees

Under GDUFA III, the annual FDF facility fee is owed by each person who owns an FDF facility that is identified in at least one approved generic drug submission owned by that person or its affiliates.[8] The CMO facility fee is owed by each person who owns an FDF facility that is identified in at least one approved ANDA but is not identified in an approved ANDA held by the owner of that facility or its affiliates.[9] Section 744B(b)(2)(C) of the FD&C Act specifies that the FDF and CMO facility fee revenue will make up 20 percent of the $638,962,000, which is $127,792,400.

To calculate the fees, data from FDA's Integrity Services (IS) were utilized as the primary source of facility information for determining the denominators of each facility fee type. IS is the master data steward for all facility information provided in generic drug submissions received by FDA. A facility's reference status in an approved generic drug submission is extracted directly from submission data rather than relying on data from self-identification. This information provided the number of facilities referenced as FDF manufacturers in at least one approved generic drug submission. These findings were compared against facility statuses from FDA's Office Regulatory Affairs (ORA) to exclude facilities that are no longer operational.

[7] Section 744B(b)(2)(C) and (D) of the FD&C Act.

[8] Section 744B(a)(4)(A) of the FD&C Act.

[9] Section 744A(5) and 744B(b)(2)(C) of the FD&C Act.

Based on these data, the FDF and CMO facility denominators are 160 FDF domestic, 311 FDF foreign, 83 CMO domestic, and 131 CMO foreign facilities for FY 2025.

GDUFA III specifies that the CMO facility fee is to be equal to 24 percent of the FDF facility fee.[10] Therefore, to generate the target collection revenue amount from FDF and CMO facility fees ($127,792,400), FDA must weight a CMO facility as 24 percent of an FDF facility. FDA set fees based on the estimate of 160 FDF domestic, 311 FDF foreign, 19.92 CMO domestic (83 multiplied by 24 percent), and 31.44 CMO foreign facilities (131 multiplied by 24 percent), which equals 522.36 total weighted FDF and CMO facilities for FY 2025.

To calculate the fee for domestic facilities, FDA first determines the total fee revenue that will result from the foreign facility differential by subtracting the fee revenue resulting from the foreign facility fee differential from the target collection revenue amount ($127,792,400) as follows: the foreign facility fee differential revenue equals the foreign facility fee differential ($15,000) multiplied by the number of FDF foreign facilities (311) plus the foreign facility fee differential ($15,000) multiplied by the number of CMO foreign facilities (131), totaling $6,630,000. This results in foreign fee differential revenue of $6,630,000 from the total FDF and CMO facility fee target collection revenue.

Subtracting the foreign facility differential fee revenue ($6,630,000) from the total FDF and CMO facility target collection revenue ($127,792,400) results in a remaining facility fee revenue balance of $121,162,400. To determine the domestic FDF facility fee, FDA divides the $121,162,400 by the total weighted number of FDF and CMO facilities (522.36), which results in a domestic FDF facility fee of $231,952. The foreign FDF facility fee is $15,000 more than the domestic FDF facility fee, or $246,952.

According to GDUFA III, the domestic CMO fee is calculated as 24 percent of the amount of the domestic FDF facility fee.[11] Therefore, the domestic CMO fee is $55,668, rounded to the nearest dollar. The foreign CMO fee is calculated as the domestic CMO fee plus the foreign fee differential of $15,000. Therefore, the foreign CMO fee is $70,668.

[10] Section 744B(b)(2)(C) of the FD&C Act.

[11] Section 744B(b)(2)(C) of the FD&C Act.

VII. API Facility Fee

Under GDUFA III, the annual API facility fee is owed by each person who owns a facility that is identified in at least one approved generic drug submission in which the facility is approved to produce one or more API or in a Type II API DMF referenced in at least one approved generic drug submission.[12] Section 744B(b)(2)(D) of the FD&C Act specifies the API facility fee will make up 6 percent of $638,962,000 in fee revenue, which is $38,337,720.

To calculate the API facility fee, data from FDA's IS were utilized as the primary source of facility information for determining the denominator. As stated above, IS is the master data steward for all facility information provided in generic drug submissions received by FDA. A facility's reference status in an approved generic drug submission is extracted directly from submission data rather than relying on data from self-identification. This information provided the number of facilities referenced as API manufacturers in at least one approved generic drug submission. These findings were compared against facility statuses from FDA's ORA to exclude facilities that are no longer operational.

Based on these data, the total number of API facilities identified was 698; of that number, 77 were domestic and 621 were foreign facilities. The foreign facility differential is $15,000. To calculate the fee for domestic facilities, FDA must first subtract the fee revenue that will result from the foreign facility fee differential. FDA takes the foreign facility differential ($15,000) and multiplies it by the number of foreign facilities (621) to determine the total fee revenue that will result from the foreign facility differential. As a result of this calculation, the foreign fee differential revenue will make up $9,315,000 of the total API fee revenue. Subtracting the foreign facility differential fee revenue ($9,315,000) from the total API facility target revenue ($38,337,720) results in a remaining balance of $29,022,720. To determine the domestic API facility fee, we divide the $29,022,720 by the total number of facilities (698), which gives us a domestic API facility fee of $41,580. The foreign API facility fee is $15,000 more than the domestic API facility fee, or $56,580.

VIII. Generic Drug Applicant Program Fee

Under GDUFA III, if a person and its affiliates own at least one but not more than five approved ANDAs on October 1, 2024, the person and its affiliates shall owe a small business generic drug applicant program fee.[13] If a person and its affiliates own at least 6 but not more than 19 approved ANDAs, the person and its affiliates shall owe a medium size operation generic drug applicant program fee.[14] If a person and its affiliates own at least 20 approved ANDAs, the person and its affiliates shall owe a large size operation generic drug applicant program fee.[15] Section 744B(b)(2)(E) of the FD&C Act specifies the GDUFA program fee will make up 36 percent of $638,962,000 in fee revenue, which is $230,026,320.

To determine the appropriate number of parent companies for each tier, FDA asked companies to claim their ANDAs and affiliates in the CDER NextGen Portal. The companies were able to confirm relationships currently present in FDA's records, while also reporting newly approved ANDAs, newly acquired ANDAs, and new affiliations.

In determining the appropriate number of approved ANDAs, FDA has factored in a number of variables that could affect the collection of the target revenue: (1) withdrawals of approved ANDAs by April 1: applicants who have submitted a written request for withdrawal of approval by April 1 of the previous fiscal year;[16] (2) inactive ANDAs: applicants who have not submitted an annual report for one or more of their approved applications within the past 2 years; (3) CBER-approved ANDAs: applicants and their affiliates with CBER-approved ANDAs are added to CDER's population of approved ANDAs; (4) Program Fee Arrears List: parent companies that are on the arrears list for any fiscal year; (5) Out of Business companies: parent companies that are no longer in operation; and (6) Tier Adjustment: the frequency of large-tier, medium-tier, and small-tier companies moving to different tiers (or as applicable, dropping out of any tier) after the completion of the program fee methodology and tier determination.

The list of original approved ANDAs from the Generic Drug Review Platform as of April 30, 2024, in addition to CBER's database, shows 241 applicants in the small business tier, 74 applicants in the medium size tier, and 81 applicants in the large size tier. Factoring in all the variables, we estimate there will be 194 applicants in

[12] Section 744B(a)(4)(A)(ii) of the FD&C Act.

[13] Sections 744B(a)(5)(A) and 744B(b)(2)(E)(i) of the FD&C Act.

[14] Id.

[15] Id.

[16] See section 744B(b)(2)(E)(ii) of the FD&C Act.

the small business tier, 68 applicants in the medium size tier, and 75 applicants in the large size tier for FY 2025.

To calculate the GDUFA program fee, GDUFA III provides that large size operation generic drug applicants pay the full fee, medium size operation applicants pay two-fifths of the full fee, and small business applicants pay one-tenth of the full fee.[17] To generate the target collection revenue amount from GDUFA program fees ($230,026,320), we must weigh medium and small tiered applicants as a subset of a large size operation generic drug applicant. FDA will set fees based on the weighted estimate of 19.40 applicants in the small business tier (194 multiplied by 10 percent), 27.2 applicants in the medium size tier (68 multiplied by 40 percent), and 75 applicants in the large size tier, arriving at 121.60 total weighted applicants for FY 2025.

To generate the large size operation GDUFA program fee, FDA divides the target revenue amount of $230,026,320 by 121.60, which equals $1,891,664. The medium size operation GDUFA program fee is 40 percent of the full fee ($756,666), and the small business GDUFA program fee is 10 percent of the full fee ($189,166).

IX. Fee Schedule for FY 2025

The fee rates for FY 2025 are set out in table 8.

TABLE 8—FEE SCHEDULE FOR FY 2025

Generic drug fee category	Fees rates for FY 2025
Applications:	
Abbreviated New Drug Application (ANDA)	$321,920
Drug Master File (DMF)	95,084
Facilities:	
Active Pharmaceutical Ingredient (API)—Domestic	41,580
API—Foreign	56,580
Finished Dosage Form (FDF)—Domestic	231,952
FDF—Foreign	246,952
Contract Manufacturing Organization (CMO)—Domestic	55,668
CMO—Foreign	70,668
GDUFA Program:	
Large size operation generic drug applicant	1,891,664
Medium size operation generic drug applicant	756,666
Small business generic drug applicant	189,166

X. Fee Payment Options and Procedures

The new fee rates are effective on October 1, 2024, and will remain in effect through September 30, 2025. Under sections 744B(a)(4) and (5) of the FD&C Act, respectively, facility and program fees are generally due on the later of the first business day on or after October 1 of each fiscal year or the first business day after the enactment of an appropriations act providing for the collection and obligation of GDUFA fees for the fiscal year.

To pay the ANDA, DMF, API facility, FDF facility, CMO facility, and GDUFA program fees, complete the Generic Drug User Fee Cover Sheet, available at *https://www.fda.gov/gdufa* and *https://userfees.fda.gov/OA_HTML/gdufaCAcdLogin.jsp,* and generate a user fee identification (ID) number. Payment must be made in U.S. currency drawn on a U.S. bank by electronic check, check, bank draft, U.S. postal money order, credit card, or wire transfer. The preferred payment method is online using electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). FDA has partnered with the U.S. Department of the Treasury to utilize *Pay.gov*, a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website after completing the Generic Drug User Fee Cover Sheet and generating the user fee ID number.

Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay.* (*Note:* Only full payments are accepted; no partial payments can be made online.) Once an invoice is located, ''Pay Now'' should be selected to be redirected to *Pay.gov.* Electronic payment options are based on the balance due. Payment by credit card is available for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

If a check, bank draft, or postal money order is submitted, make it payable to the order of the Food and Drug Administration and include the user fee ID number to ensure that the payment is applied to the correct fee(s). Payments can be mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000. If checks are to be sent by a courier that requests a street address, the courier can deliver checks to U.S. Bank, Attention: Government Lockbox 979108, 3180 Rider Trail S, Earth City, MO 63045. (*Note:* This U.S. Bank address is for courier delivery only). For questions concerning courier delivery, U.S. Bank can be contacted at 800–495–4981. This telephone number is only for questions about courier delivery.) The FDA post office box number (P.O. Box 979108) must be written on the check, bank draft, or postal money order.

For payments made by wire transfer, include the unique user fee ID number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID number, the payment may not be applied. If the payment amount is not applied, the invoice amount will be referred to collections. The originating financial institution may charge a wire transfer fee. Include applicable wire transfer fees with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should be used to send payments by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, account number: 75060099, routing number: 021030004, SWIFT:

[17] Section 744B(b)(2)(E)(i) of the FD&C Act.

FRNYUS33. FDA's tax identification number is 53–0196965.

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16896 Filed 7–30–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2865]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for Quantitative Testing for the Development of Food and Drug Administration Communications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on generic clearance for quantitative testing for the development of FDA communications, which collects individual generic quantitative information (*e.g.,* surveys, experimental studies) to test communications or educational messages on FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed while they are being developed or are in review.

DATES: Either electronic or written comments on the collection of information must be submitted by September 30, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 30, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–2865 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for Quantitative Testing for the Development of Food and Drug Administration Communications.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an

existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Generic Clearance for Quantitative Testing for the Development of FDA Communications

OMB Control Number 0910–0865—Extension

This notice requests extension of OMB approval of the FDA information collection for a generic clearance that allows FDA to use quantitative social/behavioral science data collection techniques (*i.e.,* surveys and experimental studies) to test consumers' reactions to FDA communications or educational messaging about FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed. To ensure that communications activities and educational campaigns have the highest potential to be received, understood, and accepted by those for whom they are intended, it is important to assess communications while they are under development. Understanding consumers' attitudes, motivations, and behaviors in response to potential communications and education messaging plays an important role in improving FDA's communications.

If the following conditions are not met, FDA will submit an information collection request to OMB for approval through the normal PRA process:

- The collections are voluntary;
- The collections are low burden for participants (based on considerations of total burden hours, total number of participants, or burden hours per participant) and are low cost for both the participants and the Federal Government;
- The collections are noncontroversial;
- Personally-identifiable information (PII) is collected only to the extent necessary [1] and is not retained;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions; [2] and
- The collections will not be designed or expected to yield statistical data or used as though the results are generalizable to the population of study.

To obtain approval for an individual generic collection submission that meets the conditions of this generic clearance, an abbreviated supporting statement will be submitted to OMB along with supporting documentation (*e.g.,* a copy of the survey or experimental design and stimuli for testing).

FDA will submit individual quantitative collections under this generic clearance to OMB. Individual quantitative collections will also undergo review by FDA's Human Subject Protection Program, senior leadership in the Center for Food Safety and Applied Nutrition, and PRA specialists.

Respondents to this collection of information may include a wide range of consumers and other FDA stakeholders such as producers and manufacturers who are regulated under FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cognitive Interviews Screener	720	1	720	0.083 (5 minutes)	60
Cognitive Interviews	144	1	144	1	144
Pre-test study screener	2,400	1	2,400	0.083 (5 minutes)	199
Pre-testing study	480	1	480	0.25 (15 minutes)	120
Self-administered surveys/experimental Studies Screener.	75,000	1	75,000	0.083 (5 minutes)	6,225
Self-Administered Surveys/Experimental Studies.	15,000	1	15,000	0.25 (15 minutes)	3,750
Total					10,498

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. Current estimates are based on both historical numbers of participants from past projects as well as estimates for projects to be conducted in the next 3 years. The number of participants to be included in each new survey will vary, depending on the nature of the compliance efforts and the target audience.

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16830 Filed 7–30–24; 8:45 am]

BILLING CODE 4164–01–P

[1] For example, collections that collect PII to provide remuneration for participants of focus groups and cognitive laboratory studies will be submitted under this request. All Privacy Act requirements will be met.

[2] As defined in OMB and Agency Information Quality Guidelines, ''influential'' means that ''an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions.''

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3001]

Over-the-Counter Monograph Drug User Fee Program—OTC Monograph Order Request Fee Rates for Fiscal Year 2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the over-the-counter (OTC) monograph order request (OMOR) fee rates under the OTC monograph drug user fee program (OMUFA) for fiscal year (FY) 2025. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to assess and collect user fees from qualifying manufacturers of OTC monograph drugs and submitters of OMORs. This notice publishes the OMOR fee rates under OMUFA for FY 2025. FDA plans to publish the FY 2025 OMUFA facility fee rates, *i.e.,* monograph drug facility (MDF) and contract manufacturing organization (CMO) facility fee rates, in a subsequent **Federal Register** notice (and anticipates its issuance will generally align with the timing of OMUFA facility fee rate publication for prior fiscal years).

DATES: These OTC OMORs fees are effective on October 1, 2024, and will remain in effect through September 30, 2025.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 240–402–4989; or the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 744M of the FD&C Act (21 U.S.C. 379j–72), authorizes FDA to assess and collect: (1) facility fees from qualifying owners of OTC monograph drug facilities and (2) fees from submitters of qualifying OTC monograph order requests. These fees are to support FDA's OTC monograph drug activities, which are detailed in section 744L(6) of the FD&C Act (21 U.S.C. 379j–71(6)) and include various FDA activities associated with OTC monograph drugs.[1]

For OMUFA purposes, an OTC OMOR is a request for an administrative order, with respect to an OTC monograph drug, which is submitted under section 505G(b)(5) of the FD&C Act (see section 744L(7) of the FD&C Act).

Under section 744M(a)(2)(A) of the FD&C Act, the Agency is authorized to assess and collect fees from submitters of OMORs, except for OMORs that request certain safety-related changes (as discussed below). There are two levels of OMOR fees, based on whether the OMOR at issue is a Tier 1 or Tier 2 OMOR.[2]

For FY 2025, the OMUFA fee rates for OTC OMORs are: Tier 1 OMOR fees ($559,777), Tier 2 OMOR fees ($111,955). These fees are effective for the period from October 1, 2024, through September 30, 2025. This document is issued pursuant to section 744M(a)(2) and (c)(4)(B) of the FD&C Act and describes the calculations used to set the OMUFA OMOR fees for FY 2025 in accordance with the directives in the statute.

II. Determination of FY 2025 OMOR Fees

Under OMUFA, the FY 2025 Tier 1 OMOR fee is $559,777 and the Tier 2 OMOR fee is $111,955, including an adjustment for inflation (see sections 744M(a)(2)(A)(i) and (ii) of the FD&C Act, respectively). OMOR fees are not included in the OMUFA target revenue calculation, which is based on the facility fees (see section 744M(b) of the FD&C Act).

An OMOR fee is generally assessed to each person who submits an OMOR (see section 744M(a)(2)(A) of the FD&C Act). OMOR fees are due on the date of the submission of the OMOR (see section 744M(a)(2)(B) of the FD&C Act). The payor should submit the OMOR fee that applies to the type of OMOR they are submitting (*i.e.,* Tier 1 or Tier 2). FDA will determine whether the appropriate OMOR fee has been submitted following receipt of the OMOR and the fee.

An OMOR fee will not be assessed if the OMOR seeks to make certain safety changes with respect to an OTC monograph drug. Specifically, no fee will be assessed if FDA finds that the OMOR seeks to change the drug facts labeling of an OTC monograph drug in a way that would add to or strengthen: (1) a contraindication, warning, or precaution; (2) a statement about risk associated with misuse or abuse; or (3) an instruction about dosage and administration that is intended to increase the safe use of the OTC monograph drug (see section 744M(a)(2)(C) of the FD&C Act).

III. OMOR Fee Adjustment for Inflation

Under OMUFA, the OMOR fee is adjusted for inflation for FY 2022 and each subsequent FY (see section 744M(c)(1)(B) of the FD&C Act). That provision states that the dollar amount of the inflation adjustment to the fee for OMORs is equal to the product of the applicable fee for the preceding fiscal year and the inflation adjustment percentage.[3] For FY 2025, the inflation adjustment percentage is equal to the sum of:

- The average annual percent change in the cost, per full-time equivalent position of FDA, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 FYs, multiplied by the proportion of personnel compensation and benefits costs to total costs of OTC monograph drug activities for the first 3 years of the preceding 4 FYs (see section 744M(c)(1)(C)(ii)(I) of the FD&C Act); and
- The average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of OTC monograph drug activities for the first 3 years of the preceding 4 FYs (see section 744M(c)(1)(C)(ii)(II) of the FD&C Act).

As a result of a geographical revision made by the Bureau of Labor and Statistics in January 2018, the ''Washington, DC-Baltimore'' index was discontinued and replaced with two separate indices (*i.e.,* the ''Washington-Arlington-Alexandria'' and ''Baltimore-Columbia-Towson'' indices). To continue applying a CPI that best reflects the geographic region in which FDA is located and that provides the most current data available, the ''Washington-Arlington-Alexandria'' index is used in calculating the inflation adjustment percentage.

Table 1 summarizes the actual cost and FTE data for the specified FYs, provides the percent changes from the previous FYs, and provides the average

[1] For OMUFA purposes, an OTC monograph drug is a nonprescription drug without an approved new drug application that is governed by the provisions of section 505G of the FD&C Act (21 U.S.C. 355h) (see section 744L(5) of the FD&C Act);

[2] Under OMUFA, a Tier 1 OMOR is defined as any OMOR that is not a Tier 2 OMOR (see section 744L(8) of the FD&C Act). Tier 2 OMORs are detailed in section 744L(9) of the FD&C Act.

[3] See section 744M(c)(1)(C) of the FD&C Act.

percent changes over the first 3 of the 4 FYs preceding FY 2025. The 3-year average is 3.8539 percent.

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGES

	2021	2022	2023	3-Year average
Total PC&B	$3,039,513,000	$3,165,477,000	$3,436,513,000	.....
Total FTE	18,501	18,474	18,729	.....
PC&B per FTE	$164,289	$171,348	$183,486	.....
Percent Change from Previous Year	0.1811%	4.2967%	7.0838%	3.8539%

Under the statute, this 3.8539 percent is multiplied by the proportion of PC&B costs to the total FDA costs of OTC monograph drug activities for the first 3 years of the preceding 4 FYs (see section 744M(c)(1)(C)(ii) of the FD&C Act).

Table 2 shows the PC&B and the total obligations for OTC monograph drug activities for the first 3 of the preceding 4 FYs.

TABLE 2—PC&B AS A PERCENT OF TOTAL COST OF OTC MONOGRAPH DRUG ACTIVITIES

	2021	2022	2023	3-Year average
Total PC&B	$23,133,775	$25,415,237	$39,133,075	.....
Total Costs	$35,030,659	$49,644,273	$68,480,052	.....
PC&B Percent	66.0387%	51.1947%	57.1452%	58.1262%

The payroll adjustment is 3.8539 percent from table 1 multiplied by 58.1262 percent resulting in 2.2401 percent.

Table 3 provides the summary data for the percent changes in the specified CPI for the Washington-Arlington-Alexandria, DC-VA-MD-WV. The data are published by the Bureau of Labor Statistics on its website: *https://data.bls.gov/pdq/SurveyOutputServlet?data_tool=dropmap&series_id=CUURS35ASA0,CUUSS35ASA0.*

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN CPI FOR WASHINGTON-ARLINGTON-ALEXANDRIA, DC-VA-MD-WV AREA

Year	2021	2022	2023	3-Year average
Annual CPI	277.73	296.12	305.32	.....
Annual Percent Change	3.9568%	6.6212%	3.1069%	4.5616%

The statute specifies that this 4.5616 percent be multiplied by the proportion of all costs other than PC&B to total costs of OTC monograph drug activities. Because 58.1262 percent was obligated for PC&B (as shown in table 2), 41.8738 percent is the portion of costs other than PC&B (100 percent minus 58.1262 percent equals 41.8738 percent). The non-payroll adjustment is 4.5616 percent times 41.8738 percent, or 1.9101 percent.

Next, we add the payroll adjustment (2.2401 percent) to the non-payroll adjustment (1.9101 percent), for a total inflation adjustment of 4.1502 percent (rounded) for FY 2025.

IV. OMOR Fee Calculations

Under section 744M(a)(2)(A) of the FD&C Act, each person that submits a qualifying OMOR shall be subject to a fee for an OMOR. The amount of such fee shall be:

(1) For a Tier 1 OTC monograph order request, $500,000, adjusted for inflation for the FY (see section 744M(c)(1)(B) of the FD&C Act); and

(2) For a Tier 2 OTC monograph order request, $100,000, adjusted for inflation for the FY (see section 744M(c)(1)(B) of the FD&C Act).

In addition, under section 744M(c)(1)(B) of the FD&C Act and for purposes of section 744M(a)(2) of the FD&C Act, the dollar amount of the inflation adjustment to the fee for OMORs for FY 2022 and each subsequent FY shall be equal to the product of:

(1) The applicable fee under section 744M(a)(2) of the FD&C Act for the preceding FY; and

(2) The inflation adjustment percentage under section 744M(c)(1)(C) of the FD&C Act.

Thus, for FY 2025, the base of OMOR fees taken from the preceding FY (*i.e.,* FY 2024) are: Tier 1: $537,471 and Tier 2: $107,494. The FY 2025 inflation adjustment percentage is: 4.1502%.

V. Fee Schedule

The fee rates for FY 2025 are displayed in Table 4.

TABLE 4—FEE SCHEDULE FOR FY 2025

Fee category	FY 2025 fee rates
OMOR:	
Tier 1	$559,777
Tier 2	111,955

VI. Fee Payment Options and Procedures

The new OMOR fee rates are for the period from October 1, 2024, through September 30, 2025. To pay the OMOR fees, complete an OTC Monograph User Fee Cover Sheet, available at: *https://*

userfees.fda.gov/OA_HTML/omufaCAcdLogin.jsp.

A user fee identification (ID) number will be generated. Payment must be made in U.S. currency by electronic check or wire transfer, payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck).

FDA has partnered with the U.S. Department of the Treasury to use *Pay.gov*, a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website after completing the OTC Monograph User Fee Cover Sheet and generating the user fee ID number. Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay.* (*Note:* Only full payments are accepted through *https://userfees.fda.gov/pay.* No partial payments can be made online). Once an invoice is located, ''Pay Now'' should be selected to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000 (Discover, VISA, MasterCard, American Express). If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

For payments made by wire transfer, include the unique user fee ID number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID number, the payment may not be applied, which could result in FDA not filing an OMOR request, or other consequences of nonpayment. The originating financial institution may charge a wire transfer fee. Applicable wire transfer fees must be included with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The account information for wire transfers is as follows: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16878 Filed 7–30–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3029]

Agency Information Collection Activities; Proposed Collection; Comment Request; FDA Food Safety and Nutrition Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a collection of information used to conduct a voluntary consumer survey entitled, ''FDA Food Safety and Nutrition Survey.''

DATES: Either electronic or written comments on the collection of information must be submitted by September 30, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 30, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–3029 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; FDA Food Safety and Nutrition Survey.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not

in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Food Safety and Nutrition Survey

OMB Control Number 0910–0345—Reinstatement

Under section 1003(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)(2)), we are authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the nation's food supply. In the past, FDA has conducted two separate surveys, a Food Safety Survey and a Health and Diet Survey, to measure consumers' knowledge, attitudes, and beliefs about food safety and nutrition issues. These surveys have been conducted every 3 to 5 years since the 1980s. In the **Federal Register** of August 14, 2018 (83 FR 40293), we announced the combination of these two surveys, which will now be the FDA Food Safety and Nutrition Survey (FSANS). Data from FDA's food safety and nutrition surveys have been used to support rulemaking and educational campaigns and to measure progress toward Healthy People 2010, 2020, and 2030 food safety goals. The proposed 2024 FSANS will contain many of the same questions and topics as the previous surveys to facilitate measuring trends in food safety and diet knowledge, attitudes, and behaviors over time. The proposed survey will also be updated to explore emerging consumer food safety and nutrition topics and to expand understanding of previously asked topics.

The 2024 FSANS will be both a paper-and-pencil and web-based survey. Respondents will be contacted by postal mail, using an addressed-based sampling frame. Once contacted, respondents will be encouraged to take the survey online. A paper-and-pencil version of the survey will be mailed to those who do not initially take the web-based version of the survey. One randomly selected adult from each sampled household will be invited to participate in the survey using the Hagen-Collier method.[1] A total of 5,000 respondents will be surveyed. We will sample approximately 25,000 households to offset nonresponding households and ineligible addresses and achieve 5,000 adult respondents. Participation in the survey will be voluntary. Cognitive interviews and a pre-test will be conducted prior to fielding the survey.

Description of Respondents: Respondents to this collection of information are individuals who are adults, age 18 and older, drawn from the 50 states and the District of Columbia.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cognitive interview screener	75	1	75	0.083 (5 minutes)	6
Cognitive interview	18	1	18	1	18
Pretest	100	1	100	0.33 (20 minutes)	33
Mail survey	5,000	1	5,000	0.33 (20 minutes)	1,650
Total			5,193		1,707

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's burden estimate is based on the Agency's prior experience with food safety and nutrition surveys. We will use a cognitive interview screener with 75 individuals to recruit prospective interview participants for a total of 18

[1] In this method, we randomly select a category based on gender and age (based on the gender-age composition of the household), and then take the adult in that selected category.

individuals. We estimate that it will take each screener respondent approximately 5 minutes (0.083 hours) to complete the cognitive interview screener, for a total of 6 hours. We will conduct cognitive interviews with 18 participants. We estimate that it will take each participant approximately 1 hour to complete the interview, for a total of 18 hours. Prior to the administration of the surveys, the Agency plans to conduct a pretest to identify and resolve potential survey administration problems. The pretest will be conducted with 100 participants; we estimate that it will take each participant 20 minutes (0.33 hours) for the pretest for a total of 33 hours. We estimate that 5,000 eligible adults will participate in the survey with each taking 20 minutes (0.33 hours), for a total of 1,650 hours. Thus, the total estimated burden is 1,707 hours.

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16832 Filed 7–30–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3480]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the fee rates and payment procedures for fiscal year (FY) 2025 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Drug User Fee Amendments of 2023 (ADUFA V), authorizes FDA to collect user fees for certain animal drug applications and supplemental animal drug applications, for certain animal drug products, for certain establishments where such products are made, and for certain sponsors of such animal drug applications and/or investigational animal drug submissions. This notice establishes the fee rates for FY 2025.

DATES: The application fee rates apply to applications submitted on or after October 1, 2024, and will remain in effect through September 30, 2025.

FOR FURTHER INFORMATION CONTACT: Visit FDA's website at: *https://www.fda.gov/industry/fda-user-fee-programs/animal-drug-user-fee-act-adufa* or contact Lisa Kable, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–6888, *Lisa.Kable@fda.hhs.gov.* For general questions, you may also email FDA's Center for Veterinary Medicine (CVM) at: *cvmadufa@fda.hhs.gov.*

For questions relating to this notice: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 240–402–4989; or the User Fee Support Staff at *OO-OFBAP-OFM-UFFS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 740(a) of the FD&C Act (21 U.S.C. 379j–12), as amended by ADUFA V, establishes four different types of user fees: (1) fees for certain animal drug applications and supplemental animal drug applications; (2) annual fees for certain animal drug products; (3) annual fees for certain establishments where such products are made; and (4) annual fees for certain sponsors of animal drug applications and/or investigational animal drug submissions. When certain conditions are met, FDA will waive or reduce fees per section 740(d) of the FD&C Act.

For FYs 2024 through 2028, section 740(b)(1) of the FD&C Act establishes the base revenue amount for each fiscal year. Per section 740(c)(2) and (3) of the FD&C Act, the base revenue amounts established for fiscal years after FY 2024 are subject to adjustment for inflation and workload. Beginning in FY 2025, the annual fee revenue amount is also subject to an operating reserve adjustment to allow FDA to adjust the fee revenue amount to maintain a specified operating reserve of carryover user fees, per section 740(c)(4) of the FD&C Act. FDA may increase the fee revenue amount to maintain a 12-week minimum. If FDA has an excess operating reserve, FDA will decrease the fee revenue amount so that FDA has 22 weeks of operating reserve for FY 2025, 20 weeks for FY 2026, 18 weeks for FY 2027, and 16 weeks for FY 2028.

Per section 740(b)(2) of the FD&C Act, fees for applications, establishments, products, and sponsors are to be established each year by FDA so that the percentages of the total revenue that are derived from each type of user fee will be as follows: (1) revenue from application fees shall be 20 percent of total fee revenue; (2) revenue from product fees shall be 27 percent of total fee revenue; (3) revenue from establishment fees shall be 26 percent of total fee revenue; and (4) revenue from sponsor fees shall be 27 percent of total fee revenue. The target revenue amounts for each fee category for FY 2025 are as follows: for application fees, the target revenue amount is $5,701,000; for product fees, the target revenue amount is $7,697,000; for establishment fees, the target revenue amount is $7,412,000; and for sponsor fees, the target revenue amount is $7,697,000.

For FY 2025, the animal drug user fee rates are: (1) $581,735 for an animal drug application; (2) $290,867 for a supplemental animal drug application for which safety or effectiveness data are required, for an animal drug application subject to the criteria set forth in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b), and for an application for conditional approval under section 571 of the FD&C Act (21 U.S.C. 360ccc) for which an animal drug application submitted under section 512(b)(1) of the FD&C Act has been previously approved under section 512(d)(1) of the FD&C Act for another intended use; (3) $10,705 for the annual product fee; $157,702 for the annual establishment fee; and (4) $137,446 for the annual sponsor fee. FDA will issue invoices for FY 2025 product, establishment, and sponsor fees by December 31, 2024, and payment will be due by January 31, 2025. The application fee rates are effective for applications submitted on or after October 1, 2024, and will remain in effect through September 30, 2025. Applications will not be accepted for review until FDA has received full payment of application fees and any other animal drug user fees owed under the ADUFA program.

II. Fee Revenue Amount for FY 2025

A. Statutory Fee Revenue Amounts

Section 740(b)(1) of the FD&C Act specifies that the base fee revenue amount for FY 2025 for all animal drug user fee categories totals $33,500,000.

B. Inflation Adjustment to Fee Revenue Amount

Section 740(c)(2)(A)(ii) and (iii) of the FD&C Act specifies that the annual fee revenue amount is to be adjusted for inflation increases for FY 2025 and subsequent fiscal years using two separate adjustments: one for personnel compensation and benefits (PC&B) and one for non-PC&B costs. Section 740(c)(2)(A)(ii) of the FD&C Act specifies the component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all PC&B paid per full-time equivalent position (FTE) at FDA for the

first 3 of the 4 preceding fiscal years of available data, multiplied by the average proportion of PC&B costs to total FDA costs for the first 3 of the 4 preceding fiscal years of available data. The data on total PC&B paid and numbers of FTE paid, from which the average cost per FTE can be derived, are published in FDA's Justification of Estimates for Appropriations Committees.

Table 1 summarizes the total PC&B cost per FTE for the specified fiscal years, provides the percent change from the previous fiscal year, and provides the average percent change over the first 3 of the 4 fiscal years preceding FY 2025. The 3-year average is 3.8539 percent.

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENTAGE CHANGE

Fiscal year	2021	2022	2023	3-Year average
Total PC&B	$3,039,513,000	$3,165,477,000	$3,436,513,000	.....
Total FTEs	18,501	18,474	18,729	.....
PC&B per FTE	$164,289	$171,348	$183,486	.....
Percentage Change From Previous Year	0.1811%	4.2967%	7.0838%	3.8539%

Section 740(c)(2)(A)(ii) of the FD&C Act specifies that this 3.8539 percent should be multiplied by the proportion of PC&B costs to total FDA costs for the first 3 of the preceding 4 fiscal years for which data are available. Table 2 shows the amount of PC&B and the total amount obligated by FDA for the same 3 fiscal years.

TABLE 2—PC&B AS A PERCENT OF TOTAL COST AT FDA

Fiscal year	2021	2022	2023	3-Year average
Total PC&B	$3,039,513,000	$3,165,477,000	$3,436,513,000	.....
Total Costs	$6,049,798,000	$6,251,981,000	$6,654,058,000	.....
PC&B percent	50.2416%	50.6316%	51.6454%	50.8395%

The portion of the inflation adjustment relating to payroll costs is 3.8539 percent multiplied by 50.8359 percent, or 1.9593 percent.

Section 740(c)(2)(A)(iii) of the FD&C Act specifies that the portion of the inflation adjustment for non-payroll costs is the average annual percent change that occurred in the Consumer Price Index (CPI) (Washington-Arlington-Alexandria, DC-VA-MD-WV; not seasonally adjusted; all items less food and energy; annual index) for the first 3 years of the preceding 4 years of available data multiplied by the average proportion of all costs other than PC&B costs to total FDA costs for the first 3 years of the preceding 4 fiscal years. Table 3 provides the summary data for the percent change in the specified CPI for the Washington-Arlington-Alexandria area. The data from the Bureau of Labor Statistics are shown in table 3.[1]

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENTAGE CHANGE IN CPI (LESS FOOD AND ENERGY) FOR WASHINGTON-ARLINGTON-ALEXANDRIA AREA

Fiscal year	2021	2022	2023	3-Year average
Annual CPI	287.144	302.608	313.315	.....
Annual Percent Change	3.1271%	5.3855%	3.5382%	4.0169%

Section 740(c)(2)(A)(iii) of the FD&C Act specifies to calculate the inflation adjustment for non-payroll costs, we multiply 4.0169 percent by the average proportion of all costs other than PC&B to total FDA costs for the first 3 years of the preceding 4 fiscal years. Since 50.8395 percent was obligated for PC&B as shown in table 2, 49.1605 percent is the portion of costs other than PC&B (100 percent minus the PC&B percentage of 50.8395). The portion of the inflation adjustment relating to non-payroll costs is 4.0169 percent multiplied by 49.1605 percent, or 1.9747 percent.

Next, we add the payroll component (1.9593 percent) to the non-payroll component (1.9747 percent), for an inflation adjustment of 3.9340 percent for FY 2025.

Section 740(c)(2)(B) of the FD&C Act provides for the inflation adjustment to be compounded each fiscal year after FY 2025. The inflation adjustment for FY 2025 (3.9340 percent) is compounded by adding 1 and then multiplying by 1 plus the inflation adjustment factor for FY 2024 (zero percent), which equals 1.0393 (rounded) (1.0393 multiplied 1.0). We then multiply the base revenue amount for FY 2025 ($33,500,000) by 1.0393, yielding an inflation adjusted amount of $34,817,890.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

Section 740(c)(3)(A) of the FD&C Act specifies that the annual fee revenue amounts in ADUFA V for FY 2025 and subsequent fiscal years are subject to adjustment to account for changes in FDA's review workload. The workload

[1] The data is published by the Bureau of Labor Statistics and can be found on its website at: *https://data.bls.gov/timeseries/CUURS35ASA0L1E.*

adjustment will be applied to the inflation adjusted fee revenue amount.

To determine whether a workload adjustment applies, per ADUFA V commitments FDA calculates the weighted average of the change in the total number of each of the five types of applications and submissions specified in the workload adjustment provision (animal drug applications, supplemental animal drug applications for which data with respect to safety or efficacy are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions) received over the 5-year period that ended on September 30, 2023 (the base years; 2019 through 2023), and the average number of each of these types of applications and submissions over the most recent 5-year period that ended April 30, 2024.

The results of these calculations are presented in the first two columns of table 4. Column 3 reflects the percent change in workload over the two 5-year periods. Column 4 shows the weighting factor for each type of application/submissions, reflecting how much of the total FDA animal drug review workload was accounted for by each type of application or submission in the table during the most recent 5 years. Column 5 is the weighted percent change in each category of workload and was derived by multiplying the weighting factor in each line in column 4 by the percent change from the base years in column 3. At the bottom right of the table, the sum of the values in column 5 is calculated, reflecting a total change in workload of negative 4.4338 percent for FY 2025. This is the workload adjuster for FY 2025.

TABLE 4—WORKLOAD ADJUSTER CALCULATION

Application type	Column 1 5-Year average (base years)	Column 2 Latest 5-year average	Column 3 Percent change	Column 4 Weighting factor	Column 5 Weighted percent change
New Animal Drug Application (NADAs)	11.60	12.40	6.8966	0.0355	0.2447
Supplemental NADAs With Safety or Efficacy Data	8.20	7.60	−7.3171	0.0276	−0.2021
Manufacturing Supplements	367.20	359.20	−2.1786	0.2065	−0.4499
Investigational Study Submissions	164.20	159.00	−3.1669	0.5887	−1.8644
Investigational Protocol Submissions	216.20	183.20	−15.2636	0.1416	−2.1621
FY 2025 ADUFA V Workload Adjuster					−4.4338

Section 740(c)(3)(B) of the FD&C Act specifies that under no circumstances shall the workload adjustment result in fee revenues that are less than the base fee revenues for that fiscal year as adjusted for inflation. Additionally, section 740(c)(3)(A)(ii) states that the workload adjuster must be greater than 3 percent for a second fiscal year within ADUFA V before FDA can add the adjustment to the target revenue. For FY 2025 the workload adjuster is below the 3 percent statute threshold, therefore no workload adjustment shall be applied.

D. Operating Reserve Adjustment to Inflation and Workload Adjusted Fee Revenue Amount

Section 740(c)(4)(A) of the FD&C Act specifies that for FY 2025, after the fee revenue amount established under section 740(b) of the FD&C Act is adjusted for inflation and workload, the Secretary shall increase the fee revenue amount for such fiscal year, if necessary to provide an operating reserve of not less than 12 weeks or decrease the fee revenue amount for such fiscal year, if necessary to provide for not more than 22 weeks of operating reserves.

To determine the dollar amounts for the 12-week and 22-week operating reserve thresholds, we divide the adjusted annual fee revenue amount (rounded) ($34,818,000) by 52 weeks to generate a 1-week operating reserve amount of $669,577. The 1-week operating reserve amount is then multiplied by 12 and 22. This results in a 12-week minimum threshold of $8,034,923 and a 22-week maximum threshold of $14,730,692.

To estimate the FY 2024 end-of-year operating reserve of carryover user fees, the Agency projected the user fee carryover amount at the end of July 2024 using forecasted obligations, collections, and estimated recoveries but not including carryover use fees that have not been appropriated. The operating reserve of carryover user fees is projected to be $21,041,545 or 31.43 weeks ($21,041,545 divided by $669,577).

Because the estimated FY 2024 end-of-year operating reserve of carryover user fees is not below the 12-week threshold amount of $8,034,923, FDA will not increase the fee revenue amount and fees for FY 2025.

However, because the estimated FY 2024 end-of-year operating reserve of carryover user fees of $21,041,545 exceeds the 22-week threshold of $14,730,692, FDA will apply an operating reserve adjustment of $6,310,853 to decrease the fee revenue and fees for FY 2025.

With respect to target revenue for FY 2025, subtracting the operating reserve adjustment amount of $6,310,853 from the adjusted fee revenue amount of $34,817,890 results in a total target revenue amount of $28,507,037 for FY 2025.

E. FY 2025 Fee Revenue Amounts

The fee revenue amount (rounded) for FY 2025 is $28,507,000. Section 740(b)(2) of the FD&C Act specifies that this revenue amount is to be divided as follows: 20 percent, or a total of $5,701,000 is to come from application fees; 27 percent, or a total of $7,697,000, is to come from product fees; 26 percent, or a total of $7,412,000 is to come from establishment fees; and 27 percent, or a total of $7,697,000 is to come from sponsor fees.

III. Animal Drug Application Fee Calculations for FY 2025

A. Application Fee Revenues and Numbers of Fee-Paying Applications

Section 740(a)(1)(A) of the FD&C Act states that each person that submits an animal drug application or a supplemental animal drug application shall be subject to an application fee, with limited exceptions. The term ''animal drug application'' means an application for approval of any new animal drug submitted under section 512(b)(1) of the FD&C Act or an application for conditional approval of a new animal drug submitted under section 571 of the FD&C Act. A ''supplemental animal drug

application'' is defined as a request to FDA to approve a change in an approved animal drug application, or a request to FDA to approve a change to an application approved under section 512(c)(2) of the FD&C Act for which data with respect to safety or effectiveness are required. Such applications are subject to ADUFA fees, except those fees may be waived under the circumstances described in section 740(d)(1)(D) and 740(i) of the FD&C Act.

Furthermore, ADUFA V continues to provide an exception from application fees for animal drug applications submitted under section 512(b)(1) of the FD&C Act by a sponsor who previously applied for conditional approval under section 571 of the FD&C Act for the same product and paid an application fee at the time they applied for conditional approval. The purpose of this exception is to prevent sponsors of conditionally approved products from having to pay a second application fee at the time they apply for full approval of their products under section 512(b)(1) of the FD&C Act, provided the sponsor's application for full approval is filed consistent with the timeframes established in section 571(h) of the FD&C Act.

The application fees are to be set so that they will generate $5,701,000 in fee revenue for FY 2025. The fee for a supplemental animal drug application for which safety or effectiveness data are required, for an animal drug application subject to criteria set forth in section 512(d)(4) of the FD&C Act, and for an application for conditional approval under section 571 of the FD&C Act of a new animal drug for which an animal drug application submitted under section 512(b)(1) of the FD&C Act has been previously approved under section 512(d)(1) for another intended use is to be set at 50 percent of the animal drug application fee.

To set animal drug application fees and supplemental animal drug application fees to realize $5,701,000 FDA must first make some assumptions about the number of fee-paying applications and supplemental applications the Agency will receive in FY 2025.

The Agency knows the number of applications that have been submitted in previous fiscal years. That number fluctuates annually. In estimating the fee revenue to be generated by animal drug application fees in FY 2025, FDA is assuming that the number of applications for which fees will be paid in FY 2025 will equal the average number of applications over the five most recently completed fiscal years of the ADUFA program (FY 2019 to FY 2023).

Over the 5 most recently completed fiscal years, the average number of animal drug applications subject to the full fee was 5.60. Over this same period, the average number of supplemental applications for which safety or effectiveness data are required, applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act, and applications for conditional approval of a new animal drug for which a section 512(b)(1) application has been previously approved for another intended use subject to half of the full fee was 8.40.

Based on the previous assumptions, FDA is estimating that it will receive a total of 9.80 fee-paying animal drug applications in FY 2025 (5.60 applications paying a full fee and 8.40 applications paying a half fee).

B. Application Fee Rates for FY 2025

FDA must set the fee rates for FY 2025 so that the estimated 9.80 applications that pay the fee will generate a total of $5,701,000. To generate this amount, the fee for an animal drug application, rounded to the nearest dollar, will have to be $581,735, and the fee for a supplemental animal drug application for which safety or effectiveness data are required, for applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act, and for an application for conditional approval under section 571 of the FD&C Act of a new animal drug for which an animal drug application submitted under section 512(b)(1) of the FD&C Act has been previously approved under section 512(d)(1) for another intended use will have to be $290,867.

IV. Animal Drug Product Fee Calculations for FY 2025

A. Product Fee Revenues and Numbers of Fee-Paying Products

Section 740(a)(2) of the FD&C Act specifies that the animal drug product fee must be paid annually by the person named as the applicant in a new animal drug application or supplemental new animal drug application for an animal drug product submitted for listing under section 510 of the FD&C Act (21 U.S.C. 360) and who had an animal drug application or supplemental animal drug application pending at FDA after September 1, 2003. The term ''animal drug product'' means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the National Drug Code, and for which an animal drug application or a supplemental animal drug application has been approved (see section 739(3) of the FD&C Act). The product fees are to be set so that they will generate $7,697,000 in fee revenue for FY 2025.

To set animal drug product fees to realize $7,697,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2025. FDA developed data on all animal drug products that have been submitted for listing under section 510 of the FD&C Act and matched this to the list of all persons who had an animal drug application or a supplemental animal drug application pending after September 1, 2003. As of May 2024, FDA estimates that there are 734 products submitted for listing by persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. Based on this, FDA estimates that a total of 734 products will be subject to this fee in FY 2025.

In estimating the fee revenue to be generated by animal drug product fees in FY 2025, FDA is assuming that 2 percent of the products invoiced, or 15, will not pay fees in FY 2025, due to fee waivers and reductions. FDA has made this estimate at 2 percent this year, based on historical data over the past 5 completed fiscal years of the ADUFA program.

Accordingly, the Agency estimates that a total of 719 (734 minus 15) products will be subject to product fees in FY 2025.

B. Product Fee Rates for FY 2025

FDA must set the fee rates for FY 2025 so that the estimated 719 products for which fees are paid will generate a total of $7,697,000. To generate this amount will require the fee for an animal drug product, rounded to the nearest dollar, to be $10,705.

V. Animal Drug Establishment Fee Calculations for FY 2025

A. Establishment Fee Revenues and Numbers of Fee-Paying Establishments

Section 740(a)(3) of the FD&C Act states that the animal drug establishment fee must be paid annually by the person who: (1) owns or operates, directly or through an affiliate, an animal drug establishment; (2) is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product submitted for listing under section 510 of the FD&C Act; (3) had an animal drug application or supplemental animal drug application

pending at FDA after September 1, 2003; and (4) whose establishment engaged in the manufacture of the animal drug product during the fiscal year. An establishment subject to animal drug establishment fees is assessed only one such fee per fiscal year. The term ''animal drug establishment'' is defined as a foreign or domestic place of business at one general physical location, consisting of one or more buildings, all of which are within 5 miles of each other, at which one or more animal drug products are manufactured in final dosage form (see section 739(4) of the FD&C Act). The establishment fees are to be set so that they will generate $7,412,000 in fee revenue for FY 2025.

To set animal drug establishment fees to realize $7,412,000, FDA must make some assumptions about the number of establishments for which these fees will be paid in FY 2025. FDA developed data on all animal drug establishments and matched this to the list of all persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. As of May 2024, FDA estimates that there are a total of 50 establishments owned or operated by persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. Based on this, FDA believes that 50 establishments will be subject to this fee in FY 2025.

In estimating the fee revenue to be generated by animal drug establishment fees in FY 2025, FDA is assuming that 6 percent of the establishments invoiced, or three, will not pay fees in FY 2025 due to fee waivers and reductions. FDA has made this estimate at 6 percent this year, based on historical data over the past 5 completed fiscal years.

Accordingly, the Agency estimates that a total of 47 establishments (50 minus 3) will be subject to establishment fees in FY 2025.

B. Establishment Fee Rates for FY 2025

FDA must set the fee rates for FY 2025 so that the fees paid for the estimated 47 establishments will generate a total of $7,412,000. To generate this amount will require the fee for an animal drug establishment, rounded to the nearest dollar, to be $157,702.

VI. Animal Drug Sponsor Fee Calculations for FY 2025

A. Sponsor Fee Revenues and Numbers of Fee-Paying Sponsors

The animal drug sponsor fee must be paid annually by each person who: (1) is named as the applicant in an animal drug application, except for an approved application for which all subject products have been removed from listing under section 510 of the FD&C Act, or has submitted an investigational animal drug submission that has not been terminated or otherwise rendered inactive and (2) had an animal drug application, supplemental animal drug application, or investigational animal drug submission pending at FDA after September 1, 2003 (see sections 739(6) and 740(a)(4) of the FD&C Act). An animal drug sponsor is subject to only one such fee each fiscal year (see § 740(a)(4) of the FD&C Act). The sponsor fees are to be set so that they will generate $7,697,000 in fee revenue for FY 2025.

To set animal drug sponsor fees to realize $7,697,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2025. FDA developed data on all animal drug sponsors and matched this to the list of all sponsors who had pending submissions and applications after September 1, 2003. As of May 2024, FDA estimates that a total of 176 sponsors will meet this definition in FY 2025.

In estimating the fee revenue to be generated by animal drug sponsor fees in FY 2025, FDA is assuming that 68 percent of the sponsors invoiced, or 120, will not pay sponsor fees in FY 2025 due to fee waivers and reductions. FDA has made this estimate at 68 percent this year, based on historical data over the past 5 completed fiscal years of the ADUFA program.

Accordingly, the Agency estimates that a total of 56 sponsors (176 minus 120) will be subject to and pay sponsor fees in FY 2025.

B. Sponsor Fee Rates for FY 2025

FDA must set the fee rates for FY 2025 so that the estimated 56 sponsors that pay fees will generate a total of $7,697,000. To generate this amount will require the fee for an animal drug sponsor, rounded to the nearest dollar, to be $137,446.

VII. Fee Schedule for FY 2025

The fee rates for FY 2025 are summarized in table 5.

TABLE 5—FY 2025 FEE RATES

Animal drug user fee category	Fee rate for FY 2025
Animal Drug Application Fees:	
Animal Drug Application	$581,735
Supplemental Animal Drug Application for Which Safety or Effectiveness Data are Required, Animal Drug Application Subject to the Criteria Set Forth in Section 512(d)(4) of the FD&C Act, or Application for Conditional Approval Under Section 571 of the FD&C Act for Which an Animal Drug Application Submitted Under Section 512(b)(1) of the FD&C Act Has Been Previously Approved Under Section 512(d)(1) for Another Intended Use.	290,867
Animal Drug Product Fee	10,705
Animal Drug Establishment Fee [1]	157,702
Animal Drug Sponsor Fee [2]	137,446

[1] An animal drug establishment is subject to only one such fee each fiscal year.
[2] An animal drug sponsor is subject to only one such fee each fiscal year.

VIII. Fee Waiver or Reduction; Exemption From Fees

The types of fee waivers, fee reductions, and exemptions from fees that applied during ADUFA IV still exist in ADUFA V, with one exception. After September 30, 2023, there is no longer an exemption for any person who submits to CVM a supplemental animal drug application relating to a new animal drug application approved under section 512 of the FD&C Act, solely to add the application number to the labeling of the drug in the manner specified in section 503(w) of the FD&C Act.

Remaining waivers and reductions apply for the following: barriers to innovation; where fees will exceed the cost to review the animal drug application; if the application is related

to certain free-choice medicated feeds; if the application is solely for a MUMS indication; or if the sponsor is a small business submitting its first animal drug application. See section 740(d)(1) of the FD&C Act.

A. Barrier to Innovation Waivers or Fee Reductions

Under section 740(d)(1)(A) of the FD&C Act, an animal drug applicant may qualify for a waiver or reduction of one or more ADUFA fees if the fee would present a significant barrier to innovation because of limited resources available to the applicant or other circumstances. CVM's guidance for industry (GFI) #170, entitled ''Animal Drug User Fees and Fee Waivers and Reductions,'' [2] states that the Agency interprets this provision to mean that a waiver or reduction is appropriate when: (1) the product for which the waiver is being requested is innovative, or the requestor is otherwise pursuing innovative animal drug products or technology and (2) the fee would be a significant barrier to the applicant's ability to develop, manufacture, or market the innovative product or technology. Only those applicants that meet both criteria will qualify for a waiver or reduction in user fees under this provision (see GFI #170 at pp. 6–8). For purposes of determining whether the second criterion would be met based on limited financial resources available to the applicant, FDA has determined an applicant with financial resources of less than $20,000,000 (including the financial resources of the applicant's affiliates), adjusted annually for inflation, has limited resources available. Using the CPI for urban consumers (U.S. city average; not seasonally adjusted; all items; annual index), the inflation-adjusted level for FY 2025 will be $23,258,600; this level represents the financial resource ceiling that will be used to determine if there are limited resources available to an applicant requesting a Barrier to Innovation waiver on financial grounds for FY 2025. Requests for a waiver must be submitted in writing to FDA each fiscal year not later than 180 days from when the fees are due. A waiver granted on Barrier to Innovation grounds (or any of the other grounds listed in section 740(d)(1) of the FD&C Act) is only valid for one fiscal year. If a sponsor is not granted a waiver, they are liable for the fees.

[2] CVM's GFI #170 is located at: *https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052494.pdf.*

B. Exemption or Exception From Fees

In addition to the waivers and fee reductions described above, one fee exemption and two exceptions still apply in ADUFA V.

If an animal drug application, supplemental animal drug application, or investigational submission involves the intentional genomic alteration of an animal that is intended to produce a human medical product, any person who is the named applicant or sponsor of that application or submission will not be subject to sponsor, product, or establishment fees under ADUFA based solely on that application or submission (see section 740(d)(4) of the FD&C Act).

There is an exception from application fees for animal drug applications submitted under section 512(b)(1) of the FD&C Act by a sponsor who previously applied for conditional approval under section 571 of the FD&C Act for the same product and paid an application fee at the time they applied for conditional approval, provided the sponsor has submitted the application under section 512(b)(1) of the FD&C Act within the timeframe specified in section 571(h) of the FD&C Act. There is also an exception from application fees for previously filed applications that were not approved or were withdrawn (without waiver or refund). Both exceptions are detailed in section 740(a)(1)(C) of the FD&C Act.

IX. Procedures for Paying the FY 2025 Fees

A. Application Fees and Payment Instructions

The FY 2025 fee established in the new fee schedule must be paid for an animal drug application or supplement subject to fees under ADUFA V that is submitted on or after October 1, 2024. The payment must be made in U.S. currency from a U.S. bank by one of the following methods: wire transfer, electronically, check, bank draft, or U.S. postal money order made payable to the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Electronic payment options are based on the balance due. Payment by credit card is available only for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay*, or the *Pay.gov* payment option is available to you after you submit a cover sheet. (Note: only full payments are accepted. No partial payments can be made online.) Once you search for and find your invoice, select ''Pay Now'' to be redirected to *www.pay.gov.* Payments must be made using U.S. bank accounts as well as U.S. credit cards.

When paying by check, bank draft, or U.S. postal money order, please write your application's unique Payment Identification Number (PIN), beginning with the letters AD, on the upper right-hand corner of your completed Animal Drug User Fee Cover Sheet. Also write the FDA's post office box number (P.O. Box 979033) and PIN on the enclosed check, bank draft, or money order. Mail the payment and a copy of the completed Animal Drug User Fee Cover Sheet to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000. Note: In no case should the payment for the fee be submitted to FDA with the application.

When paying by wire transfer, the invoice number or PIN needs to be included. Without the invoice number or PIN, the payment may not be applied, and the invoice amount would be referred to collections. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required to add that amount to the payment to ensure that the invoice is paid in full.

Use the following account information when sending a payment by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account Number: 75060099, U.S. Department of the Treasury routing/transit number: 021030004, SWIFT Number: FRNYUS33.

To send a check by a courier such as FedEx, the courier must deliver the check and printed copy of the cover sheet to U.S. Bank: U.S. Bank, Attn: Government Lockbox 979033, 3180 Rider Trail South, Earth City, MO 63045. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 855–259–3064. This telephone number is only for questions about courier delivery.)

It is important that the fee arrives at the bank at least a day or two before the application arrives at FDA's CVM. FDA records the official application receipt date as the later of the following: the date the application was received by CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Department of the Treasury notifies FDA of receipt of an electronic or wire transfer payment. U.S. Bank and the

U.S. Department of the Treasury are required to notify FDA within 1 working day, using the PIN described previously. The tax identification number of FDA is 53–0196965.

B. Application Cover Sheet Procedures

Step One: Create a user account and password. Log on to the ADUFA website at *https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/animal-drug-user-fee-cover-sheet* and, under Application Submission Information, click on ''Create ADUFA User Fee Cover Sheet.'' For security reasons, each firm applying will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two: Create an Animal Drug User Fee Cover Sheet, transmit it to the FDA, and print a copy. After logging into your account with your username and password, complete the steps required to create an Animal Drug User Fee Cover Sheet. One cover sheet is needed for each animal drug application or supplement. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it electronically to the FDA and you will be able to print a copy of your cover sheet showing your unique PIN.

Step Three: Send the payment for your application as described in section IX.A above.

Step Four: Submit your application.

C. Product, Establishment, and Sponsor Fees

By December 31, 2024, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2025 using this fee schedule. Payment will be due by January 31, 2025. FDA will issue invoices in November 2025 for any products, establishments, and sponsors subject to fees for FY 2025 that qualify for fees after the December 2024 billing.

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16894 Filed 7–30–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3481]

Animal Generic Drug User Fee Program Rates and Payment Procedures for Fiscal Year 2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the fee rates and payment procedures for fiscal year (FY) 2025 generic new animal drug program user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Generic Drug User Fee Amendments of 2023 (AGDUFA IV), authorizes FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, for certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (JINAD's), and for certain submissions related to JINAD files. This notice establishes the fee rates for FY 2025.

DATES: The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2024, and will remain in effect through September 30, 2025. The fee rates for requests to establish a JINAD file, and for certain submissions to JINAD files established prior to October 1, 2023, are effective on October 1, 2024, and will remain in effect through September 30, 2025.

FOR FURTHER INFORMATION CONTACT: Visit FDA's website at: *https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm* or contact: Lisa Kable, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–6888, *Lisa.Kable@fda.hhs.gov*. For general questions, you may also email the Center for Veterinary Medicine (CVM) at: *cvmagdufa@fda.hhs.gov.*

For questions relating to this notice: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 240–402–4989; or the User Fee Support Staff at *OO-OFBAP-OFM-UFFS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 741(a) of the FD&C Act (21 U.S.C. 379j–21(a)), establishes four different types of generic new animal drug user fees: (1) fees for certain abbreviated applications for generic new animal drugs; (2) annual fees for certain generic new animal drug products; (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs; and (4) JINAD file fees. When certain conditions are met, section 741(d) of the FD&C Act authorizes FDA to waive or reduce fees for generic new animal drugs intended solely to provide for a minor use or minor species indication.

Section 741(b)(1) of the FD&C Act establishes a base revenue amount for each fiscal year. Per section 741(c)(2) and (3) of the FD&C Act, the base revenue amounts established for fiscal years after FY 2024 are subject to adjustment for inflation and workload. Beginning FY 2026, the annual fee revenue amounts are also subject to adjustment to reduce workload-based increases by the amount of certain excess collections. Section 741(b) of the FD&C Act establishes fees each year so that the percentage allocations for each of the fee categories is as follows: 20 percent shall be derived from fees for abbreviated applications for a generic new animal drug and JINAD file fees; 40 percent shall be derived from fees for generic new animal drug products; and 40 percent shall be derived from fees for generic new animal drug sponsors. The target revenue amounts for each fee category for FY 2025 are as follows: for application and/or JINAD file fees, the target revenue amount is $5,196,700; for product fees, the target revenue amount is $10,393,400; and for sponsor fees, the target revenue amount is $10,393,400.

For FY 2025, the AGDUFA rates are: $161,907 for each abbreviated application for a generic new animal drug other than those subject to the criteria in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); $80,954 for each abbreviated application for a generic new animal drug subject to the criteria in section 512(d)(4) of the FD&C Act; $50,000 for each JINAD file request or certain submissions to established JINAD files; $16,139 for each generic new animal drug product; $270,204 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; $202,653 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and $135,102 for each generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will

issue invoices for FY 2025 product and sponsor fees by December 31, 2024, and payment will be due by January 31, 2025. The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2024, and will remain in effect through September 30, 2025. The fee rate for requests to establish a JINAD file, and for certain submissions to JINAD files established prior to October 1, 2023, is effective on October 1, 2024, and will remain in effect through September 30, 2025.

Applications will not be accepted for review until FDA has received full payment of application fees and any other fees owed under the AGDUFA program. Similarly, a request to establish a JINAD file or a submission to an existing JINAD file will not be accepted for action by FDA until FDA has received full payment of all fees owed under the AGDUFA program.

II. Fee Revenue Amount for FY 2025

A. Statutory Fee Revenue Amounts

Section 741(b)(1) of the FD&C Act specifies that the base fee revenue amount for FY 2025 for all generic animal drug user fee categories totals $25,000,000.

B. Inflation Adjustment to Fee Revenue Amount

Section 741(c)(2)(A) of the FD&C Act specifies that the annual fee revenue amount is to be adjusted for inflation increases for FY 2025 and subsequent fiscal years using two separate factors—one for personnel compensation and benefits (PC&B) costs and one for non-PC&B costs.

Section 741(c)(2)(A)(ii) of the FD&C Act specifies the component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all PC&B, per full-time equivalent (FTE) position of the FDA, for the first 3 of the preceding 4 fiscal years of available data, multiplied by the average proportion of PC&B costs to total FDA costs for the first 3 of the 4 preceding fiscal years of available data. The data on total PC&B paid and numbers of FTE paid, from which the average cost per FTE can be derived, are published in FDA's Justification of Estimates for Appropriations Committees.

Table 1 summarizes the total PC&B costs per FTE for the specified fiscal years, provides the percentage change from the previous fiscal year, and provides the average percentage change over the first 3 of the 4 fiscal years preceding FY 2025. The 3-year average is 3.8539 percent.

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGE

Fiscal year	2021	2022	2023	3-Year average
Total PC&B	$3,039,513,000	$3,165,477,000	$3,436,513,000	.....
Total FTEs	18,501	18,474	18,729	.....
PC&B per FTE	$164,289	$171,348	$183,486	.....
Percent Change from Previous Year	0.1811%	4.2967%	7.0838%	3.8539%

Section 741(c)(2)(A)(ii) of the FD&C Act specifies that the 3.8539 percent should be multiplied by the average proportion of PC&B costs to total FDA costs for the first 3 of the preceding 4 fiscal years for which data are available. Table 2 shows the amount of PC&B and the total costs obligated by FDA for the same 3 fiscal years.

TABLE 2—PC&B AS A PERCENT OF TOTAL COST

Fiscal year	2021	2022	2023	3-Year average
Total PC&B	$3,039,513,000	$3,165,477,000	$3,436,513,000	.....
Total Costs	$6,049,798,000	$6,251,981,000	$6,654,058,000	.....
PC&B percent	50.2416%	50.6316%	51.6454%	50.8395%

The portion of the inflation adjustment relating to payroll costs is 3.8539 percent multiplied by 50.8359 percent, or 1.9593 percent.

Section 741(c)(2)(A)(iii) of the FD&C Act specifies that the non-payroll costs adjustment factor is calculated by multiplying the average annual percentage change that occurred in the Consumer Price Index for Urban Consumers (Washington-Arlington-Alexandria, DC-VA-MD-WV; Not Seasonally Adjusted; All Items Less Food and Energy; Annual Index) for the first 3 years of the preceding 4 years of available data by the average proportion of all non-PC&B costs to total FDA costs for the first 3 years of the preceding 4 fiscal years. Table 3 provides the summary data for the percentage change in the specified CPI for the Washington-Arlington-Alexandria area.[1]

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN CPI (LESS FOOD AND ENERGY) FOR WASHINGTON-ARLINGTON-ALEXANDRIA AREA

Fiscal year	2021	2022	2023	3-Year average
Annual CPI	287.144	302.608	313.315	.....
Annual Percent Change	3.1271%	5.3855%	3.5382%	4.0169%

[1] The data is published by the Bureau of Labor Statistics and can be found on its website at: *https://data.bls.gov/timeseries/CUURS35ASA0L1E.*

Section 741(c)(2)(A)(iii) of the FD&C Act specifies to calculate the inflation adjustment for non-payroll costs, we multiply 4.0169 percent by the average proportion of all costs other than PC&B to total FDA costs for the first 3 years of the preceding 4 fiscal years. Since 50.8395 percent was obligated for PC&B as shown in table 2, 49.1605 percent is the portion of costs other than PC&B (100 percent minus the PC&B percentage of 50.8395). The portion of the inflation adjustment relating to non-payroll costs is 4.0169 percent multiplied by 49.1605 percent, or 1.9747 percent.

Next, we add the payroll component (1.9593 percent) to the non-payroll component (1.9747 percent), for an inflation adjustment of 3.9340 percent for FY 2025.

Section 741(c)(2)(B) of the FD&C Act provides for the inflation adjustment to be compounded each fiscal year after FY 2025. The inflation adjustment for FY 2025 (3.9340 percent) is compounded by adding 1 and then multiplying by 1 plus the inflation adjustment factor for FY 2024 (zero percent), which equals 1.0393 (rounded) (1.0393 × 1.0). We then multiply the base revenue amount for FY 2025 ($25,000,000) by 1.0393, yielding an inflation adjusted amount of $25,983,500.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

Section 741(c)(3)(A) of the FD&C Act specifies that fee revenue amounts for FY 2025 and subsequent fiscal years are subject to adjustment to account for changes in FDA's review workload. The workload adjustment would be applied to the inflation adjusted fee revenue amount.

To determine whether a workload adjustment applies, per AGDUFA IV commitments FDA calculates the weighted average of the change in the total number of each of the six types of applications and submissions specified in the workload adjustment provision (abbreviated applications for generic new animal drugs, manufacturing supplemental abbreviated applications for generic new animal drugs, investigational generic new animal drug study submissions, investigational generic new animal drug protocol submissions, generic investigational new animal drug file requests, and generic investigational new animal drug meeting requests) received over the 5-year period that ended on September 30, 2023 (the base years; 2019 through 2023), and the average number of each of these types of applications and submissions over the most recent 5-year period that ended April 30, 2024.

The results of these calculations are presented in the first two columns of table 4. Column 3 reflects the percent change in workload over the two 5-year periods. Column 4 shows the weighting factor for each type of application/submission, reflecting how much of the total FDA generic new animal drug review workload was accounted for by each type of application or submission in the table during the most recent 5 years. Column 5 is the weighted percent change in each category of workload and was derived by multiplying the weighting factor in each line in column 4 by the percent change from the base years in column 3. At the bottom right of the table, the sum of the values in column 5 is calculated, reflecting a total change in workload of negative 0.9977 percent for FY 2025. This is the workload adjuster for FY 2025.

TABLE 4—WORKLOAD ADJUSTER CALCULATION

Application type	Column 1 5-Year average (base years)	Column 2 Latest 5-year average	Column 3 Percent change	Column 4 Weighting factor	Column 5 Weighted percent change
Abbreviated Application for a Generic New Animal Drug (ANADAs)	28.00	31.60	12.8571	0.0902	1.1600
Manufacturing Supplements ANADAs	249.40	249.20	−0.0802	0.2321	−0.0186
Generic Investigational Study Submissions	171.80	167.00	−2.7939	0.4759	−1.3296
Generic Investigational Protocol Submissions	58.00	54.60	−5.8621	0.1068	−0.6263
Generic Investigational New Animal Drug File Requests (JINAD)	49.20	47.20	−4.0650	0.0183	−0.0744
Generic Investigational New Animal Drug Meeting Requests (JINAD)	28.20	27.80	−1.4184	0.0767	−0.1087
FY 2025 AGDUFA IV Workload Adjuster					−0.9977

Per section 741(c)(3)(C) of the FD&C Act under no circumstances shall the workload adjustment result in fee revenues that are less than the base fee revenues for that fiscal year as adjusted for inflation. For FY 2025 the workload adjustment would result in fee revenues less than the base fee revenues as adjusted for inflation, therefore no workload adjustment shall be applied.

E. FY 2025 Fee Revenue Amounts

AGDUFA IV specifies that the revenue amount of $25,983,500 for FY 2025 is to be divided as follows: 20 percent, or a total of $5,196,700, is to come from application and/or JINAD file fees; 40 percent, or a total of $10,393,400, is to come from product fees; and 40 percent, or a total of $10,393,400 is to come from sponsor fees (See section 741(b) of the FD&C Act).

III. Abbreviated Application Fee and Generic Investigational New Animal Drug (JINAD) File Fee Calculations for FY 2025

A. Fee Revenues and Numbers of Fee-Paying Applications and Submissions

Section 741(a)(1)(A) of the FD&C Act states that each person who submits an abbreviated application for a generic new animal drug shall be subject to an application fee, with limited exceptions. The term ''abbreviated application for a generic new animal drug'' means an abbreviated application for the approval of any generic new animal drug submitted under section 512(b)(2) of the FD&C Act. FDA will assess fees related to JINAD files under section 741(a)(4)(A)(i) of the FD&C Act when a person submits a request to establish a new JINAD file. FDA will assess a fee under section 741(a)(4)(A)(ii) and (iii) of the FD&C Act for a person's first submission, as described below, to a JINAD file on or after October 1, 2023, where the JINAD file had been established prior to that date. The JINAD file fee is set in accordance with

section 741(c)(1)(C) of the FD&C Act at $50,000. FDA will set the abbreviated application fee so that such fees combined with the JINAD file fees will generate a combined total of $5,196,700 in fee revenue for FY 2025.

To set fees for abbreviated applications for generic new animal drugs, FDA must first make some assumptions about the number of fee-paying abbreviated applications it will receive during FY 2025, the number of requests to establish new JINAD files it will receive during FY 2025, and the number of existing (prior to October 1, 2023) JINAD files to which it will receive submissions during FY 2025.

Regarding the fee for a person's first submission to an existing (prior to October 1, 2023) JINAD file on or after October 1, 2023, FDA intends to assess a fee only for the first data (or ''P'') submission to the Bioequivalence (BE) or Chemistry, Manufacturing, and Controls (CMC) technical sections of the JINAD file. The Agency has selected P submissions to the BE or CMC technical sections as the basis for assessing this fee because P submissions to these sections consistently entail the substantial use of FDA review hours during the phased review process.

The Agency knows the numbers of applications and submissions that have been submitted in previous years. Those numbers fluctuate annually. In estimating the fee revenue to be generated by application and submission fees in FY 2025, FDA is assuming that the number of applications and submissions for which fees will be paid in FY 2025 will equal the average number of applications and submissions over the 5 most recently completed fiscal years of the AGDUFA program (FY 2019–FY 2023).

In addition, under section 741(a)(1)(C)(ii) of the FD&C Act an abbreviated application for a generic new animal drug subject to the criteria in section 512(d)(4) of the FD&C Act and submitted on or after October 1, 2013, shall be subject to 50 percent of the fee applicable to all other abbreviated applications for a generic new animal drug.

The average number of original submissions of abbreviated applications for generic new animal drugs over the 5 most recently completed fiscal years is 15 applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 6.4 submissions subject to the criteria in section 512(d)(4). Each of the submissions described under section 512(d)(4) of the FD&C Act pays 50 percent of the fee paid by the other applications and will be counted as one half of a fee. Adding all of the applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 50 percent of the number that are subject to such criteria results in a total of 18.20 anticipated full fees.

Based on the previous assumptions, FDA is estimating that it will receive a total of 18.20 fee-paying generic new animal drug applications in FY 2025 (15.0 original applications paying a full fee and 6.4 applications paying a half fee).

For estimating the number of requests to establish a new JINAD file and the number of P submissions to the BE or CMC section of an existing (prior to October 1, 2023) JINAD file the Agency will receive in FY 2025, FDA took the number of new JINAD file requests and P submissions to the BE or CMC section of an existing JINAD file received in FY 2024. The number of requests to establish new JINAD files and P submissions to the BE or CMC section of existing JINAD files during FY 2024 as of June is 45.

Based on the previous assumptions, FDA is estimating that it will receive a total of 45 fee-paying JINAD file submissions in FY 2025 (including both requests to establish new JINAD files and first P submissions to the BE or CMC section of existing (prior to October 1, 2023) JINAD files).

B. Application Fee Rates for FY 2025

FDA must set the fee rates for FY 2025 so that the estimated 18.20 abbreviated application fees and 45 JINAD file fees will generate a total of $5,196,700. The fee for a new JINAD file request or the first submission to an existing (prior to October 1, 2023) JINAD file is $50,000 under section 741(c)(1)(C) of the FD&C Act. Therefore, the JINAD fees will generate a total of $2,250,000. Abbreviated application fees will have to generate a total of $2,946,700.

To generate this amount, the fee for a generic new animal drug application will be $161,907 and for those applications that are subject to the criteria set forth in section 512(d)(4) of the FD&C Act, 50 percent of that amount, or $80,954.

IV. Generic New Animal Drug Product Fee Calculations For FY 2025

A. Product Fee Revenues and Numbers of Fee-Paying Products

The generic new animal drug product fee must be paid annually by the person named as the applicant in an abbreviated application or supplemental abbreviated application for a generic new animal drug product submitted for listing under section 510 of the FD&C Act (21 U.S.C. 360), and who had an abbreviated application or supplemental abbreviated application for a generic new animal drug product pending at FDA after September 1, 2008 (21 U.S.C. 379j–21(a)(2)). Section 741(k)(6) of FD&C Act defines ''generic new animal drug product'' as a specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the National Drug Code, and for which an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug has been approved. The product fees are to be set so that they will generate $10,393,400 in fee revenue for FY 2025.

To set generic new animal drug product fees to realize $10,393,400, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2025. FDA gathered data on all generic new animal drug products that have been submitted for listing under section 510 of the FD&C Act and matched this to the list of all persons who FDA estimated would have a generic new animal drug application or supplemental abbreviated application pending after September 1, 2008. As of May 2024, FDA estimates that there is a total of 651 products submitted for listing by persons who had an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug pending after September 1, 2008. Based on this, FDA believes that a total of 651 products will be subject to this fee in FY 2025.

Per section 741(d) of the FD&C Act in estimating the fee revenue to be generated by generic new animal drug product fees in FY 2025, FDA is estimating that 1 percent of the products invoiced, or 7 products, will not pay fees in FY 2025, due to fee waivers and reductions. FDA has made this estimate at 1 percent this year, based on historical data over the past 5 completed fiscal years of the AGDUFA program.

Accordingly, the Agency estimates that a total of 644 (651 minus 7) products will be subject to product fees in FY 2025.

B. Product Fee Rates for FY 2025

FDA must set the fee rates for FY 2025 so that the estimated 644 products for which fees are paid will generate a total of $10,393,400. To generate this amount will require the fee for a generic new animal drug product, rounded to the nearest dollar, to be $16,139.

V. Generic New Animal Drug Sponsor Fee Calculations for FY 2025

A. Sponsor Fee Revenues and Numbers of Fee-Paying Sponsors

The generic new animal drug sponsor fee must be paid annually by each person who: (1) is named as the applicant in an abbreviated application for a generic new animal drug, except for an approved application for which all subject products have been removed from listing under section 510 of the FD&C Act, or has submitted an investigational submission for a generic new animal drug that has not been terminated or otherwise rendered inactive and (2) had an abbreviated application for a generic new animal drug, supplemental abbreviated application for a generic new animal drug, or investigational submission for a generic new animal drug pending at FDA after September 1, 2008. See section 741(k)(7) and (a)(3) of the FD&C Act.

Per section 741(a)(3)(C) of the FD&C Act, a generic new animal drug sponsor is subject to only one such fee each fiscal year. Applicants with more than 6 approved abbreviated applications will pay 100 percent of the sponsor fee; applicants with more than 1 and fewer than 7 approved abbreviated applications will pay 75 percent of the sponsor fee; and applicants with 1 or fewer approved abbreviated applications will pay 50 percent of the sponsor fee. The sponsor fees are to be set so that they will generate $10,393,400 in fee revenue for FY 2025.

To set generic new animal drug sponsor fees to realize $10,393,400, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2025. FDA developed data on all generic new animal drug sponsors and matched this to the list of all sponsors who had pending submissions and applications after September 1, 2008. As of May, 2024, FDA estimates that in FY 2025, 15 sponsors will pay 100 percent fees, 15 sponsors will pay 75 percent fees, and 26 sponsors will pay 50 percent fees. The total of these figures is the equivalent of 39.25 full sponsor fees (15 times 100 percent or 15, plus 15 times 75 percent or 11.25 plus 26 times 50 percent or 13).

FDA estimates that about 2 percent of all of these sponsors, or 0.79, will not pay fees in FY 2025, due to fee waivers and reductions. FDA has made the estimate of the percentage of sponsors that will not pay fees at 2 percent this year, based on historical data over the past 5 completed fiscal years of the AGDUFA program. See section 741(d) of the FD&C Act.

Accordingly, the Agency estimates that the equivalent of 38.47 full sponsor fees (39.25 minus 0.78) are likely to be paid in FY 2025.

B. Sponsor Fee Rates for FY 2025

FDA must set the fee rates for FY 2025 so that the estimated equivalent of 38.47 full sponsor fees will generate a total of $10,393,400. To generate this amount will require the 100 percent fee for a generic new animal drug sponsor, rounded to the nearest dollar, to be $270,204. Accordingly, the fee for those paying 75 percent of the full sponsor fee will be $202,653, and the fee for those paying 50 percent of the full sponsor fee will be $135,102.

VI. Fee Schedule for FY 2025

The fee rates for FY 2025 are summarized in table 5.

TABLE 5—FY 2025 FEE RATES

User fee category	Fee rate for FY 2025
Abbreviated Application Fee for Generic New Animal Drug except those subject to the criteria in section 512(d)(4)	$161,907
Abbreviated Application Fee for Generic New Animal Drug subject to the criteria in section 512(d)(4)	80,954
Generic Investigational New Animal Drug File Fee (JINAD)	50,000
Generic New Animal Drug Product Fee	16,139
100% Generic New Animal Drug Sponsor Fee [1]	270,204
75% Generic New Animal Drug Sponsor Fee [1]	202,653
50% Generic New Animal Drug Sponsor Fee [1]	135,102

[1] An animal drug sponsor is subject to only one fee each fiscal year.

VIII. Fee Waiver or Reduction; Exemption From Fees

Per section 741(d)(1), of the FD&C Act the types of fees waivers and reductions that applied last fiscal year still exist for FY 2025. However, after September 30, 2023, there is no longer an exemption for any person who submits to CVM a supplemental abbreviated application relating to a generic new animal drug approved under section 512 of the FD&C Act, solely to add the application number to the labeling of the drug in the manner specified in section 502(w)(3) of the FD&C Act (21 U.S.C. 352(w)(3)).

Waivers or reductions remain available for abbreviated applications for generic new animal drugs intended solely for a minor use/minor species indication; see section 741(d) of the FD&C Act.

IX. Procedures for Paying FY 2025 Fees

A. Abbreviated Application Fees, JINAD File Fees, and Payment Instructions

The FY 2025 fees established in the new fee schedule must be paid for the following applications/submissions that are subject to fees under AGDUFA IV and submitted on or after October 1, 2024: a generic new animal drug application, a submission requesting to establish a JINAD file, or the first BE or CMC submission to a JINAD file that was established prior to October 1, 2023. The payment must be made in U.S. currency from a U.S. bank by one of the following methods: wire transfer, electronically, check, bank draft, or U.S. postal money order made payable to the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Electronic payment options are based on the balance due. Payment by credit card is available only for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/*pay or the *Pay.gov* payment option is available to you after you submit a cover sheet. (*Note:* only full payments are accepted. No partial payments can be made online.) Once you find your invoice, select ''Pay Now'' to be redirected to *Pay.gov.* Payments must be made using U.S. bank accounts as well as U.S. credit cards.

When paying by check, bank draft, or U.S. postal money order, please write your application's unique Payment Identification Number (PIN), beginning

with the letters ''AG'', on the upper right-hand corner of your completed Animal Generic Drug User Fee Cover Sheet. Also write FDA's post office box number (P.O. Box 979033) and PIN on the enclosed check, bank draft, or money order. Mail the payment and a copy of the completed Animal Generic Drug User Fee Cover Sheet to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000. *Note:* In no case should the payment for the fee be submitted to FDA with the application or JINAD file submission.

When paying by wire transfer, the invoice number or PIN needs to be included. Without the invoice number or PIN, the payment may not be applied, and the invoice amount would be referred to collections. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required to add that amount to the payment to ensure that the invoice is paid in full. Use the following account information when sending a payment by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account Number: 75060099, U.S. Department of the Treasury routing/transit number: 021030004, SWIFT Number: FRNYUS33.

To send a check by a courier such as FedEx, the courier must deliver the check and printed copy of the cover sheet to U.S. Bank: U.S. Bank, Attn: Government Lockbox 979033, 3180 Rider Trail S, Earth City, MO 63045. (*Note:* This address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 855–259–3064. This telephone number is only for questions about courier delivery.)

It is important that the fee arrives at the bank at least a day or two before the abbreviated application or JINAD submission arrives at FDA's CVM. FDA records the official abbreviated application or JINAD submission receipt date as the later of the following: the date the application or submission was received by CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Department of the Treasury notifies FDA of payment. U.S. Bank and the U.S. Department of the Treasury are required to notify FDA within 1 working day, using the PIN described previously.

The tax identification number of FDA is 53–0196965.

B. Application and JINAD File Submission Cover Sheet Procedures

Step One: Create a user account and password. Log onto the AGDUFA website at *https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm137049.htm* and, under Application Submission Information, click on ''Create AGDUFA User Fee Cover Sheet'' and follow the directions. For security reasons, each firm submitting an application and/or a JINAD file submission will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two: Create an Animal Generic Drug User Fee Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your username and password, complete the steps required to create an Animal Generic Drug User Fee Cover Sheet. One cover sheet is needed for each abbreviated application for a generic new animal drug or JINAD file submission. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique PIN.

Step Three: Send the payment for your application or JINAD file submission as described in section IX.A.

Step Four: Submit your application or JINAD file submission.

C. Product and Sponsor Fees

By December 31, 2024, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2025 using this fee schedule. Payment will be due by January 31, 2025. FDA will issue invoices in November 2025 for any products and sponsors subject to fees for FY 2025 that qualify for fees after the December 2024 billing.

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16885 Filed 7–30–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3005]

Outsourcing Facility Fee Rates for Fiscal Year 2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2025 rates for the establishment and reinspection fees related to entities that compound human drugs and elect to register as outsourcing facilities under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FD&C Act authorizes FDA to assess and collect an annual establishment fee from outsourcing facilities, as well as a reinspection fee for each reinspection of an outsourcing facility. This document establishes the FY 2025 rates for the small business establishment fee ($6,488), the non-small business establishment fee ($21,534), and the reinspection fee ($19,465) for outsourcing facilities; provides information on how the fees for FY 2025 were determined; and describes the payment procedures outsourcing facilities should follow.

DATES: These fee rates are effective October 1, 2024, and will remain in effect through September 30, 2025.

FOR FURTHER INFORMATION CONTACT: For more information on human drug compounding and outsourcing facility fees, visit FDA's website at: *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding.*

For questions relating to this notice: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 240–402–4989; or the User Fee Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under section 503B of the FD&C Act (21 U.S.C. 353b), a human drug compounder can register with FDA as an ''outsourcing facility.'' Outsourcing facilities, as defined in section 503B(d)(4), are facilities that meet all the conditions described in section 503B(a), including registering with FDA as an outsourcing facility and paying an annual establishment fee. If the conditions of section 503B are met, a

drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from three sections of the FD&C Act: (1) section 502(f)(1) (21 U.S.C. 352(f)(1)), concerning the labeling of drugs with adequate directions for use; (2) section 505 (21 U.S.C. 355), concerning the approval of human drug products under new drug applications or abbreviated new drug applications; and (3) section 582 (21 U.S.C. 360eee–1), concerning drug supply chain security requirements. Drugs compounded in outsourcing facilities are not exempt from the requirements of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)), concerning current good manufacturing practice requirements for drugs.

Section 744K of the FD&C Act (21 U.S.C. 379j–62) authorizes FDA to assess and collect the following fees associated with outsourcing facilities: (1) an annual establishment fee from each outsourcing facility and (2) a reinspection fee from each outsourcing facility subject to a reinspection (see section 744K(a)(1) of the FD&C Act). Under statutorily defined conditions, a qualified applicant may pay a reduced small business establishment fee (see section 744K(c)(4) of the FD&C Act).

FDA announced in the **Federal Register** of November 24, 2014 (79 FR 69856), the availability of a final guidance for industry entitled ''Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act.'' The guidance provides additional information on the annual fees for outsourcing facilities and adjustments required by law, reinspection fees, how to submit payment, the effect of failure to pay fees, and how to qualify as a small business to obtain a reduction of the annual establishment fee. This guidance can be accessed on FDA's website at: *https://www.fda.gov/media/136683/download.*

II. Fees for FY 2025

A. Methodology for Calculating FY 2025 Adjustment Factors

1. Inflation Adjustment Factor

Section 744K(c)(2) of the FD&C Act specifies the annual inflation adjustment for outsourcing facility fees. The inflation adjustment has two components: one based on FDA's payroll costs and one based on FDA's non-payroll costs for the first 3 of the 4 previous fiscal years. The payroll component of the annual inflation adjustment is calculated by taking the average change in FDA's per full-time equivalent (FTE) personnel compensation and benefits (PC&B) in the first 3 of the 4 previous fiscal years (see section 744K(c)(2)(A)(ii) of the FD&C Act). FDA's total annual spending on PC&B is divided by the total number of FTEs per fiscal year to determine the average PC&B per FTE.

Table 1 summarizes the actual cost and FTE data for the specified fiscal years and provides the percent change from the previous fiscal year and the average percent change over the first 3 of the 4 fiscal years preceding FY 2025. The 3-year average is 3.8539 percent.

TABLE 1—FDA PC&BS EACH YEAR AND PERCENT CHANGE

	FY 2021	FY 2022	FY 2023	3-Year average
Total PC&B	$3,039,513,000	$3,165,477,000	$3,436,513,000	
Total FTE	$18,501	$18,474	$18,729	
PC&B per FTE	$164,289	$171,348	$183,486	
Percent Change From Previous Year	0.1811%	4.2967%	7.0838%	3.8539%

Section 744K(c)(2)(A)(ii) of the FD&C Act specifies that this 3.8539 percent should be multiplied by the proportion of PC&B to total costs of an average FDA FTE for the same 3 fiscal years.

TABLE 2—FDA PC&BS AS A PERCENT OF FDA TOTAL COSTS OF AN AVERAGE FTE

	FY 2021	FY 2022	FY 2023	3-Year average
Total PC&B (proportion of costs)	$3,039,513,000	$3,165,477,000	$3,436,513,000	
Total Costs	$6,105,480,000	$6,251,981,000	$6,654,058,000	
PC&B percent	49.7834%	50.6316%	51.6454%	50.6868%

The payroll adjustment is 3.8539 percent multiplied by 50.6868 percent, or 1.9534 percent.

Section 744K(c)(2)(A)(iii) of the FD&C Act specifies that the portion of the inflation adjustment for non-payroll costs for FY 2025 is equal to the average annual percent change in the Consumer Price Index (CPI) for urban consumers (U.S. City Average; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data, multiplied by the proportion of all non-PC&B costs to total costs of an average FDA FTE for the same period.

Table 3 provides the summary data for the percent change in the specified CPI for U.S. cities. These data are published by the Bureau of Labor Statistics and can be found on its website: *https://data.bls.gov/cgi-bin/surveymost?cu.* The data can be viewed by checking the box marked ''U.S. city average, All items—CUUR0000SA0'' and then selecting ''Retrieve Data.''

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN U.S. CITY AVERAGE CPI

	2021	2022	2023	3-Year average
Annual CPI	270.970	292.655	304.702	
Annual Percent Change	4.6980%	8.0027%	4.1165%	5.6057%

Section 744K(c)(2)(A)(iii) of the FD&C Act specifies that this 5.6057 percent should be multiplied by the proportion of all non-PC&B costs to total costs of an average FTE for the same 3 fiscal years. The proportion of all non-PC&B costs to total costs of an average FDA FTE for FYs 2021 to 2023 is 49.3132 percent (100 percent minus 50.6868 percent equals 49.3132 percent). Therefore, the non-pay adjustment is 5.6057 percent times 49.3132 percent, or 2.7644 percent.

The PC&B component (1.9534 percent) is added to the non-PC&B component (2.7644 percent), for a total inflation adjustment of 4.7178 percent (rounded). Section 744K(c)(2)(A)(i) of the FD&C Act specifies that one is added to that figure, making the inflation adjustment 1.047178.

Section 744K(c)(2)(B) of the FD&C Act provides for this inflation adjustment to be compounded after FY 2015. This factor for FY 2025 (4.7178 percent) is compounded by adding one to it, and then multiplying it by one plus the inflation adjustment factor for FY 2024 (23.9215 percent), as published in the **Federal Register** on July 28, 2023 (88 FR 48878). The result of this multiplication of the inflation factors for the 10 years since FY 2015 (1.047178×1.239215) becomes the inflation adjustment for FY 2025. For FY 2025, the inflation adjustment is 29.7679 percent (rounded). We then add one, making the FY 2025 inflation adjustment factor 1.297679.

2. Small Business Adjustment Factor

Section 744K(c)(3) of the FD&C Act specifies that in addition to the inflation adjustment factor, the establishment fee for non-small businesses is to be further adjusted for a small business adjustment factor. Section 744K(c)(3)(B) of the FD&C Act provides that the small business adjustment factor is the adjustment to the establishment fee for non-small businesses that is necessary to achieve total fees equaling the amount that FDA would have collected if no entity qualified for the small business exception in section 744K(c)(4) of the FD&C Act. Additionally, section 744K(c)(5)(A) states that in establishing the small business adjustment factor for a fiscal year, FDA shall provide for the crediting of fees from the previous year to the next year if FDA overestimated the amount of the small business adjustment factor for such previous fiscal year.

Therefore, to calculate the small business adjustment to the establishment fee for non-small businesses for FY 2025, FDA must estimate: (1) the number of outsourcing facilities that will pay the reduced fee for small businesses for FY 2025 and (2) the total fee revenue it would have collected if no entity had qualified for the small business exception (*i.e.,* if each entity that registers as an outsourcing facility for FY 2025 were to pay the inflation-adjusted fee amount of $19,465).

With respect to (1), FDA estimates that 11 entities will qualify for small business exceptions and will pay the reduced fee for FY 2025. With respect to (2), to estimate the total number of entities that will register as outsourcing facilities for FY 2025, FDA used data submitted by outsourcing facilities through the voluntary registration process, which began in December 2013. Accordingly, FDA estimates that 80 outsourcing facilities, including 11 small businesses, will be registered with FDA in FY 2025.

If the projected 80 outsourcing facilities paid the full inflation-adjusted fee of $19,465, this would result in total revenue of $1,557,200 in FY 2025 ($\$19,465 \times 80$). However, 11 of the entities that are expected to register as outsourcing facilities for FY 2025 are projected to qualify for the small business exception and to pay one-third of the full fee ($\$6,488 \times 11$), totaling $71,368 instead of paying the full fee ($\$19,465 \times 11$), which would total $214,115. This would leave a potential shortfall of $142,747 ($214,115 minus $71,368).

Additionally, section 744K(c)(5)(A) of the FD&C Act states that in establishing the small business adjustment factor for a fiscal year, FDA shall provide for the crediting of fees from the previous year to the next year if FDA overestimated the amount of the small business adjustment factor for such previous fiscal year. FDA has determined that it is appropriate to credit excess fees collected from the last completed fiscal year, due to the inability to conclusively determine the amount of excess fees from the fiscal year that is in progress at the time this calculation is made. This crediting is done by comparing the small business adjustment factor for the last completed fiscal year, FY 2023 ($1,747), to what would have been the small business adjustment factor for FY 2023 ($2,011) if FDA had estimated perfectly.

The calculation for what the small business adjustment would have been if FDA had estimated perfectly begins by determining the total target collections ($15{,}000 \times$ [inflation adjustment factor] $\times$ [number of registrants]). For the most recent complete fiscal year, FY 2023, this was $1,354,548 ($\$17{,}823 \times 76$). The actual FY 2023 revenue from the 76 total registrants (*i.e.,* 65 registrants paying FY 2023 non-small business establishment fee and 11 small business registrants) paying establishment fees is $1,223,846. $1,223,846 is calculated as follows: (FY 2023 Non-Small Business Establishment Fee adjusted for inflation only) $\times$ (total number of registrants in FY 2023 paying Non-Small Business Establishment Fee) + (FY 2023 Small Business Establishment Fee) $\times$ (total number of small business registrants in FY 2023 paying Small Business Establishment Fee). $\$17{,}823 \times 65 + \$5{,}824 \times 11 = \$1{,}223{,}846$. This left a shortfall of $130,702 from the estimated total target collection amount ($1,354,548 minus $1,223,846). This amount ($130,702) divided by the total number of registrants in FY 2023 paying Standard Establishment Fee (65) equals $2,011.

The difference between the small business adjustment factor used in FY 2023 and the small business adjustment factor that would have been used had FDA estimated perfectly is $-\$263$ ($1,747 minus $2,011). The $-\$263$ (rounded to the nearest dollar) is then multiplied by the number of actual registrants who paid the standard fee for FY 2023 (65), which provides us a total collection deficit of $-\$17{,}124$ in FY 2023. No credit will be applied in FY 2025.

Therefore, to calculate the small business adjustment factor for FY 2025, FDA divides the projected shortfall of $142,747 for FY 2025 by 69 (the number of expected non-small businesses for FY 2025), which is $2,069 (rounded to the nearest dollar).

B. FY 2025 Rates for Small Business Establishment Fee, Non-Small Business Establishment Fee, and Reinspection Fee

1. Establishment Fee for Qualified Small Businesses [1]

The amount of the establishment fee for a qualified small business is equal to $15,000 multiplied by the inflation adjustment factor for that fiscal year, divided by 3 (see section 744K(c)(4)(A) and (c)(1)(A) of the FD&C Act). The inflation adjustment factor for FY 2025 is 1.297679. See section II.A.1 of this document for the methodology used to calculate the FY 2025 inflation adjustment factor. Therefore, the establishment fee for a qualified small business for FY 2025 is one third of $19,465, which equals $6,488 (rounded to the nearest dollar).

2. Establishment Fee for Non-Small Businesses

Under section 744K(c) of the FD&C Act, the amount of the establishment fee for a non-small business is equal to $15,000 multiplied by the inflation adjustment factor for that fiscal year, plus the small business adjustment factor for that fiscal year, and plus or minus an adjustment factor to account for over or under collections due to the small business adjustment factor in the prior year. The inflation adjustment factor for FY 2025 is 1.297609. The small business adjustment amount for FY 2025 is $2,069. See section II.A.2 of this document for the methodology used to calculate the small business adjustment factor for FY 2025. Therefore, the establishment fee for a non-small business for FY 2025 is $15,000 multiplied by 1.297679 plus $2,069, which equals $21,534 (rounded to the nearest dollar).

3. Reinspection Fee

Section 744K(c)(1)(B) of the FD&C Act provides that the amount of the FY 2025 reinspection fee is equal to $15,000, multiplied by the inflation adjustment factor for that fiscal year. The inflation adjustment factor for FY 2025 is 1.297679. Therefore, the reinspection fee for FY 2025 is $15,000 multiplied by 1.297679, which equals $19,465 (rounded to the nearest dollar). There is no reduction in this fee for small businesses.

C. Summary of FY 2025 Fee Rates

TABLE 4—OUTSOURCING FACILITY FEES

Qualified Small Business Establishment Fee	$6,488
Non-Small Business Establishment Fee	21,534
Reinspection Fee	19,465

III. Fee Payment Options and Procedures

A. Establishment Fee

Once an entity submits registration information and FDA has determined that the information is complete, the entity will incur the annual establishment fee. FDA will send an invoice to the entity, via email to the email address indicated in the registration file. The invoice will contain information regarding the obligation incurred, the amount owed, and payment procedures. A facility will not be registered as an outsourcing facility until it has paid the annual establishment fee under section 744K of the FD&C Act. Accordingly, it is important that facilities seeking to operate as outsourcing facilities pay all fees immediately upon receiving an invoice. If an entity does not pay the full invoiced amount within 15 calendar days after FDA issues the invoice, FDA will consider the submission of registration information to have been withdrawn and adjust the invoice to reflect that no fee is due.

Outsourcing facilities that registered in FY 2024 and wish to maintain their status as an outsourcing facility in FY 2025 must register during the annual registration period that lasts from October 1, 2024, to December 31, 2024. Failure to register and complete payment by December 31, 2024, will result in a loss of status as an outsourcing facility on January 1, 2025. Entities should submit their registration information no later than December 10, 2024, to allow enough time for review of the registration information, invoicing, and payment of fees before the end of the registration period.

B. Reinspection Fee

FDA will issue invoices for each reinspection after the conclusion of the reinspection, via email to the email address indicated in the registration file or via regular mail if email is not an option. Payments must be made within 30 days of the invoice date.

C. Fee Payment Procedures

1. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay.* (*Note:* only full payments are accepted. No partial payments can be made online.) Once you search for your invoice, click ''Pay Now'' to be redirected to *Pay.gov.* Electronic payment options are based on the balance due. Payment by credit card is available for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

2. If a check, bank draft, or postal money order is submitted, make it payable to the order of the Food and Drug Administration and include the user fee ID number to ensure that the payment is applied to the correct fee(s). Payments can be mailed to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000. If a check, bank draft, or money order is to be sent by a courier that requests a street address, the courier should deliver your payment to: U.S. Bank, Attention: Government Lockbox 979033, 3180 Rider Trail S, Earth City, MO 63045. (*Note:* This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact the U.S. Bank at 800–495–4981. This telephone number is only for questions about courier delivery). Please make sure that the FDA post office box number (P.O. Box 979033) is written on the check, bank draft, or postal money order.

3. For payments made by wire transfer, the invoice number must be included. Without the invoice number, the payment may not be applied. Regarding reinspection fees, if the payment amount is not applied, the invoice amount will be referred to collections. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required that the outsourcing facility add that amount to the payment to ensure that the invoice is paid in full. Use the following account information when sending a wire transfer: U.S. Dept of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

[1] To qualify for a small business reduction of the FY 2025 establishment fee, entities had to submit their exception requests by April 30, 2024. *See* section 744K(c)(4)(B) of the FD&C Act. The time for requesting a small business exception for FY 2025 has now passed. An entity that wishes to request a small business exception for FY 2026 should consult section 744K(c)(4) of the FD&C Act and section III.D of FDA's guidance for industry entitled ''Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act,'' which can be accessed on FDA's website at *https://www.fda.gov/media/136683/download.*

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16876 Filed 7–30–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0007]

Prescription Drug User Fee Rates for Fiscal Year 2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the rates for prescription drug user fees for fiscal year (FY) 2025. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Prescription Drug User Fee Amendments of 2022 (PDUFA VII), authorizes FDA to collect application fees for certain applications for the review of human drug and biological products and prescription drug program fees for certain approved products. This notice establishes the fee rates for FY 2025.

DATES: These fees apply to the period from October 1, 2024, through September 30, 2025.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave, Silver Spring, MD 20903, 240–402–4989; and the User Fee Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Sections 735 and 736 of the FD&C Act (21 U.S.C. 379g and 379h) establish two different kinds of user fees. Fees are assessed as follows: (1) application fees are assessed on certain types of applications for the review of human drug and biological products and (2) prescription drug program fees are assessed on certain approved products (section 736(a) of the FD&C Act). The statute also includes conditions under which such fees may be waived or reduced (section 736(d) of the FD&C Act), or under which fee exceptions, refunds, or exemptions apply (sections 736(a)(1)(C) through (H), 736(a)(2)(B) through (C), and 736(k) of the FD&C Act).

For FY 2023 through FY 2027, the base revenue amounts for the total revenues from all PDUFA fees are established by PDUFA VII. The base revenue amount for FY 2025 is $1,358,764,346. The FY 2025 base revenue amount is adjusted for inflation, strategic hiring and retention, and for the resource capacity needs for the process for the review of human drug applications (the capacity planning adjustment (CPA)). This amount is further adjusted to include the additional dollar amount as specified in the statute (see section 736(b)(1)(G) of the FD&C Act) to provide for additional full-time equivalent (FTE) positions to support PDUFA VII initiatives. If applicable, an operating reserve adjustment is added to provide sufficient operating reserves of carryover user fees. The amount from the preceding adjustments is then adjusted to provide for additional direct costs to fund PDUFA VII initiatives. Fee amounts are to be established each year so that revenues from application fees provide 20 percent of the total revenue, and prescription drug program fees provide 80 percent of the total revenue (see section 736(b)(2) of the FD&C Act).

This document provides fee rates for FY 2025 for an application requiring covered clinical data [1] ($4,310,002), for an application not requiring covered clinical data ($2,155,001), and for the prescription drug program fee ($403,889). These fees are effective on October 1, 2024, and will remain in effect through September 30, 2025. For applications that are submitted on or after October 1, 2024, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2025

The base revenue amount for FY 2025 is $1,358,764,346 (see section 736(b)(1)(A) and (b)(3) of the FD&C Act). This amount is prior to any adjustments made for inflation, the strategic hiring and retention adjustment, CPA, additional dollar amount, operating reserve adjustment (if applicable), and additional direct costs (see section 736(b)(1) of the FD&C Act).

A. FY 2025 Statutory Fee Revenue Adjustments for Inflation

PDUFA VII specifies that the $1,358,764,346 is to be adjusted for inflation increases for FY 2025 using two separate adjustments: one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 736(c)(1) of the FD&C Act).

The component of the inflation adjustment for payroll costs is the average annual percent change in the cost of all PC&B paid per FTE positions at FDA for the first 3 of the preceding 4 fiscal years, multiplied by the proportion of PC&B costs to total FDA costs of the process for the review of human drug applications for the first 3 of the preceding 4 fiscal years (see section 736(c)(1)(A) and (B)(i) of the FD&C Act).

Table 1 summarizes the actual cost and FTE data for the specified fiscal years, provides the percent changes from the previous fiscal years, and provides the average percent changes over the first 3 of the 4 fiscal years preceding FY 2025. The 3-year average is 3.8539 percent.

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGES

	2021	2022	2023	3-Year average
Total PC&B	$3,039,513,000	$3,165,477,000	$3,436,513,000	.....
Total FTEs	18,501	18,474	18,729	.....
PC&B per FTE	$164,289	$171,348	$183,486	.....
Percent Change from Previous Year	0.1811%	4.2967%	7.0838%	3.8539%

The statute specifies that this 3.8539 percent be multiplied by the proportion of PC&B costs to the total FDA costs of the process for the review of human drug applications. Table 2 shows the PC&B and the total obligations for the process for the review of human drug applications for the first 3 of the preceding 4 fiscal years.

[1] As used herein, ''covered clinical data'' is ''clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness [that] are required for approval'' (see section 736(a)(1)(A) of the FD&C Act).

TABLE 2—PC&B AS A PERCENT OF TOTAL COST OF THE PROCESS FOR THE REVIEW OF HUMAN DRUG APPLICATIONS

	2021	2022	2023	3-Year average
Total PC&B (proportion of costs)	$959,387,333	$931,302,114	$1,040,590,183	
Total Costs	$1,499,064,056	$1,480,601,875	$1,686,733,841	
PC&B percent	63.9991%	62.9002%	61.6926%	62.8640%

The payroll adjustment is 3.8539 percent from table 1 multiplied by 62.8640 percent from table 2 resulting in 2.4227 percent.

The statute specifies that the portion of the inflation adjustment for non-payroll costs is the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Arlington-Alexandria, DC-VA-MD-WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 735(6)) for the first 3 years of the preceding 4 fiscal years (see section 736(c)(1)(A) and (B)(ii)). Table 3 provides the summary data for the percent changes in the specified CPI for the Washington-Arlington-Alexandria area.[2]

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN CPI FOR WASHINGTON-ARLINGTON-ALEXANDRIA AREA

	2021	2022	2023	3-Year average
Annual CPI	277.73	296.12	305.32	
Annual Percent Change	3.9568%	6.6212%	3.1069%	4.5616%

The statute specifies that this 4.5616 percent be multiplied by the proportion of all costs other than PC&B to total costs of the process for the review of human drug applications obligated. Because 62.8640 percent was obligated for PC&B (as shown in table 2), 37.1360 percent is the portion of costs other than PC&B (100 percent minus 62.8640 percent equals 37.1360 percent). The non-payroll adjustment is 4.5616 percent times 37.1360 percent, or 1.6940 percent.

Next, we add the payroll adjustment (2.4227 percent) to the non-payroll adjustment (1.6940 percent), for a total inflation adjustment of 4.1167 percent (rounded) for FY 2025.

We then multiply the base revenue amount for FY 2025 ($1,358,764,346) by 4.1167 percent, which produces an inflation adjustment amount of $55,936,252. Adding this amount to the base revenue amount yields an inflation-adjusted base revenue amount of $1,414,700,598.

TABLE 4—BASE REVENUE AMOUNT AND SECTION 736(c)(1) ADJUSTMENT AMOUNT

Fee	Amount
Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	$1,358,764,346
Inflation Adjustment (section 736(c)(1) of the FD&C Act)	55,936,252
Revenue Amount after Adjustments in sections 736(c)(1) of the FD&C Act	1,414,700,598

B. FY 2025 Strategic Hiring and Retention Adjustment

For each fiscal year, after the annual base revenue established in section II is adjusted for inflation in accordance with section II.A, the statute directs FDA to further increase the fee revenue and fees to support strategic hiring and retention. For FY 2025, this amount is $4,000,000 (see section 736(c)(2)(A) of the FD&C Act).

TABLE 5—BASE REVENUE AMOUNT AND SECTION 736(c)(1) THROUGH (2) ADJUSTMENT AMOUNTS

Fee	Amount
Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	$1,358,764,346
Inflation Adjustment (section 736(c)(1) of the FD&C Act)	55,936,252
Strategic Hiring and Retention Adjustment (section 736(c)(2) of the FD&C Act)	4,000,000
Revenue Amount after Adjustments in sections 736(c)(1) and (2) of the FD&C Act	1,418,700,598

C. FY 2025 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that after the base revenue amount for FY 2025 of $1,358,764,346 has been adjusted as described in sections II.A and II.B, this amount shall be further adjusted to reflect changes in the resource capacity needs for the process of human drug application reviews (see section 736(c)(3) of the FD&C Act). Following a process agreed upon by FDA and

[2] The data are published by the Bureau of Labor Statistics and can be found on its website at: *https://data.bls.gov/pdq/SurveyOutputServlet?data_tool=dropmap&series_id=CUURS35ASA0,CUUSS35ASA0.*

industry during PDUFA VI reauthorization discussions and subsequently required in statute, FDA established a new CPA methodology and first applied it in the setting of FY 2021 fees. The establishment of this methodology is described in the **Federal Register** of August 3, 2020 (85 FR 46651). This methodology includes a continuous, iterative improvement approach, under which the Agency intends to refine its data and estimates for the core review activities to improve their accuracy over time. An adjustment for workload has been a critical aspect of the PDUFA program since PDUFA III in FY 2003 as it enables the program to adjust to shifts in review workload resulting from industry submissions to the Agency. The annual adjustment process allows greater accuracy than would be expected if workload adjustments were fixed at the start of the reauthorization period. The capacity planning adjustment is an evolution of the PDUFA workload adjuster and was implemented through a process agreed to by FDA and industry during PDUFA VI. The capacity planning adjustment builds on the concepts of the workload adjuster but realizes enhancements including the use of leading indicators of workload, use of full-time reporting data, the introduction of a managerial adjustment process as an internal check on the reasonableness of any adjustment, outputs measured in full-time equivalent employees, and the incorporation of adjustments into the base revenue amounts to ensure sustainability of payroll to support any new hires.

Improvements adopted for the FY 2025 CPA include the incorporation of hiring plans and attrition estimates within the capacity calculation. In prior years, the impacts of expected hiring on the review capacity of the program were considered within a step in the managerial adjustment process. The FY 2025 resource capacity number includes an estimate of the onboard capacity for direct review work, as well as an estimate of the additional capacity that would be provided from any additional positions expected to be added through the course of FY 2024. No additional deduction for positions planned to be added prior to the end of FY 2024 then need to be deducted within the managerial adjustment moving forward. Because of this change, the resource capacity numbers presented in this **Federal Register** Notice cannot be directly compared to those provided in prior years' fee-setting notices.

The CPA methodology includes four steps:

1. *Forecast workload volumes:* predictive models estimate the volume of workload for the upcoming FY.

2. *Forecast the resource needs:* forecast algorithms are generated utilizing time reporting data. These algorithms estimate the required demand in FTEs [3] for direct review related effort. This is then compared to current available resources for the direct review related workload.

The current available resources for the direct review related workload (presented as current resource capacity below) is a measure of the percentage of time onboard staff report to direct review workload activities, plus a percentage of the additional positions that are targeted to be hired within the remainder of FY 2024. Of note, the current resource capacity is not directly a function of the change in submission volume from one year to the next, but rather a summation of the percent of total staff time plus vacancies estimated to be available for direct review work. As time reporting is a direct input into the current review capacity calculations, the current review capacity may be impacted by factors such as shifts in the level of effort required for review work, staff reporting time exceed their tour of duty, or other shifts impacting the workload of the program.

3. *A managerial adjustment to assess the resource forecast in the context of additional internal factors:* program leadership examines operational, financial, and resourcing data to assess whether FDA will be able to utilize additional funds during the FY, and whether the funds are required to support additional review capacity. FTE amounts are adjusted, if needed.

The managerial adjustment process includes consideration of prior years' forecast performance, future year considerations, hiring capacity considerations, and other relevant considerations. While in some years FDA has over forecasted some submission volumes, it has managerially adjusted down the FTE delta considerably to take relatively small adjustments. For example, in FY23 CDER had a forecasted delta of 151 FTE but only took an adjustment for 27 FTE.

4. *Convert the FTE need to dollars:* utilizing FDA's fully loaded FTE cost model, the final feasible FTEs are converted to an equivalent dollar amount. The fully loaded FTE cost model is higher in FY 2025 than in prior years primarily due to the impact of inflation.

To determine the FY 2025 CPA, FDA calculated a CPA for the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) individually. The final center-level results were then combined to determine the total FY 2025 PDUFA CPA. The following section outlines the major components of each center's FY 2025 PDUFA CPA.

Table 6 summarizes the forecasted workload volumes for CDER in FY 2025 based on predictive models, as well as historical actuals from FY 2023 for comparison.

TABLE 6—CDER ACTUAL FY 2023 WORKLOAD VOLUMES AND PREDICTED FY 2025 WORKLOAD VOLUMES

Workload category	FY 2023 actuals	FY 2025 predictions
Efficacy Supplements	232	233
Labeling Supplements	917	1,191
Manufacturing Supplements	2,372	2,320
NDA/BLA[1] Original	145	133
PDUFA Industry Meetings (including WROs[2])	3,570	3,783
Active Commercial INDs[3]	9,882	10,788
Annual Reports[4]	3,465	3,556
PMR/PMC-Related Documents[4]	1,696	1,605
Active REMS Programs[4 5]	23	23

[1] New drug applications (NDA)/biological license applications (BLA).
[2] Written responses only (WROs).

[3] Full-time equivalents refer to a paid staff year, rather than a count of individual employees.

[3] For purpose of the CPA, this is defined as an active commercial investigational new drug (IND) for which a document has been received in the past 18 months.
[4] Represents activities related to the review of materials submitted to the application file after approval.
[5] Represents the percentage of active risk evaluation and management strategy (REMS) programs proportional to Center and User Fee by total number of qualifying products with the exclusion of the Opioid Shared System.

Utilizing the resource forecast algorithms, the forecasted workload volumes for FY 2025 were then converted into estimated FTE needs for CDER's PDUFA direct review related work. The resulting expected FY 2025 FTE need for CDER was compared to current resource capacity for direct review related work to determine the FY 2025 resource delta, as summarized in table 7. Hiring and inclusion of hiring plans into the current resource capacity increased the value over prior years.

TABLE 7—CDER FY 2025 PDUFA RESOURCE DELTA

Center	Current resource capacity	FY 2025 resource forecast	Predicted FY 2025 FTE delta
CDER	2,055	2,078	23

The projected 23 FTEs delta was then assessed by FDA through the managerial adjustment process to ensure that any fee adjustment is only made for resources that can be utilized in the fiscal year and for which funds are required to support additional review capacity. FDA observes that the CDER delta has been declining each year as measured by the CPA. This indicates that resources are coming into approximate alignment with the workload as measured by the CPA. The adjusted 23 FTE delta would represent about 1 percent growth above the current resource capacity of 2,055. FDA notes, however, that through the managerial adjustment process it was observed that review work related to rare and/or orphan disease conditions has been growing disproportionality. After consideration of additional negotiated positions to be added in FY 2025 that overlap with the scope of the CPA (3), and other factors related to the CPA, CDER is adjusting the FTE delta to 4 FTE. These 4 FTEs positions will be allocated in a manner to address the growth in workload resulting from rare and/or orphan disease conditions. The FY 2025 PDUFA CPA for CDER is therefore $1,522,700, as summarized in table 8.

TABLE 8—CDER FY 2025 PDUFA CPA

Center	Additional FTEs for FY 2025	Cost for each additional FTE	CDER FY 2025 PDUFA CPA
CDER	4	$380,675	$1,522,700

To calculate the FY 2025 PDUFA CPA for CBER, FDA followed the approach outlined above. Table 9 summarizes the forecasted workload volumes for CBER in FY 2025 as well as the corresponding historical actuals from FY 2023 for comparison.

TABLE 9—CBER ACTUAL FY 2023 WORKLOAD VOLUMES AND PREDICTED FY 2025 WORKLOAD VOLUMES

Workload category	FY 2023 actuals	FY 2025 predictions
Efficacy Supplements	25	30
Labeling Supplements	58	62
Manufacturing Supplements	752	767
NDA/BLA[1] Original	14	15
PDUFA Industry Meetings (including WROs[2])	756	778
Active Commercial INDs[3]	1,829	2,027
Annual Reports[4]	314	319
PMR/PMC-Related Documents[4]	143	188
Active REMS Programs[4 5]	2	2

[1] New drug applications (NDA)/biological license applications (BLA).
[2] Written responses only (WROs).
[3] For purpose of the CPA, this is defined as an active commercial investigational new drug (IND) for which a document has been received in the past 18 months.
[4] Represents activities related to the review of materials submitted to the application file after approval.
[5] Represents the percentage of active REMS programs proportional to Center and User Fee by total number of qualifying products with the exclusion of the Opioid Shared System.

The forecasted CBER PDUFA workload for FY 2025 was then converted into expected FTE resources and compared to current resource capacity for PDUFA direct review work, as summarized in table 10. Hiring and inclusion of hiring plans into the current resource capacity increased the value over prior years.

TABLE 10—CBER FY 2025 PDUFA RESOURCE DELTA

Center	Current resource capacity	FY 2025 resource forecast	Predicted FY 2025 FTE delta
CBER	492	507	15

The projected 15 FTEs delta for CBER was also assessed by FDA through the managerial adjustment process to ensure the need and/or feasibility of obtaining the additional resources. After considering additional negotiated positions to be added in FY 2025 that overlap with the scope of the CPA (12), current statuses for PDUFA vacancies, and other factors related to the CPA, CBER adjusted the FTE delta to 0 additional FTEs for FY 2025. The FY 2025 CPA for CBER is therefore $0, as summarized in table 11.

TABLE 11—CBER FY 2025 PDUFA CPA

Center	Additional FTEs for FY 2025	Cost for each additional FTE	CBER FY 2025 CPA
CBER	0	$372,270	$0

The CDER and CBER CPA amounts were then added together to determine the PDUFA CPA for FY 2025 of $1,522,700, as outlined in table 12. FDA will track the utilization of the CPA funds to ensure they are supporting the organizational components engaged in PDUFA direct review work to enhance resources and expand staff capacity and capability. Should FDA be unable to utilize any amounts of the CPA funds during the fiscal year, it will not spend those funds and the unspent funds will be transferred to the carryover balance at the end of the fiscal year.

TABLE 12—FY 2025 PDUFA CPA

Center	FY 2025 PDUFA CPA
CDER	$1,522,700
CBER	0
Total	1,522,700

TABLE 13—BASE REVENUE AMOUNT AND SECTION 736(c)(1) THROUGH (3) ADJUSTMENT AMOUNTS

Fee	Amount
Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	$1,358,764,346
Inflation Adjustment (section 736(c)(1) of the FD&C Act)	55,936,252
Strategic Hiring and Retention Adjustment (section 736(c)(2) of the FD&C Act)	4,000,000
Capacity Planning Adjustment (section 736(c)(3) of the FD&C Act)	1,522,700
Revenue Amount after Adjustments in sections 736(c)(1), (2), and (3) of the FD&C Act	1,420,223,298

D. FY 2025 Statutory Fee Revenue Adjustments for Additional Dollar Amounts

PDUFA VII provides an additional dollar amount for each of the 5 fiscal years covered by PDUFA VII for additional FTEs to support enhancements outlined in the PDUFA VII commitment letter. The additional dollar amount for FY 2025 as outlined in statute is $14,154,169 (see section 736(b)(1)(G)(iii) of the FD&C Act). This amount will be added to the total FY 2025 PDUFA VII revenue amount.

TABLE 14—BASE REVENUE AMOUNT AND SECTION 736(c)(1) THROUGH (3) ADJUSTMENT AMOUNTS

Fee	Amount
Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	$1,358,764,346
Inflation Adjustment (section 736(c)(1) of the FD&C Act)	55,936,252
Strategic Hiring and Retention Adjustment (section 736(c)(2) of the FD&C Act)	4,000,000
Capacity Planning Adjustment (section 736(c)(3) of the FD&C Act)	1,522,700
Additional Dollar Amounts Adjustment (section 736(b)(1)(G) of the FD&C Act)	14,154,169
Cumulative Revenue Amount after Adjustments in sections 736(c)(1), (2), and (3) of the FD&C Act	1,434,377,467

E. FY 2025 Statutory Fee Revenue Adjustments for Operating Reserve

PDUFA VII provides for an operating reserve adjustment that may result in an increase or decrease in fee revenue and fees for a given FY (see section 736(c)(4) of the FD&C Act). For FY 2025, FDA is required to further increase fee revenue and fees if an adjustment is necessary to provide for at least 10 weeks of operating reserves of carryover user fees (see section 736(c)(4)(A)(iii) of the FD&C Act). If FDA has carryover balances of user fees in excess of 14 weeks of operating reserves, FDA is required to decrease fee revenue and fees to provide for not more than 14 weeks of operating reserves of carryover user fees (see section 736(c)(4)(B) of the FD&C Act).

To determine the dollar amounts for the 10-week and 14-week operating reserve thresholds, the adjustments (inflation, strategic hiring and retention, capacity planning, and additional dollar amount) discussed in sections II.A, II.B, II.C, and II.D are applied to the FY 2025 base revenue (see section 736(c)(4)(A) of the FD&C Act), resulting in $1,434,377,467. This amount is then divided by 52 to generate the 1-week operating amount of $27,584,182. The 1-week operating amount is then multiplied by 10 and 14. This results in a 10-week threshold amount of $275,841,821 and a 14-week threshold amount of $386,178,549.

To determine the FY 2024 end-of-year operating reserves of carryover user fees, the Agency assessed the operating reserve of carryover fees at the end of June 2024 and forecasted collections and obligations in the fourth quarter of FY 2024 combined. This provides an estimated end-of-year FY 2024 operating reserve of carryover user fees of $270,834,409, which equates to 9.82 weeks of operations.[4]

Because the estimated FY 2024 end-of-year operating reserves of carryover user fees does not exceed the 14-week threshold amount, FDA will not reduce the FY 2025 fees or fee revenue. However, because the estimated FY 2024 end-of-year operating reserves of carryover user fees of $270,834,409 is below the 10-week threshold amount of $275,841,821, FDA will apply an operating reserve adjustment of $5,007,412 to increase the fee revenue and fees for FY 2025.

TABLE 15—BASE REVENUE AMOUNT AND SECTION 736(c)(1) THROUGH (4) ADJUSTMENT AMOUNTS

Fee	Amount
Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	$1,358,764,346
Inflation Adjustment (section 736(c)(1) of the FD&C Act)	55,936,252
Strategic Hiring and Retention Adjustment (section 736(c)(2) of the FD&C Act)	4,000,000
Capacity Planning Adjustment (section 736(c)(3) of the FD&C Act)	1,522,700
Additional Dollar Amounts Adjustment (section 736(b)(1)(G) of the FD&C Act)	14,154,169
Operating Reserve Adjustment (section (736(c)(4) of the FD&C Act)	5,007,412
Cumulative Revenue Amount after Adjustments in sections 736(c)(1), (2), (3), and (4) of the FD&C Act	1,439,384,879

F. FY 2025 Statutory Fee Revenue Adjustments for Additional Direct Cost

PDUFA VII specifies that an additional direct cost of $39,355,553 is to be added to the total FY 2025 PDUFA revenue amount (see section 736(c)(5)(ii) of the FD&C Act). With respect to target revenue for FY 2025, adding the additional direct cost amount of $39,355,553 to the inflation, strategic hiring and retention, CPA, additional dollar amount, and operating reserve adjustment results in the total revenue amount of $1,478,740,000 (rounded to the nearest thousand dollars).

TABLE 16—TOTAL ESTIMATED ADJUSTED REVENUE AMOUNT

Fee	Amount
Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	$1,358,764,346
Inflation Adjustment (section 736(c)(1) of the FD&C Act)	55,936,252
Strategic Hiring and Retention Adjustment (section 736(c)(2)(B) of the FD&C Act)	4,000,000
Capacity Planning Adjustment (section 736(c)(3) of the FD&C Act)	1,522,700
Additional Dollar Amounts Adjustment (section 736(b)(1)(G) of the FD&C Act)	14,154,169
Operating Reserve Adjustment (section (736(c)(4) of the FD&C Act)	5,007,412
Additional Direct Cost Adjustment (section 736(c)(5) of the FD&C Act)	39,355,553
Cumulative Revenue Amount after Adjustments in sections 736(c)(1), (2), (3), (4), and (5) of the FD&C Act	1,478,740,432
Cumulative Revenue Amount after Adjustments in sections 736(c)(1), (2), (3), (4), and (5) of the FD&C Act (rounded to the nearest thousand)	1,478,740,000

III. Application Fee Calculations

A. Application Fee Revenues and Application Fees

Application fees will be set to generate 20 percent of the total revenue amount, amounting to $295,748,000 in FY 2025.

B. Estimate of the Number of Fee-Paying Applications and Setting the Application Fees

FDA has estimated the total number of fee-paying full application equivalents (FAEs) it expects to receive during the next fiscal year by averaging the number of fee-paying FAEs received in the ten most recently completed fiscal years. For FY 2025 fee setting, the 10 relevant fiscal years are FY 2014–2023. While a 3-year average has been used in recent years' fee setting FRNs, FDA is using a 10-year average for FY 2025 to address volatility in the number of FAEs. Prior year FAE totals are

[4] For purposes of the operating reserve adjustment under PDUFA VII, the operating reserve of carryover user fees includes only user fee funds that are available for obligation. FDA excludes from the operating reserve of carryover user fee funds that were collected prior to 2010 and that are held by FDA, but which are considered unavailable for obligation due to lack of an appropriation ($78,850,995).

updated annually to reflect refunds and waivers processed after the close of the fiscal year.[5]

In estimating the number of fee-paying FAEs, an application requiring covered clinical data[6] counts as one FAE. An application not requiring covered clinical data counts as one-half of an FAE. An application that is withdrawn before filing, or refused for filing, counts as one-fourth of an FAE if the applicant initially paid a full application fee, or one-eighth of an FAE if the applicant initially paid one-half of the full application fee amount.

As table 17 shows, the average number of fee-paying FAEs received annually in FY 2014 through FY 2023 is 68.619. FDA will set fees for FY 2025 based on this estimate as the number of full application equivalents that will be subject to fees.

TABLE 17—FEE-PAYING FAEs

	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	10-year average
Fee-Paying FAEs	73.375	81.956	70.483	79.750	68.875	80.000	56.750	78.875	45.125	51.000	68.619

Note: Prior year FAE totals are updated annually to reflect refunds and waivers processed after the close of the fiscal year.

The FY 2025 application fee is estimated by dividing the average number of full applications that paid fees from FY 2014 through FY 2023, 68.619, into the fee revenue amount to be derived from application fees in FY 2025, $295,748,000. The result is a fee of $4,310,002 per full application requiring clinical data, and $2,155,001 per application not requiring clinical data.

IV. Fee Calculation for Prescription Drug Program Fees

PDUFA VII assesses prescription drug program fees for certain prescription drug products. Program fees will be set to generate 80 percent of the total target revenue amounting to $1,182,992,000 in FY 2025.

An applicant will not be assessed more than five program fees for a FY for prescription drug products identified in a single approved NDA or BLA (see section 736(a)(2)(C) of the FD&C Act). Applicants are assessed a program fee for a FY for user fee eligible prescription drug products identified in a human drug application approved as of October 1 of such FY. Additionally, applicants are assessed a program fee for a product that is not a prescription drug product on October 1 because it is included in the discontinued section of the Orange Book or the CDER/CBER Billable Biologics List on that date, if the product becomes a fee-eligible prescription drug product during the FY.

FDA estimates 3,049 program fees will be invoiced in FY 2025 before factoring in waivers, refunds, exceptions, and exemptions. FDA approximates that there will be 81 waivers and refunds granted. Additionally, FDA approximates that another 39 program fees will be exempted in FY 2025 based on the orphan drug exemption in section 736(k) of the FD&C Act.

FDA estimates 2,929 program fees in FY 2025, after allowing for an estimated 120 waivers and reductions, including the orphan drug exemptions, excepted and exempted fee-liable products. The FY 2025 prescription drug program fee rate is calculated by dividing the adjusted total revenue from program fees ($1,182,992,000) by the estimated 2,929 program fees, resulting in a FY 2025 program fee of $403,889 (rounded to the nearest dollar).

V. Fee Schedule for FY 2025

The fee rates for FY 2025 are displayed in table 18.

TABLE 18—FEE SCHEDULE FOR FY 2025

Fee category	Fee rates for FY 2025
Application:	
Requiring clinical data	$4,310,002
Not requiring clinical data	2,155,001
Program	403,889

VI. Fee Payment Options and Procedures

A. Application Fees

The appropriate application fee established in the new fee schedule must be paid for any application subject to fees under PDUFA VII that is submitted on or after October 1, 2024. Payment must be made in U.S. currency by electronic check, check, bank draft, wire transfer, or U.S. postal money order payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express).

FDA has partnered with the U.S. Department of the Treasury to use *Pay.gov*, a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on FDA's website after completing the Prescription Drug User Fee Cover Sheet and generating the user fee ID number. Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* (*Note:* only full payments are accepted. No partial payments can be made online). Once an invoice is located, ''Pay Now'' should be selected to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

If a check, bank draft, or postal money order is submitted, make it payable to the order of the Food and Drug Administration and include the user fee ID number to ensure that the payment is applied to the correct fee(s). Payments can be mailed to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197–9000. If a check, bank draft, or money order is to be sent by a courier that requests a street address, the courier should deliver your payment to: U.S. Bank, Attention: Government Lockbox 979107, 3180 Rider Trail S, Earth City, MO 63045. (*Note:* This U.S. Bank address is for courier delivery only). If you have any questions concerning courier delivery, contact the U.S. Bank at 800–495–4981. This phone number is designated for courier use only and is not intended for payment and billing inquiries. Please make sure that the FDA post office box number (P.O. Box 979107) is written on the

[5] In the PDUFA fee setting FRNs for FYs 2023 and 2024, this adjustment for refunds was erroneously excluded, resulting in an overstatement of the historical FAE data.

[6] As defined in section 736(a)(1)(A)(i) of the FD&C Act.

check, bank draft, or postal money order.

For payments made by wire transfer, include the unique user fee ID number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID number, the payment may not be applied, which could result in FDA not filing an application and other penalties. Note: the originating financial institution may charge a wire transfer fee, especially for international wire transfers. Applicable wire transfer fees must be included with payment to ensure fees are paid in full. Questions about wire transfer fees should be addressed to the financial institution. The account information for wire transfers is as follows: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

B. Prescription Drug Program Fees

FDA will issue invoices and payment instructions for FY 2025 program fees under the new fee schedule in August 2024. Under section 736(a)(2)(A)(i) of the FD&C Act, prescription drug program fees are due on October 1, 2024.

FDA will issue invoices in December 2025 for products that qualify for FY 2025 program fee assessments after the October 2024 billing.

C. Fee Waivers and Refunds

To qualify for consideration for a waiver or reduction under section 736(d) of the FD&C Act, an exemption under section 736(k) of the FD&C Act, or the return of an application or program fee paid under section 736 of the FD&C Act, including if the fee is claimed to have been paid in error, a person must submit to FDA a written request justifying such waiver, reduction, exemption or return not later than 180 days after such fee is due (section 736(i) of the FD&C Act). A request submitted under this paragraph must include any legal authorities under which the request is made.

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16875 Filed 7–30–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3383]

Food Safety Modernization Act Third-Party Certification Program User Fee Rate for Fiscal Year 2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the fiscal year (FY) 2025 annual fee rate for recognized accreditation bodies and accredited certification bodies, and the initial and renewal fee rate for accreditation bodies applying to be recognized in the third-party certification program that is authorized by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA). We are also announcing the fee rate for certification bodies that are applying to be directly accredited by FDA.

DATES: The fees apply to the period from October 1, 2024, through September 30, 2025.

FOR FURTHER INFORMATION CONTACT:

For Questions Related to FSMA Program Fees: FSMAFeeStaff@fda.hhs.gov.

For Questions Related to This Notice: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave, Silver Spring, MD 20903, 240–402–4989; or the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 307 of FSMA (Pub. L. 111–353), Accreditation of Third-Party Auditors, amended the FD&C Act to create a new provision, section 808, under the same name. Section 808 of the FD&C Act (21 U.S.C. 384d) directs FDA to establish a program for accreditation of third-party certification bodies [1] conducting food safety audits and issuing food and facility certifications to eligible foreign entities (including registered foreign food facilities) that meet our applicable requirements. Under this provision, we established a system for FDA to recognize accreditation bodies to accredit certification bodies, except for limited circumstances in which we may directly accredit certification bodies to participate in the third-party certification program.

Section 808(c)(8) of the FD&C Act directs FDA to establish a reimbursement (user fee) program by which we assess fees and require reimbursement for the work FDA performs to establish and administer the third-party certification program under section 808 of the FD&C Act. The user fee program for the third-party certification program was established by a final rule entitled ''Amendments to Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications To Provide for the User Fee Program'' (81 FR 90186, December 14, 2016).

The FSMA FY 2025 third-party certification program user fee rate announced in this notice is effective on October 1, 2024 and will remain in effect through September 30, 2025.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2025

FDA must estimate its costs for each activity in order to establish fee rates for FY 2025. In each year, the costs of salary (or personnel compensation) and benefits for FDA employees account for between 50 and 60 percent of the funds available to, and used by, FDA. Almost all the remaining funds (operating funds) available to FDA are used to support FDA employees by paying for rent, travel, utility, information technology, and other operating costs.

A. Estimating the Full Cost per Direct Work Hour in FY 2025

Full-time Equivalent (FTE) reflects the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered ''hours worked'' for purposes of defining FTE employment.

In general, the starting point for estimating the full cost per direct work hour is to estimate the cost of an FTE or paid staff year. Calculating an Agency-wide total cost per FTE requires three primary cost elements: payroll, non-payroll, and rent.

We have used an average of past year cost elements to predict the FY 2025

[1] For the reasons explained in the third-party certification final rule (80 FR 74570 at 74578–74579, November 27, 2015), and for consistency with the implementing regulations for the third-party certification program in 21 CFR parts 1, 11, and 16, this notice uses the term ''third-party certification body'' rather than the term ''third-party auditor'' used in section 808(a)(3) of the FD&C Act.

cost. The FY 2025 FDA-wide average cost for payroll (salaries and benefits) is $213,556; non-payroll (including equipment, supplies, information technology, general and administrative overhead) is $131,739; and rent (including cost allocation analysis and adjustments for other rent and rent-related costs) is $23,750 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, non-payroll, and rent, brings the FY 2025 average fully supported cost to $369,046 [2] per FTE, excluding travel costs. FDA will use this base unit fee in determining the hourly fee rate for third-party certification user fees for FY 2025 prior to including travel costs as applicable for the activity.

To calculate an hourly rate, FDA must divide the FY 2025 average fully supported cost of $369,046 per FTE by the average number of supported direct FDA work hours in FY 2023 (the last FY for which data are available). See table 1.

TABLE 1—SUPPORTED DIRECT FDA WORK HOURS IN A PAID STAFF YEAR IN FY 2023

Total number of hours in a paid staff year	2,080
Less:	
11 paid holidays	−88
20 days of annual leave	−160
10 days of sick leave	−80
12.5 days of training	−100
22 days of general administration	−176
26.5 days of travel	−212
2 hours of meetings per week	−104
Net Supported Direct FDA Work Hours Available for Assignments	1,160

Dividing the average fully supported FTE cost in FY 2025 ($369,046) by the total number of supported direct work hours available for assignment in FY 2023 (1,160) results in an average fully supported cost of $318 (rounded to the nearest dollar), excluding travel costs, per supported direct work hour in FY 2025.

B. Adjusting FY 2023 Travel Costs for Inflation To Estimate FY 2025 Travel Costs

To adjust the hourly rate for FY 2025, FDA must estimate the cost of inflation in each year for FY 2024 and FY 2025. FDA uses the method prescribed for estimating inflationary costs under the Prescription Drug User Fee Act (PDUFA) provisions of the FD&C Act (section 736(c)(1) (21 U.S.C. 379h(c)(1))), the statutory method for inflation adjustment in the FD&C Act that FDA has used consistently. FDA previously determined the FY 2024 inflation rate to be 3.8896 percent; this rate was published in the FY 2024 PDUFA user fee rates notice in the **Federal Register** (July 28, 2023, 88 FR 48881). Utilizing the method set forth in section 736(c)(1) of the FD&C Act, FDA has calculated an inflation rate of 3.8896 percent for FY 2024 and 4.1167 percent for FY 2025. FDA intends to use this inflation rate to make inflation adjustments for FY 2025; the derivation of this rate will be published in the **Federal Register** in the FY 2025 notice for the PDUFA user fee rates. The compounded inflation rate for FYs 2024 and 2025, therefore, is 1.08166 (or 8.166 percent) (calculated as 1 plus 3.8896 percent times 1 plus 4.1167 percent).

The average fully supported cost per supported direct FDA work hour, excluding travel costs, of $318 already takes into account inflation as the calculation above is based on FY 2025 predicted costs. FDA will use this base unit fee in determining the hourly fee rate for third-party certification program fees for FY 2025 prior to including travel costs as applicable for the activity. For the purpose of estimating the fee, we are using the travel cost rate for foreign travel because we anticipate that the vast majority of onsite assessments made by FDA under this program will require foreign travel. In FY 2023, the Office of Regulatory Affairs spent a total of $2,629,906 on 431 foreign inspection trips related to FDA's Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine field activities programs, which averaged a total of $6,102 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $6,102 per trip by 120 hours per trip results in an additional cost of $51 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2023. To adjust $51 for inflationary increases in FY 2024 and FY 2025, FDA must multiply it by the same inflation factor mentioned previously in this document (1.08166 or 8.166 percent), which results in an estimated cost of $55 per paid hour in addition to $318 for a total of $373 per paid hour ($318 plus $55) for each direct hour of work requiring foreign inspection travel. FDA will use this rate in charging fees in FY 2025 when travel is required for the third-party certification program.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2025

Fee category	Fee rates for FY 2025
Hourly rate without travel	$318
Hourly rate if travel is required	373

III. Fees for Accreditation Bodies and Certification Bodies in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

The third-party certification program assesses application fees and annual fees. In FY 2025, the only fees that could be collected by FDA under section 808(c)(8) of the FD&C Act are the initial application fee for accreditation bodies seeking recognition, the annual fee for recognized accreditation bodies, the annual fee for certification bodies accredited by a recognized accreditation body, the initial application fee for a certification body seeking direct accreditation from FDA, and the renewal application fee for recognized accreditation bodies. Table 3 provides an overview of the fees for FY 2025.

[2] Total includes rounding.

TABLE 3—FSMA THIRD-PARTY CERTIFICATION PROGRAM USER FEE SCHEDULE FOR FY 2025

Fee category	Fee rates for FY 2025
Initial Application Fee for Accreditation Body Seeking Recognition	$53,520
Annual Fee for Recognized Accreditation Body	2,505
Annual Fee for Accredited Certification Body	3,131
Initial Application Fee for a Certification Body Seeking Direct Accreditation from FDA	53,520
Renewal Application Fee for Recognized Accreditation Body	32,802

A. Application Fee for Accreditation Bodies Applying for Recognition in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

Section 1.705(a)(1) (21 CFR 1.705(a)(1)) establishes an application fee for accreditation bodies applying for initial recognition that represents the estimated average cost of the work FDA performs in reviewing and evaluating initial applications for recognition of accreditation bodies.

The fee is based on the fully supported FTE hourly rates and estimates of the number of hours it would take FDA to perform relevant activities. These estimates represent FDA's current thinking, and as the program evolves, FDA will continue to reconsider the estimated hours. Based on data we have acquired since starting the program, we estimate that it would take, on average, 80 person-hours to review an accreditation body's submitted application, 48 person-hours for an onsite performance evaluation of the applicant (including travel and other steps necessary for a fully supported FTE to complete an onsite assessment), and 32 person-hours to prepare a written report documenting the onsite assessment.

FDA employees review applications and prepare reports from their worksites, so we use the fully supported FTE hourly rate excluding travel, $318 per hour, to calculate the portion of the user fee attributable to those activities: $318/hour × (80 hours (application review) + 32 hours (written report)) = $35,616. FDA employees will likely travel to foreign countries for the onsite performance evaluations because most accreditation bodies are anticipated to be located in foreign countries. For this portion of the fee, we use the fully supported FTE hourly rate for work requiring travel, $373 per hour, to calculate the portion of the user fee attributable to those activities: $373/hour × 48 hours (*i.e.,* two fully supported FTEs × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $17,904. The estimated average cost of the work FDA performs in total for reviewing an initial application for recognition for an accreditation body based on these figures would be $35,616 + $17,904 = $53,520. Therefore, the application fee for accreditation bodies applying for recognition in FY 2025 will be $53,520.

B. Annual Fee for Accreditation Bodies Participating in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

To calculate the annual fee for each recognized accreditation body, FDA takes the estimated average cost of work FDA performs to monitor performance of a single recognized accreditation body and annualizes that over the average term of recognition. At this time, we assume an average term of recognition of 5 years. We also assume that FDA will monitor 10 percent of recognized accreditation bodies onsite. As the program proceeds, we will adjust the term of recognition as appropriate. We estimate that for one performance evaluation of a recognized accreditation body, it would take, on average (taking into account that not all recognized accreditation bodies would be monitored onsite), 22 hours for FDA to conduct records review, 8 hours to prepare a report detailing the records review and onsite performance evaluation, and 8 hours of onsite performance evaluation. Using the fully supported FTE hourly rates in table 2, the estimated average cost of the work FDA performs to monitor performance of a single recognized accreditation body would be $9,540 ($318/hour × (22 hours (records review) + 8 hours (written report))) plus $2,984 ($373/hour × 8 hours (onsite evaluation)), which is $12,524. Annualizing this amount over 5 years would lead to an annual fee for recognized accreditation bodies of $2,505 for FY 2025.

C. Annual Fee for Certification Bodies Accredited by a Recognized Accreditation Body in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

To calculate the annual fee for a certification body accredited by a recognized accreditation body, FDA takes the estimated average cost of work FDA performs to monitor performance of a single certification body accredited by a recognized accreditation body and annualizes that over the average term of accreditation. At this time, we assume an average term of accreditation of 4 years. This fee is based on the fully supported FTE hourly rates and estimates of the number of hours it would take FDA to perform relevant activities. We estimate that FDA would conduct, on average, the same activities, for the same amount of time to monitor certification bodies accredited by a recognized accreditation body as we would to monitor an accreditation body recognized by FDA. Using the fully supported FTE hourly rates in table 2, the estimated average cost of the work FDA performs to monitor performance of a single accredited certification body would be $9,540 ($318/hour × (22 hours (records review) + 8 hours (written report))) plus $2,984 ($373/hour × 8 hours (onsite evaluation)), which is $12,524. Annualizing this amount over 4 years would lead to an annual fee for accredited certification bodies of $3,131 for FY 2025.

D. Initial Application Fee for Certification Bodies Seeking Direct Accreditation From FDA in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

Section 1.705(a)(3) establishes an application fee for certification bodies applying for direct accreditation from FDA that represents the estimated average cost of the work FDA performs in reviewing and evaluating initial applications for direct accreditation of certification bodies.

The fee is based on the fully supported FTE hourly rates and estimates of the number of hours it would take FDA to perform relevant activities. These estimates represent FDA's current thinking, and as the program evolves, FDA will reconsider the estimated hours. We estimate that it would take, on average, 80 person-hours to review a certification body's submitted application, 48 person-hours for an onsite performance evaluation of the applicant (including travel and other steps necessary for a fully supported FTE to complete an onsite assessment),

and 32 person-hours to prepare a written report documenting the onsite assessment.

FDA employees are likely to review applications and prepare reports from their worksites, so we use the fully supported FTE hourly rate excluding travel, $318 per hour, to calculate the portion of the user fee attributable to those activities: $318/hour × (80 hours (application review) + 32 hours (written report)) = $35,616. FDA employees will likely travel to foreign countries for the onsite performance evaluations because most certification bodies are anticipated to be located in foreign countries. For this portion of the fee, we use the fully supported FTE hourly rate for work requiring travel, $373 per hour, to calculate the portion of the user fee attributable to those activities: $373/hour × 48 hours (*i.e.,* two fully supported FTEs × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $17,904. The estimated average cost of the work FDA performs in total for reviewing an initial application for direct accreditation of a certification body based on these figures would be $35,616 + $17,904 = $53,520. Therefore, the application fee for certification bodies applying for direct accreditation from FDA in FY 2025 will be $53,520.

E. Renewal Application Fee for Accreditation Bodies Participating in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

Section 1.705(a)(2) establishes a renewal application fee for recognized accreditation bodies that represents the estimated average cost of the work FDA performs in reviewing and evaluating renewal applications for recognition of accreditation bodies.

The fee is based on the fully supported FTE hourly rates and estimates of the number of hours it would take FDA to perform relevant activities. These estimates represent FDA's current thinking, and as the program evolves, FDA will reconsider the estimated hours. We estimate that it would take, on average, 43 person-hours to review an accreditation body's submitted renewal application, 24 person-hours for an onsite performance evaluation of the applicant (including travel and other steps necessary for a fully supported FTE to complete an onsite assessment), and 32 person-hours to prepare a written report documenting the onsite assessment.

FDA employees are likely to review renewal applications and prepare reports from their worksites, so we use the fully supported FTE hourly rate excluding travel, $318 per hour, to calculate the portion of the user fee attributable to those activities: $318/hour × (43 hours (application review) + 32 hours (written report)) = $23,850. FDA employees will likely travel to foreign countries for the onsite performance evaluations because most certification bodies are anticipated to be located in foreign countries. For this portion of the fee, we use the fully supported FTE hourly rate for work requiring travel, $373 per hour, to calculate the portion of the user fee attributable to those activities: $373/hour × 24 hours (*i.e.,* fully supported FTE × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $8,952. The estimated average cost of the work FDA performs in total for reviewing a renewal application for recognition of an accreditation body based on these figures would be $23,850 + $8,952 = $32,802. Therefore, the renewal application fee for recognized accreditation bodies in FY 2025 will be $32,802.

IV. Estimated Fees for Accreditation Bodies and Certification Bodies in Other Fee Categories for FY 2025

Section 1.705(a) also establishes application fees for certification bodies applying for renewal of direct accreditation. Section 1.705(b) also establishes annual fees for certification bodies directly accredited by FDA.

Although we will not be collecting these other fees in FY 2025, for transparency and planning purposes, we have provided an estimate of what these fees would be for FY 2025 based on the fully supported FTE hourly rates for FY 2025 and estimates of the number of hours it would take FDA to perform relevant activities as outlined in the Final Regulatory Impact Analysis for the Third-Party Certification Regulation. Table 4 provides an overview of the estimated fees for other fee categories.

TABLE 4—ESTIMATED FEE RATES FOR OTHER FEE CATEGORIES UNDER THE FSMA THIRD-PARTY CERTIFICATION PROGRAM

Fee category	Estimated fee rates for FY 2025
Renewal application fee for directly accredited certification body	$32,802
Annual fee for certification body directly accredited by FDA	25,096

V. How must the fee be paid?

Accreditation bodies seeking initial recognition must submit the application fee with the application. For recognized accreditation bodies and accredited certification bodies, an invoice will be sent annually. Payment must be made within 30 days of the invoice date. The payment must be made in U.S. currency from a U.S. bank by one of the following methods: wire transfer, electronically, check, bank draft, or U.S. postal money order made payable to the Food and Drug Administration. The preferred payment method is online using an electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay.* (Note: only full payments are accepted. No partial payments can be made online.) Once you have found your invoice, select ''Pay Now'' to be redirected to *Pay.gov.* Electronic payment options are based on the balance due. Payment by credit card is available only for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards. When paying by check, bank draft, or U.S. postal money order, please include the invoice number. Also write the FDA post office box number (P.O. Box 979108) on the enclosed check, bank draft, or money order. Mail the payment, including the invoice number on the check stub, to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000.

When paying by wire transfer, it is required that the invoice number is included; without the invoice number the payment may not be applied. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required to add that

amount to the payment to ensure that the invoice is paid in full. For international wire transfers, please inquire with the financial institutions prior to submitting the payment. Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account No.: 75060099, Routing No.: 021030004, Swift No.: FRNYUS33.

To send a check by a courier such as Federal Express, the courier must deliver the check to: U.S. Bank, Attn: Government Lockbox 979108, 3180 Rider Trail S., Earth City, MO 63045. (Note: this address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 855–259–3064. This phone number is only for questions about courier delivery.) The tax identification number of FDA is 53–0196965.

VI. What are the consequences of not paying this fee?

The consequences of not paying these fees are outlined in 21 CFR 1.725. If FDA does not receive an application fee with an application for recognition, the application will be considered incomplete, and FDA will not review the application. If a recognized accreditation body fails to submit its annual user fee within 30 days of the due date, we will suspend its recognition. If the recognized accreditation body fails to submit its annual user fee within 90 days of the due date, we will revoke its recognition. If an accredited certification body fails to pay its annual fee within 30 days of the due date, we will suspend its accreditation. If the accredited certification body fails to pay its annual fee within 90 days of the due date, we will withdraw its accreditation.

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3381]

Food Safety Modernization Act Voluntary Qualified Importer Program User Fee Rate for Fiscal Year 2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2025 annual fee rate for importers approved to participate in the Voluntary Qualified Importer Program (VQIP) that is authorized by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA). This fee is effective on August 1, 2024, and will remain in effect through September 30, 2025.

FOR FURTHER INFORMATION CONTACT: *For questions related to FSMA program fees: FSMAFeeStaff@fda.hhs.gov. For questions related to this notice:* Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 240–402–4989; or the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 302 of FSMA, VQIP, amended the FD&C Act to create a new provision, section 806, under the same name. Section 806 of the FD&C Act (21 U.S.C. 384b) directs FDA to establish a program to provide for the expedited review and importation of food offered for importation by importers who have voluntarily agreed to participate in such program, and a process, consistent with section 808 of the FD&C Act (21 U.S.C. 384d), for the issuance of a facility certification to accompany a food offered for importation by importers participating in VQIP.

Section 743 of the FD&C Act (21 U.S.C. 379j–31) authorizes FDA to assess and collect fees from each importer participating in VQIP to cover FDA's costs of administering the program. Each fiscal year, fees are to be established based on an estimate of 100 percent of the costs for the year. The fee rates must be published in a **Federal Register** notice not later than 60 days before the start of each fiscal year (section 743(b)(1) of the FD&C Act). After FDA approves a VQIP application, the user fee must be paid before October 1, the start of the VQIP fiscal year, to begin receiving benefits for that VQIP fiscal year.

The FY 2025 VQIP user fee will support benefits from October 1, 2024, through September 30, 2025.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2025

FDA is required to estimate 100 percent of its costs for each activity in order to establish fee rates for FY 2025. In each year, the costs of salary (or personnel compensation) and benefits for FDA employees account for between 50 and 60 percent of the funds available to, and used by, FDA. Almost all of the remaining funds (operating funds) available to FDA are used to support FDA employees by paying for rent, travel, utility, information technology (IT), and other operating costs.

A. Estimating the Full Cost Per Direct Work Hour in FY 2025

Full-time Equivalent (FTE) reflects the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered ''hours worked'' for purposes of defining FTE employment.

In general, the starting point for estimating the full cost per direct work hour is to estimate the cost of an FTE or paid staff year. Calculating an Agency-wide total cost per FTE requires three primary cost elements: payroll, non-payroll, and rent.

We have used an average of past year cost elements to predict the FY 2025 cost. The FY 2025 FDA-wide average cost for payroll (salaries and benefits) is $213,556; non-payroll—including equipment, supplies, IT, general and administrative overhead—is $131,739; and rent, including cost allocation analysis and adjustments for other rent and rent-related costs, is $23,750 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, non-payroll, and rent, brings the FY 2025 average fully supported cost to $369,046 [1] per FTE, excluding travel costs. FDA will use this base unit fee in determining the hourly fee rate for VQIP fees for FY 2025 prior to including domestic or foreign travel costs as applicable for the activity.

To calculate an hourly rate, FDA must divide the FY 2025 average fully supported cost of $369,046 per FTE by the average number of supported direct FDA work hours in FY 2023—the last FY for which data are available. See table 1.

TABLE 1—SUPPORTED DIRECT FDA WORK HOURS IN A PAID STAFF YEAR IN FY 2023

Total number of hours in a paid staff year	2,080
Less:	
11 paid holidays	−88
20 days of annual leave	−160

[1] Total includes rounding.

TABLE 1—SUPPORTED DIRECT FDA WORK HOURS IN A PAID STAFF YEAR IN FY 2023—Continued

Total number of hours in a paid staff year	2,080
10 days of sick leave	−80
12.5 days of training	−100
22 days of general administration	−176
26.5 days of travel	−212
2 hours of meetings per week	−104
Net Supported Direct FDA Work Hours Available for Assignments	1,160

Dividing the average fully supported FTE cost in FY 2025 ($369,046) by the total number of supported direct work hours available for assignment in FY 2023 (1,160) results in an average fully supported cost of $318 (rounded to the nearest dollar), excluding inspection travel costs, per supported direct work hour in FY 2025.

B. Adjusting FY 2023 Travel Costs for Inflation To Estimate FY 2025 Travel Costs

To adjust the hourly rate for FY 2025, FDA must estimate the cost of inflation in each year for FYs 2024 and 2025. FDA uses the method prescribed for estimating inflationary costs under the Prescription Drug User Fee Act (PDUFA) provisions of the FD&C Act (section 736(c)(1) (21 U.S.C. 379h(c)(1))), the statutory method for inflation adjustment in the FD&C Act that FDA has used consistently. FDA previously determined the FY 2024 inflation rate to be 3.8896 percent; this rate was published in the FY 2024 PDUFA user fee rates notice in the **Federal Register** (July 28, 2023, 88 FR 48881). Utilizing the method set forth in section 736(c)(1) of the FD&C Act, FDA has calculated an inflation rate of 3.8896 percent for FY 2024 and 4.1167 percent for FY 2025, and FDA intends to use these inflation rates to make inflation adjustments for FY 2025; the derivation of this rate will be published in the **Federal Register** in the FY 2025 notice for the PDUFA user fee rates. The compounded inflation rate for FYs 2024 and 2025, therefore, is 1.08166 (or 8.166 percent) (calculated as 1 plus 3.8896 percent times 1 plus 4.1167 percent).

The average fully supported cost per supported direct FDA work hour, excluding travel costs, of $318 already takes into account inflation as the calculation above is based on FY 2025 predicted costs. FDA will use this base unit fee in determining the hourly fee rate for VQIP fees for FY 2025 prior to including domestic or foreign travel costs as applicable for the activity.

In FY 2023, FDA's Office of Regulatory Affairs (ORA) spent a total of $7,463,679 for domestic regulatory inspection travel costs and General Services Administration Vehicle costs related to FDA's Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM) field activities programs. The total ORA domestic travel costs spent is then divided by the 8,811 CFSAN and CVM domestic inspections, which averages a total of $847 per inspection. These inspections average 41.35 hours per inspection. Dividing $847 per inspection by 41.35 hours per inspection results in a total and an additional cost of $20 (rounded to the nearest dollar) per hour spent for domestic inspection travel costs in FY 2023. To adjust for the $20 per hour additional domestic cost inflation increases for FY 2024 and FY 2025, FDA must multiply the FY 2024 PDUFA inflation rate adjustor (1.038896) by the FY 2025 PDUFA inflation rate adjustor (1.041167) times the $20 additional domestic cost, which results in an estimated cost of $22 (rounded to the nearest dollar) per paid hour in addition to $318 for a total of $340 per paid hour ($318 plus $22) for each direct hour of work requiring domestic inspection travel. FDA will use these rates in charging fees in FY 2025 when domestic travel is required.

In FY 2023, ORA spent a total of $2,629,906 on 431 foreign inspection trips related to FDA's CFSAN and CVM field activities programs, which averaged a total of $6,102 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $6,102 per trip by 120 hours per trip results in a total and an additional cost of $51 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2023. To adjust $51 for inflationary increases in FY 2024 and FY 2025, FDA must multiply it by the same inflation factors mentioned previously in this document (1.038896 and 1.041167), which results in an estimated cost of $55 (rounded to the nearest dollar) for each direct hour of work requiring foreign inspection travel. FDA will use these rates in charging fees in FY 2025 when foreign travel is required.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2025

Fee category	Fee rates for FY 2025
Hourly rate without travel	$318
Hourly rate if domestic travel is required	340
Hourly rate if foreign travel is required	373

III. Fees for Importers Approved To Participate in the Voluntary Qualified Importer Program Under Section 743 of the FD&C Act

FDA assesses fees for VQIP annually. Table 3 provides an overview of the fees for FY 2025.

TABLE 3—FSMA VQIP USER FEE SCHEDULE FOR FY 2025

Fee category	Fee rates for FY 2025
VQIP User Fee	$9,999

Section 743 of the FD&C Act requires that each importer participating in VQIP pay a fee to cover FDA's costs of administering the program. This fee represents the estimated average cost of the work FDA performs in reviewing and evaluating a VQIP importer. At this time, FDA is not offering an adjusted fee for small businesses. As required by section 743(b)(2)(B)(iii) of the FD&C Act, FDA previously published a set of guidelines in consideration of the burden of the VQIP fee on small businesses and provided for a period of public comment on the guidelines (80 FR 32136, June 5, 2015). While we did receive some comments in response, they did not address the questions posed, *i.e.,* how a small business fee reduction should be structured, what percentage of fee reduction would be appropriate, or what alternative structures FDA might consider to indirectly reduce fees for small businesses by charging different fee amounts to different VQIP participants. We plan on monitoring costs and collecting data to determine if, in future fiscal years, we will provide for a small business fee reduction. Consistent with section 743(b)(2)(B)(iii) of the FD&C Act, we will adjust the fee schedule for small businesses only through notice and comment rulemaking.

The fee is based on the fully supported FTE hourly rates and estimates of the number of hours it would take FDA to perform relevant activities. These estimates represent FDA's current thinking, and as the program evolves, FDA will reconsider the estimated hours. We estimate that it would take, on average, 39 person-hours to review a new VQIP application (including communication provided through the VQIP Importer's Help Desk), 28 person-hours to review a returning VQIP application (including communication provided through the VQIP Importer's Help Desk), 16 person-hours for an onsite performance evaluation of a domestic VQIP importer

(including travel and other steps necessary for a fully supported FTE to complete and document an onsite assessment), and 34 person-hours for an onsite performance evaluation of a foreign VQIP importer (including travel and other steps necessary for a fully supported FTE to complete and document an onsite assessment).

Based on updated data, FDA anticipates that there may be up to seven returning VQIP applicants and up to one new applicant this fiscal year. FDA employees are likely to review new VQIP applications from their worksites, so we use the fully supported FTE hourly rate excluding travel, $318/hour, to calculate the portion of the user fee attributable to those activities: $318/hour × (39 hours) = $12,402. FDA employees are likely to review returning VQIP applications from their worksites, so we use the fully supported FTE hourly rate excluding travel, $318/hour, to calculate the portion of the user fee attributable to those activities: $318/hour × (28 hours) = $8,904.

FDA employees will conduct a VQIP inspection to verify the eligibility criteria and full implementation of the food safety and food defense systems established in the Quality Assurance Program. A VQIP importer may be located inside or outside of the United States. However, this fiscal year, all VQIP importers will be located inside the United States. One VQIP applicant may have an associated VQIP inspection.

FDA employees are likely to prepare for and report on the performance evaluation of a domestic VQIP importer at an FTE's worksite, so we use the fully supported FTE hourly rate excluding travel, $318/hour, to calculate the portion of the user fee attributable to those activities: $318/hour × (8 hours) = $2,544. For the portion of the fee covering onsite evaluation of a domestic VQIP importer, we use the fully supported FTE hourly rate for work requiring domestic travel, $340/hour, to calculate the portion of the user fee attributable to those activities: $340/hour × 8 hours (*i.e.,* one fully supported FTE × (1 day onsite × 8 hours)) = $2,720. Therefore, the total cost of conducting the domestic performance evaluation of a VQIP importer is determined to be $2,544 + $2,720 = $5,264.

Coordination of the onsite performance evaluation of a foreign VQIP importer is estimated to take place at an FTE's worksite, so we use the fully supported FTE hourly rate excluding travel, $318/hour, to calculate the portion of the user fee attributable to those activities: $318/hour × (10 hours) = $3,180. For the portion of the fee covering onsite evaluation of a foreign VQIP importer, we use the fully supported FTE hourly rate for work requiring foreign travel, $373/hour, to calculate the portion of the user fee attributable to those activities: $373/hour × 24 hours (*i.e.,* one fully supported FTE × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $8,952. Therefore, the total cost of conducting the foreign performance evaluation of a VQIP importer is determined to be $3,180 + $8,952 = $12,132.

Therefore, the estimated average cost of the work FDA performs in total for approving an application for a VQIP importer in FY 2025 based on these figures would be ($12,402 × ⅛) + ($8,904 × ⅞) + ($5,264 × ⅛) = $9,999.

IV. How must the fee be paid?

An invoice will be sent to VQIP importers approved to participate in the program. Payment must be made prior to October 1, 2024, to be eligible for VQIP participation for the benefit year beginning October 1, 2024. FDA will not refund the VQIP user fee for any reason.

The payment must be made in U.S. currency from a U.S. bank by one of the following methods: wire transfer, electronically, check, bank draft, or U.S. postal money order made payable to the Food and Drug Administration. The preferred payment method is online using an electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay.* (Note: only full payments are accepted. No partial payments can be made online.) Once you have found your invoice, select ''Pay Now'' to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available only for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

When paying by check, bank draft, or U.S. postal money order, please include the invoice number on the check stub. Also write the FDA post office box number (P.O. Box 979108) on the enclosed check, bank draft, or money order. Mail the payment including the invoice number on the check stub to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000.

When paying by wire transfer, it is required that the invoice number is included; without the invoice number the payment may not be applied. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required to add that amount to the payment to ensure that the invoice is paid in full. For international wire transfers, please inquire with the financial institutions prior to submitting the payment. Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account No.: 75060099, Routing No.: 021030004, Swift No.: FRNYUS33.

To send a check by a courier such as Federal Express, the courier must deliver the check to: U.S. Bank, Attn: Government Lockbox 979108, 3180 Rider Trail S., Earth City, MO 63045. (*Note:* This address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 855–259–3064. This phone number is only for questions about courier delivery.)

The tax identification number of FDA is 53–0196965.

V. What are the consequences of not paying this fee?

The consequences of not paying these fees are outlined in Section J of ''FDA's Voluntary Qualified Importer Program; Guidance for Industry'' document (available at *https://www.fda.gov/media/92196/download*). If the user fee is not paid before October 1, a VQIP importer will not be eligible to participate in VQIP. For the first year a VQIP application is approved, if the user fee is not paid before October 1, 2024, you are not eligible to participate in VQIP. If you subsequently pay the user fee, FDA will begin your benefits after we receive the full payment. The user fee may not be paid after December 31, 2024. For a subsequent year, if you do not pay the user fee before October 1, FDA will send a Notice of Intent to Revoke your participation in VQIP. If you do not pay the user fee within 30 days of the date of the Notice of Intent to Revoke, we will revoke your participation in VQIP.

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16891 Filed 7–30–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS—60D–0990–New]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before September 30, 2024.

ADDRESSES: Submit your comments to *Sherrette.funn@hhs.gov* or by calling (202) 264–0041 and *PRA@HHS.GOV*

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–New–60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov, PRA@HHS.GOV* or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send their comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of Information Collection: Performance and Evaluation Measurement Systems (PEMS).

Type of Collection: New Data Collection.

OMB No.: 0990–New.

Abstract: The U.S. Department of Health and Human Services (HHS) Office of Minority Health (OMH) is requesting OMB approval for PEMS. The proposed information collection activity will allow OMH to collect grant management and performance data and disparity impact information for all OMH-funded projects. The clearance is needed to support data collection using Grant Solutions, a system that enables OMH to comply with Federal reporting requirements and monitor and evaluate performance by enabling the efficient collection of performance-oriented data tied to OMH-wide performance reporting needs. The ability to monitor and evaluate performance in this manner, and to work towards continuous program improvement are basic functions that OMH must be able to accomplish to carry out its mandate with the most effective and appropriate use of resources.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Disparity Impact Statement Template	125	1	1	125
OMH Performance Progress Report	125	4	1.5	750
Total	250	5	2.5	875

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2024–16818 Filed 7–30–24; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Drug Abuse.

This will be a hybrid meeting held in-person and virtually and will be open to the public, as indicated below, with attendance limited to space available. Individuals who plan to attend in-person or view the virtual meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Dr. Gillian Acca via email at *gillian.acca@nih.gov* five days in advance of the meeting. The open session of the meeting can be accessed from the NIH Videocast at the following link: *https://videocast.nih.gov/.*

A portion of the meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Drug Abuse.

Date: September 11, 2024.

Closed: 10:30 a.m. to 11:45 a.m.

Agenda: To review and evaluate grant applications.

Open: 1:00 p.m. to 5:00 p.m.

Agenda: Presentations and other business of the Council.

Place: Neuroscience Center, Conference Room 1145/1155, National Institutes of Health, 6001 Executive Boulevard, Rockville, MD 20852 (Hybrid Meeting).

Contact Persons:

Susan R.B. Weiss, Ph.D., Director, Division of Extramural Research, Office of the Director, National Institute on Drug Abuse, NIH, Three White Flint North, RM 09D08, 11601 Landsdown Street, Bethesda, MD 20852, 301–443–6480, *sweiss@nida.nih.gov.*

Gillian Acca, Ph.D., Health Science Policy Analyst, Division of Extramural Research, Office of Extramural Policy, National Institute on Drug Abuse, NIH, Three White Flint North, RM 09C70, 11601 Landsdown Street, Bethesda, MD 20852, 301–827–5863, *gillian.acca@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to Dr. Gillian Acca via email at *gillian.acca@nih.gov.* The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has procedures at *https://www.nih.gov/about-nih/visitor-information/campus-access-*

security for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *www.drugabuse.gov/NACDA/NACDAHome.html,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: July 25, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–16814 Filed 7–30–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism.

This will be a hybrid meeting held in-person and virtually and will be open to the public as indicated below. Individuals who plan to attend in-person or view the virtual meeting and need special assistance or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: *https://videocast.nih.gov/.*

A portion of this meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Alcohol Abuse and Alcoholism.

Date: September 12, 2024.

Closed: 10:00 a.m. to 10:50 a.m.

Agenda: To review and evaluate grant applications.

Open: 11:00 a.m. to 3:30 p.m.

Agenda: Presentations and other business of the Council.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, Conference Rooms A, B & C, 6700B Rockledge Drive, Bethesda, MD 20817 (Hybrid Meeting).

Contact Person: Philippe Marmillot, Ph.D., Director, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 6700B Rockledge Drive, Room 2118, Bethesda, MD 20892, (301) 443–2861, *marmillotp@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has procedures at *https://www.nih.gov/about-nih/visitor-information/campus-access-security* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://www.niaaa.nih.gov/AboutNIAAA/AdvisoryCouncil/Pages/default.aspx,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.273, Alcohol Research Programs, National Institutes of Health, HHS)

Dated: July 25, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–16815 Filed 7–30–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute, Special Emphasis Panel; SEP–1: NCI Clinical and Translational Cancer Research.

Date: September 19, 2024.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W108, Rockville, Maryland 20850 (Virtual Meeting).

Contact Person: Clifford W. Schweinfest, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W108, Rockville, Maryland 20850, 240–276–6343, *schweinfestcw@mail.nih.gov.*

Name of Committee: National Cancer Institute, Special Emphasis Panel; SEP–4: NCI Clinical and Translational Cancer Research.

Date: September 24, 2024.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W264, Rockville, Maryland 20850 (Virtual Meeting).

Contact Person: Ombretta Salvucci, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W264, Rockville, Maryland 20850, 240–276–7286, *salvucco@mail.nih.gov.*

Name of Committee: National Cancer Institute, Special Emphasis Panel; Projects in Physical Sciences and Oncology (U01) Review.

Date: September 25, 2024.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W640, Rockville, Maryland 20850 (Virtual Meeting).

Contact Person: Saejeong J. Kim, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W640, Rockville, Maryland 20850, 240–276–7684, *saejeong.kim@nih.gov.*

Name of Committee: National Cancer Institute, Special Emphasis Panel; Clinical Trials Planning Program.

Date: October 4, 2024.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room

7W106, Rockville, Maryland 20850 (Virtual Meeting).

Contact Person: Eduardo Emilio Chufan, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W106, Rockville, Maryland 20850, 240–276–7975, *chufanee@mail.nih.gov.*

Name of Committee: National Cancer Institute, Special Emphasis Panel; SEP–9: NCI Clinical and Translational Cancer Research.

Date: October 9, 2024.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W640, Rockville, Maryland 20850 (Virtual Meeting).

Contact Person: Saejeong J. Kim, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W640, Rockville, Maryland 20850, 240–276–7684, *saejeong.kim@nih.gov.*

Name of Committee: National Cancer Institute, Special Emphasis Panel; SEP–12: NCI Clinical and Translational Cancer Research.

Date: October 16, 2024.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W246, Rockville, Maryland 20850 (Virtual Meeting).

Contact Person: Jun Fang, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W246, Rockville, Maryland 20850, 240–276–5460, *jfang@mail.nih.gov.*

Name of Committee: National Cancer Institute, Special Emphasis Panel; SEP–8: NCI Clinical and Translational Cancer Research.

Date: October 29–30, 2024.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W110, Rockville, Maryland 20850 (Virtual Meeting).

Contact Person: Priya Srinivasan, Ph.D., Scientific Review Officer, Resource and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W110, Rockville, Maryland 20850, 240–276–5619, *priya.srinivasan@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Date: July 19, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–16813 Filed 7–30–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Cancer Advisory Board.

This will be a hybrid meeting held in-person and virtually and will be open to the public as indicated below. Individuals who plan to attend in-person or view the virtual meeting and need special assistance or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: *https://videocast.nih.gov/.*

A portion of the meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Advisory Board.

Date: September 3, 2024.

Open: 6:00 p.m. to 9:00 p.m.

Agenda: National Cancer Advisory Board Subcommittee Meetings.

Place: Gaithersburg Marriott Washingtonian Center, Room—TBD, 9751 Washington Boulevard, Gaithersburg, MD 20878.

Contact Person: Paulette S. Gray, Ph.D., Director, Division of Extramural Activities, National Cancer Institute—Shady Grove, National Institutes of Health, 9609 Medical Center Drive, 7th Floor, Room 7W444, Bethesda, MD 20892, 240–276–6340, *grayp@mail.nih.gov.*

Name of Committee: National Cancer Advisory Board.

Date: September 4, 2024.

Open: 9:00 a.m. to 3:50 p.m.

Agenda: Director and Program Reports and Presentations. Business of the Board.

Closed: 3:50 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute—Shady Grove, 9609 Medical Center Drive, Room TE406 & 408, Rockville, MD 20850 (Hybrid Meeting).

Contact Person: Paulette S. Gray, Ph.D., Director, Division of Extramural Activities, National Cancer Institute—Shady Grove, National Institutes of Health, 9609 Medical Center Drive, 7th Floor, Room 7W444, Bethesda, MD 20892, 240–276–6340, *grayp@mail.nih.gov.*

Name of Committee: National Cancer Advisory Board.

Date: September 5, 2024.

Open: 9:00 a.m. to 12:00 p.m.

Agenda: Program Reports and Presentations. Business of the Board.

Place: National Cancer Institute—Shady Grove, 9609 Medical Center Drive, Room TE406 & 408, Rockville, MD 20850 (Hybrid Meeting).

Contact Person: Paulette S. Gray, Ph.D., Director, Division of Extramural Activities, National Cancer Institute—Shady Grove, National Institutes of Health, 9609 Medical Center Drive, 7th Floor, Room 7W444, Bethesda, MD 20892, 240–276–6340, *grayp@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NCI—Shady Grove campus. All visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: NCAB: *http://deainfo.nci.nih.gov/advisory/ncab/ncab.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 3.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: July 25, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–16816 Filed 7–30–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

[Docket Number DHS–2024–0027]

Agency Information Collection Activities: VULNERABILITY DISCOVERY PROGRAM, OMB CONTROL NO. 1601–0028

AGENCY: Department of Homeland Security (DHS).

ACTION: 60-Day notice and request for comments.

SUMMARY: The Department of Homeland Security will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted until September 30, 2024. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: You may submit comments, identified by docket number Docket # DHS–2024–0027, at:

○ *Federal eRulemaking Portal: http://www.regulations.gov.* Please follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number Docket # DHS–2024–2027. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

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

SUPPLEMENTARY INFORMATION: Security vulnerabilities, defined in section 102(17) of the Cybersecurity Information Sharing Act of 2015, are any attribute of hardware, software, process, or procedure that could enable or facilitate the defeat of a security control. Security vulnerability mitigation is a process starting with discovery of the vulnerability leading to applying some solution to resolve the vulnerability. There is constantly a search for security vulnerabilities within information systems, from individuals or nation states wishing to bypass security controls to gain invaluable information, to researchers seeking knowledge in the field of cyber security. Bypassing such security controls in the DHS and other Federal Agencies information systems can cause catastrophic damage including but not limited to loss in Personally Identifiable Information (PII), sensitive information gathering, and data manipulation.

Pursuant to section 101 of the Strengthening and Enhancing Cyber-capabilities by Utilizing Risk Exposure Technology Act, (commonly known as the SECURE Technologies Act) individuals, organizations, and/or companies may submit any discovered security vulnerabilities found associated with the information system of any Federal agency. This collection is used by these individuals, organizations, and/or companies who choose to submit a discovered vulnerability found associated with the information system of any Federal agency.

Specifically, DHS and Federal cybersecurity agencies are working to address vulnerabilities within DHS's components. While DHS had previously obtained approval to collect this information on its own behalf, recent cyberattacks and trends exploiting vulnerabilities have exemplified the need to have this capability government-wide. In June 2023, a major and widespread cyberattack occurred by Russian cybercriminals, that impacted multiple U.S. federal government agencies. This was reported to be a result of cybercriminals exploiting a vulnerability in widely used software known as MOVEit. Cybercriminals gained the opportunity exploit the software that agencies use to transfer data. This attack was reported to be widespread and allowed for cybercriminals to break into multiple networks due to lack of remediation. Impacted organizations included The Energy Department, Johns Hopkins University, and University of Georgia. The MOVEit exploitation appears to have affected at least 122 organizations and exposed the data of roughly 15 million people. These numbers are based on posts from CL0P, the Russian ransomware group that has claimed responsibility for the attacks. This is just a single example among a myriad of vulnerabilities and incidents that we strive to avoid.

Public Law 116–283, Sec. 1705 (which amended 44 U.S.C. 3553) permits extensive sharing of information regarding cybersecurity and the protection of information and information systems from cybersecurity risks between Federal Agencies covered by the Federal Information Security Modernization Act and the Department of Homeland Security. This unique authority makes DHS well positioned to host the approval of this information collection on behalf of other Federal agencies

DHS is requesting pursuant to 44 US Code 33554(a)(1)(B), that the information collection continue to be designated for any Federal agency's ability to utilize the standardized DHS online Vulnerability Disclosure Form to collect their own agency's vulnerability information and post the information on their own agency websites.

DHS leverages the form to collect information about vulnerabilities impacting DHS assets. The form includes the following: vulnerable host(s), necessary information for reproducing the security vulnerability, remediation or suggestions for remediation of the vulnerability, and potential impact on host, if not remediated.

This form allows Federal agencies to complete the following actions; (1) allow the individuals, organizations, and/or companies who discover vulnerabilities in the information systems to report their findings to the agency, and (2) provide the agencies initial insight into any newly discovered vulnerabilities, as well as zero-day vulnerabilities in order to mitigate the security issues prior to malicious actors acting upon the vulnerability for malicious intent.

The form also benefits researchers and provides a safe and lawful method to practice and discover new cyber methods to discover the vulnerabilities. It provides the same benefit to Federal agencies and promotes the enhancement of Federal information system security policies.

Respondents may electively submit their information directly to the agency in which they would like to report a vulnerability. Federal Agencies provide the form electronically via their agency's website. The information collected does not have an impact on small business or other small entities.

The collection of this information is related to the discovery of security vulnerabilities by individuals, organizations, and/or companies is needed to fulfill the congressional mandate in Section 101 of the SECURE Technologies Act related to creating Vulnerability Disclosure Policies. In addition, without the ability to collect information on newly discovered security vulnerabilities associated with Federal agency information systems, Federal agencies will rely solely on the internal security personnel and/or the discovery through a post occurrence breach of security controls.

There are no assurances of confidentiality provide. Any PII that is collected is for the sole purpose of feedback and dialogue. This information collection is covered by a Privacy Impact Assessment (PIA), DHS/ALL/PIA–006 DHS General Contacts List (June 15, 2007), and a System of Records Notice, DHS/ALL–002 Department of

Homeland Security (DHS) Mailing and Other Lists System, 73 FR 71659 (November 25, 2008).

The Office of Management and Budget is particularly interested in comments which:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Analysis

Agency: Department of Homeland Security (DHS).

Title: VULNERABILITY DISCOVERY PROGRAM.

OMB Number: 1601–0028.

Frequency: Annually.

Affected Public: Individuals, Organizations, and/or Companies.

Number of Respondents: 3,000.

Estimated Time per Respondent: 3 hours.

Total Burden Hours: 9,000.

Robert Dorr,

Executive Director, Business Management Directorate.

[FR Doc. 2024–16855 Filed 7–30–24; 8:45 am]

BILLING CODE 9112–FL–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7080–N–33]

30-Day Notice of Proposed Information Collection: OMB Circular A–11 Section 280 Customer Experience Clearance OMB Control No.: 2511–0001

AGENCY: Office of Policy Development and Research, Chief Data Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 30 days of public comment.

DATES: *Comments Due Date:* August 30, 2024.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal.

Written comments and recommendations for the proposed information collection can be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410; telephone (202) 402–3577 (this is not a toll-free number) or email: *PaperworkReductionActOffice@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email *Colette.Pollard@hud.gov* or telephone (202) 402–3400. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit: *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: : This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on May 17, 2024, at 89 FR 43423.

A. Overview of Information Collection

Title of Information Collection: Renewal of OMB Circular A–11 Section 280 Customer Experience Clearance.

OMB Approval Number: 2511–0001.

OMB Expiration Date: 09/30/2024.

Type of Request: Extension of an existing collection.

Form Number: None.

Description of the need for the information and proposed use: Under the PRA, (*44 U.S.C. 3501–3520*) Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in *44 U.S.C. 3502(3)* and *5 CFR 1320.3(c)* and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires Federal Agencies to provide a 60-day and a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, HUD published the 60-day notice in the **Federal Register** on 05/17/2024 and is now publishing this 30-day notice of the proposed collection of information set forth in this document.

Whether seeking a loan, Social Security benefits, veterans' benefits, or other services provided by the Federal Government, individuals and businesses expect Government customer services to be efficient and intuitive, just like services from leading private-sector organizations. Yet the 2016 American Consumer Satisfaction Index and the 2017 Forrester Federal Customer Experience Index show that, on average, Government services lag nine percentage points behind the private sector.

A modern, streamlined and responsive customer experience means: Raising government-wide customer experience to the average of the private sector service industry; developing indicators for high-impact Federal programs to monitor progress towards excellent customer experience and mature digital services; and providing the structure (including increasing transparency) and resources to ensure customer experience is a focal point for agency leadership. To support this, OMB Circular A–11 Section 280 established government-wide standards for mature customer experience organizations in government and measurement. To enable Federal programs to deliver the experience taxpayers deserve, they must undertake three general categories of activities: Conduct ongoing customer research, gather and share customer feedback, and test services and digital products.

These data collection efforts may be either qualitative or quantitative in nature or may consist of mixed methods. Additionally, data may be collected via a variety of means, including but not limited to electronic or social media, direct or indirect observation (*i.e.,* in person, video and audio collections), interviews, questionnaires, surveys, and focus groups. HUD will limit its inquiries to data collections that solicit strictly voluntary opinions or responses. Steps will be taken to ensure anonymity of respondents in each activity covered by this request.

The results of the data collected will be used to improve the delivery of Federal services and programs. It will include the creation of personas, customer journey maps, and reports and summaries of customer feedback data and user insights. It will also provide government-wide data on customer experience that can be displayed on *performance.gov* to help build transparency and accountability of Federal programs to the customers they serve.

Respondents: Collections will be targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future. For the purposes of this request, ''customers'' are individuals, businesses, and organizations that interact with a Federal Government agency or program, either directly or via a Federal contractor. This could include individuals or households; businesses or other for-profit organizations; not-for-profit institutions; State, local or tribal governments; Federal government; and Universities.

Estimated Number of Respondents: 1,500,000.

Estimated Number of Responses: 1,500,000.

Frequency of Response: One time per collection.

Average Hours per Response: Varied, dependent upon the data collection method used. The possible response time to complete a questionnaire or survey may be 3 minutes or up to 2 hours to participate in an interview.

Estimated Burden: 75,000.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions. (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Colette Pollard,

Department Reports Management Officer, Office of Policy Development and Research, Chief Data Officer.

[FR Doc. 2024–16857 Filed 7–30–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6485–N–01]

Announcement of the Housing Counseling Federal Advisory Committee; Notice of Public Meeting

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, Department of Housing and Urban Development (HUD).

ACTION: Notice of Housing Counseling Federal Advisory Committee Public Meeting.

SUMMARY: This gives notice of a Housing Counseling Federal Advisory Committee (HCFAC) meeting and sets forth the proposed agenda. The HCFAC meeting will be held on Wednesday, September 11, 2024. The meeting is open to the public and is accessible to individuals with disabilities.

DATES: The hybrid meeting (virtual and in-person meeting) will be held on Wednesday, September 11, 2024, starting at 10:00 a.m. Eastern Daylight Time (EDT).

FOR FURTHER INFORMATION CONTACT: Virginia F. Holman, Housing Program Technical Specialist, Office of Housing Counseling, U.S. Department of Housing and Urban Development; telephone number 540–894–7790 (this is not a toll-free number); email *virginia.f.holman@hud.gov.* HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit: *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.* Individuals may also email *HCFACCommittee@hud.gov* for information.

SUPPLEMENTARY INFORMATION: HUD is convening a hybrid meeting (virtual and in-person meeting) of the HCFAC on Wednesday, September 11, 2024, from 10:00 a.m. to 4:00 p.m. Eastern Daylight Time (EDT). The virtual meeting will be held via ZOOM. The in-person meeting will be held at Norfolk State University, 700 Park Avenue, Norfolk, Virginia 23504. This meeting notice is provided in accordance with the Federal Advisory Committee Act, 5 U.S.C. 1009(a)(2).

Draft Agenda—Housing Counseling Federal Advisory Committee Meeting

Wednesday September 11, 2024

Housing Solutions for Military Families How HUD Certified Housing Counselors Can Help

I. Welcome
II. Presentations and HCFAC Member Discussion
III. Public Comment
IV. Next Steps
V. Adjourn

Registration

The public is invited to attend this 6-hour hybrid meeting (virtual and in-person meeting) using ZOOM for the virtual meeting. Advance registration is required to attend. To register, please visit *https://us06web.zoom.us/webinar/register/WN_hiN_XLEDSoWdMum6TPOfFw* and complete the registration form no later than September 9, 2024. Registration will be closed after September 9, 2024. After submitting the registration form, registrants for the virtual meeting will receive a confirmation email with the meeting link and passcode needed to attend. Registrants asking to attend in-person will receive details about the meeting location and how to access the building If you have any questions about registration, please email *HCFACCommittee@ajantaconsulting.com.*

Public Comments

The public will have an opportunity to give written and oral comments

relative to agenda topics for the HCFAC's consideration. Written comments can be provided on the registration form or by emailing *HCFACCommittee@ajantaconsulting.com.* All written comments must be provided by September 9, 2024. Please note, written comments will not be read during the meeting, but will be provided to the HCFAC members. Oral comments may be provided during the meeting. Comments from the public will be received at the end of the meeting to ensure all agenda items can be completed. Each person providing oral comments will be allocated two minutes. This time will be allocated on a first-come first-served basis by HUD. The meeting registration confirmation will contain additional instructions for providing oral comments, virtually or in-person. The HCFAC will not respond to individual written or oral statements during the meeting but will take all public comments into account in its deliberations.

Meeting Records

Records and documents discussed during the meeting, as well as other information about the work of the HCFAC, will be available for public viewing as they become available at *https://www.hud.gov/program_offices/housing/sfh/hcc/housing_counseling.*

Information on the Committee is also available at *https://www.hud.gov/program_offices/housing/sfh/hcc/housing_counseling* and on HUD Exchange at *https://www.hudexchange.info/programs/housing-counseling/federal-advisory-committee/.*

Julia R. Gordon,

Assistant Secretary for Housing—FHA Commissioner.

[FR Doc. 2024–16842 Filed 7–30–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2024–0123; FXIA16710900000–245–FF09A30000]

Foreign Endangered Species; Receipt of Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on applications to conduct certain activities with foreign species that are listed as endangered under the Endangered Species Act (ESA). With some exceptions, the ESA prohibits activities with listed species unless Federal authorization is issued that allows such activities. The ESA also requires that we invite public comment before issuing permits for any activity otherwise prohibited by the ESA with respect to any endangered species.

DATES: We must receive comments by August 30, 2024.

ADDRESSES:

Obtaining Documents: The applications, application supporting materials, and any comments and other materials that we receive will be available for public inspection at *https://www.regulations.gov* in Docket No. FWS–HQ–IA–2024–0123.

Submitting Comments: When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. You may submit comments by one of the following methods:

- *Internet: https://www.regulations.gov.* Search for and submit comments on Docket No. FWS–HQ–IA–2024–0123.
- *U.S. mail:* Public Comments Processing, Attn: Docket No. FWS–HQ–IA–2024–0123; U.S. Fish and Wildlife Service Headquarters, MS: PRB/3W; 5275 Leesburg Pike; Falls Church, VA 22041–3803.

For more information, see Public Comment Procedures under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Timothy MacDonald, by phone at 703–358–2185 or via email at *DMAFR@fws.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I comment on submitted applications?

We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

You may submit your comments and materials by one of the methods in **ADDRESSES**. We will not consider comments sent by email or to an address not in **ADDRESSES**. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**).

When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. Provide sufficient information to allow us to authenticate any scientific or commercial data you include. The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) those that include citations to, and analyses of, the applicable laws and regulations.

B. May I review comments submitted by others?

You may view and comment on others' public comments at *https://www.regulations.gov* unless our allowing so would violate the Privacy Act (5 U.S.C. 552a) or Freedom of Information Act (5 U.S.C. 552).

C. Who will see my comments?

If you submit a comment at *https://www.regulations.gov,* your entire comment, including any personal identifying information, will be posted on the website. If you submit a hardcopy comment that includes personal identifying information, such as your address, phone number, or email address, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(c) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), we invite public comments on permit applications before final action is taken. With some exceptions, the ESA prohibits certain activities with listed species unless Federal authorization is issued that allows such activities. Permits issued under section 10(a)(1)(A) of the ESA allow otherwise prohibited activities for scientific purposes or to enhance the propagation or survival of the affected species. Service regulations

regarding prohibited activities with endangered species, captive-bred wildlife registrations, and permits for any activity otherwise prohibited by the ESA with respect to any endangered species are available in title 50 of the Code of Federal Regulations in part 17.

III. Permit Applications

We invite comments on the following applications.

Applicant: East Coast Zoological Society of Florida, Inc. dba Brevard Zoo, Melbourne, FL; Permit No. PER11200311

The applicant requests a permit to import one live captive-born female jaguar (*Panthera onca*) from Zoo de Granby, Granby, Canada, for the purpose of enhancing the propagation or survival of the species. This notification is for a single import.

Applicant: Staten Island Zoo, Staten Island, NY; Permit No. PER11277351

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the following species, to enhance the propagation or survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Common name	Scientific name
Aruba Island rattlesnake.	*Crotalus unicolor.*
Black-and-white ruffed lemur.	*Varecia variegata.*
Chinese alligator	*Alligator sinensis.*
Cotton-top marmoset	*Saguinus oedipus.*
Leopard	*Panthera pardus.*
Ring-tailed lemur	*Lemur catta.*

Applicant: Tulsa Zoo, Tulsa, OK; Permit No. PER11295255

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the following species, to enhance the propagation or survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Common name	Scientific name
Fiji banded iguana	*Brachylophus fasciatus.*
Aquatic box turtle	*Terrapene coahuila.*
Radiated Madagascar tortoise.	*Geochelone radiata.*
San Esteban Island chuckwalla.	*Sauromalus varius.*
Komodo Island monitor.	*Varanus komodoensis.*
Jamaican boa	*Epicrates subflavus.*
Chinese alligator	*Alligator sinensis.*
Siberian white crane	*Grus leucogeranus.*
African penguin	*Spheniscus demersus.*
Golden parakeet	*Guaruba guarouba.*
Rothschild's starling	*Leucopsar rothschildi.*
Asian elephant	*Elephas maximus.*
Black-and-white ruffed lemur.	*Varecia variegata.*
Golden-headed lion tamarin.	*Leontopithecus chrysomelas.*
Diana monkey	*Cercopithecus diana.*
Siamang	*Symphalangus syndactylus.*
Chimpanzee	*Pan troglodytes.*
Black-footed cat	*Felis nigripes.*
Lion	*Panthera leo.*
Malayan tiger	*Panthera tigris.*
Snow leopard	*Panthera uncia.*
African wild dog	*Lycaon pictus.*
White rhinoceros	*Ceratotherium simum.*

Applicant: DNCR State of North Carolina dba North Carolina Zoo, Asheboro, NC; Permit No. PER11439122

The applicant requests to renew their captive-bred wildlife registration under 50 CFR 17.21(g) for Komodo Island monitor (*Varanus komodoensis*), to enhance the propagation or survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Daniel Pearson, Micanopy, FL; Permit No. PER11444722

The applicant requests to renew their captive-bred wildlife registration under 50 CFR 17.21(g) for Madagascar radiated tortoise (*Geochelone radiata*), to enhance the propagation or survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

The following applicants request permits to import sport-hunted trophies of male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancing the propagation or survival of the species.

- *Applicant:* Zachary Boles, Cumming, GA; Permit No. PER11541505
- *Applicant:* Tony Boles, Cumming, GA; Permit No. PER11541207

IV. Next Steps

After the comment period closes, we will make decisions regarding permit issuance. If we issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**. You may locate the notice announcing the permit issuance by searching *https://www.regulations.gov* for the permit number listed above in this document. For example, to find information about the potential issuance of Permit No. 12345A, you would go to *regulations.gov* and search for ''12345A''.

V. Authority

We issue this notice under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and its implementing regulations.

Timothy MacDonald,

Government Information Specialist, Branch of Permits, Division of Management Authority.

[FR Doc. 2024–16769 Filed 7–30–24; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WAOR 057423]

Public Land Order No. 7944; Extension of Public Land Order No. 7614 for Halliday Fen Research Natural Area, Washington

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order extends the duration of the withdrawal created by Public Land Order (PLO) No. 7614 for an additional 20-year period. PLO No. 7614 withdrew 646.40 acres of National Forest System lands in the Colville National Forest near Metaline, Washington from location and entry under the United States mining laws to protect the Halliday Fen Research Natural Area (RNA). A **Federal Register** notice published on September 29, 2023, revised the legal land description and acreage written in PLO No. 7614 to reflect the Bureau of Land Management (BLM) Cadastral Survey's current standards for Specifications for Descriptions of Land.

DATES: This PLO takes effect on September 10, 2024.

FOR FURTHER INFORMATION CONTACT: Luke Poff, Realty Specialist, BLM Oregon/Washington State Office, (503) 808–6249, by email at *lpoff@blm.gov.* The US Forest Service can be reached at the Colville National Forest Supervisor's Office, 765 South Main St., Colville, Washington, 99114, (509) 684–7000. Individuals in the United States who are deaf, blind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The extension of PLO No. 7614 is required in order to continue the protection of

the unique characteristics, sensitive fauna, hydrology, and research values of the Halliday Fen RNA, which includes a marl fen, western red cedar and western hemlock forests, and habitat for a variety of rare plant and animal species. The RNA is also within the Salmo Priest Grizzly Bear Management Unit, which is part of the Selkirk Grizzly Bear Recovery Zone in Pend Oreille County, Washington.

Order

By virtue of the authority vested in the Secretary of the Interior by section 204(d) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(d), it is ordered as follows:

1. PLO No. 7614 (69 FR 55448 (2004)), as corrected (88 FR 67349 (2023)), which withdrew 646.40 acres of National Forest System lands from location and entry under the United States mining laws, subject to valid existing rights, to protect the Halliday Fen RNA, is hereby extended for an additional 20-year period. The legal land description and acreage was revised to reflect the BLM Cadastral Survey's Specifications for Descriptions of Land, which is as follows:

Colville National Forest

Willamette Meridian

T. 40 N., R. 44 E.,
Sec. 31, W½NE¼, SE¼NE¼, SE¼NW¼, E½SW¼, and NW¼SE¼.

Together with portions of the following lands as specifically identified and described by metes and bounds in the ''Boundary Description for Halliday Fen Research Natural Area to be Withdrawn from Mineral Location'' dated April 19, 2002, in the official records of the BLM Oregon/Washington State Office and the Colville National Forest Office, Colville, Washington:

T. 39 N., R. 43 E.,
Sec. 1, lot 1.
T. 40 N., R. 43 E.,
Sec. 36, E½SE¼.
T. 39 N., R. 44 E.,
Sec. 6, lots 2 thru 5, and SE¼NW¼.
T. 40 N., R. 44 E.,
Sec. 30, SE¼SW¼, NW¼SE¼, and S½SE¼;
Sec. 31, lots 1 thru 4, NE¼NE¼, NE¼NW¼, NE¼SE¼, and S½SE¼;
Sec. 32, W½NW¼ and NW¼SW¼.

The areas described aggregate 646.37 acres.

2. This withdrawal will expire 20 years from the effective date of this order unless, as a result of a review conducted prior to the expiration date pursuant to Section 204(f) of the Federal Land Policy and Management Act, the Secretary determines that the withdrawal shall be further extended.

(Authority: 43 U.S.C. 1714)

Robert T. Anderson,

Solicitor.

[FR Doc. 2024–16897 Filed 7–30–24; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_ID_FRN_MO4500181054]

Filing of Plats of Survey: Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of official filing of plats of surveys.

SUMMARY: The plats of survey of the following described lands are scheduled to be officially filed in the Bureau of Land Management (BLM), Idaho State Office (ISO), Boise, Idaho, 30 days from the date of this publication. The plats were prepared to meet administrative needs of various Federal agencies.

ADDRESSES: A copy of the plat may be obtained from the Public Room at the Bureau of Land Management, Idaho State Office, 1387 S Vinnell Way, Boise, Idaho 83709, upon required payment.

FOR FURTHER INFORMATION CONTACT: Daniel S. Young, Branch of Cadastral Survey, BLM, 1387 South Vinnell Way, Boise, Idaho, 83709–1657; (208) 373–3994; email: *dsyoung@blm.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 7–1–1 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Boise Meridian, Idaho

T. 8 N., R. 33 E., Sections 19, 30, and 31, accepted May 17, 2024.
T. 48 N., R. 2 E., Sections 21 and 22, accepted July 1, 2024.
T. 2 S., R. 3 W., Section 18, accepted July 16, 2024.
T. 2 S., R. 4 W., Section 13, accepted July 16, 2024.
T. 4 N., R. 3 E., Sections 1, 4, 5, 8, 10, 11, 14, 15, 23, 24, 25, 26, and 35, accepted July 19, 2024.
T. 4 N., R. 4 E., Sections 6 and 30, accepted July 19, 2024.

The plat, in one sheet, incorporating the field notes of the dependent resurvey of a portion of the 8th Auxiliary Meridian East (west boundary) and a portion of the subdivisional lines, and the subdivision of sections 19, 30, and 31, T. 8 N., R. 33 E., Boise Meridian, Idaho, Group Number 1549, accepted May 17, 2024.

The plat, in three sheets, of the corrective dependent resurvey of a portion of the subdivisional lines, and the dependent resurvey of portions of the subdivisional lines and certain mineral surveys, and the metes-and-bounds survey of Tract 47, T. 48 N., R. 2 E, Boise Meridian, Idaho, Group Number 1432, accepted July 1, 2024.

The plat, in one sheet, incorporating the field notes of the dependent resurvey of a portion of the subdivisional lines, and the subdivision of section 18, T. 2 S., R. 3 W., Boise Meridian, Idaho, Group Number 1566, accepted July 16, 2024.

The plat, in one sheet, incorporating the field notes of the dependent resurvey of portions of the east boundary and the subdivisional lines, and the subdivision of section 13, T. 2 S., R. 4 W., Boise Meridian, Idaho, Group Number 1566, accepted July 16, 2024.

The plat, in two sheets, incorporating the field notes of the dependent resurvey of portions of the north, south, and east boundaries, and a portion of the subdivisional lines, and the boundaries of Mineral Survey Number 1661, and the subdivision of sections 1, 4, 5, 8, 10, 11, 14, 15, 23, 24, 25, 26, and 35, T. 4 N., R. 3 E., Boise Meridian, Idaho, Group Number 1452, accepted July 19, 2024.

The plat, in one sheet, incorporating the field notes of the dependent resurvey of portions of the west and north boundaries, and a portion of the subdivisional lines, and the subdivision of sections 6 and 30, T. 4 N., R. 4 E., Boise Meridian, Idaho, Group Number 1478, accepted July 19, 2024.

If you wish to protest one or more plats of survey identified above, you must file a written notice of protest with the Chief Cadastral Surveyor for Idaho, BLM within 30 calendar days from the date of this publication at the address listed in the **ADDRESSES** section of this notice. The protest must identify the plat(s) of survey being protested and contain all reasons and evidence in support of the protest. A protest is considered filed on the date it is received by the Chief Cadastral Surveyor for Idaho during regular business hours; if received after regular business hours, a protest will be considered filed the next business day.

Before including your address, phone number or email address in a protest, you should be aware the documents you submit, including your personal identifying information, may be made publicly available in their entirety. While you can ask to withhold your personal identifying information from public review, we cannot guarantee this.

(Authority: 43 U.S.C. chapter 3.)

Michael L. Hart,

Chief Cadastral Surveyor for Idaho.

[FR Doc. 2024–16839 Filed 7–30–24; 8:45 am]

BILLING CODE 4331–19–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000 245S180110; S2D2S SS08011000 SX064A000 24XS501520; OMB Control Number 1029–0047]

Agency Information Collection Activities; Permanent Program Performance Standards—Surface and Underground Mining Activities

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before August 30, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Please provide a copy of your comments to Mark Gehlhar, Office of Surface Mining Reclamation and Enforcement, 1849 C Street NW, Room 1544–MIB, Washington, DC 20240, or by email to *mgehlhar@osmre.gov.* Please reference OMB Control Number 1029–0047 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Mark Gehlhar by email at *mgehlhar@osmre.gov,* or by telephone at (202) 208–2716. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on April 17, 2024 (89 FR 27448). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: Sections 515 and 516 of the Surface Mining Control and Reclamation Act of 1977 provide that permittees conducting coal mining operations shall meet all applicable performance standards of the Act. The information collected is used by the regulatory authority to monitor and inspect surface coal mining activities to ensure that they are conducted in compliance with the requirements of the Act.

Title of Collection: Permanent Program Performance Standards—Surface and Underground Mining Activities.

OMB Control Number: 1029–0047.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Businesses and State governments.

Total Estimated Number of Annual Respondents: 524.

Total Estimated Number of Annual Responses: 264,783.

Estimated Completion Time per Response: Varies from 2 hours to 336 hours, depending on activity.

Total Estimated Number of Annual Burden Hours: 1,068,422.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Annually.

Total Estimated Annual Nonhour Burden Cost: $20,650,947.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Mark J. Gehlhar,

Information Collection Clearance Officer, Office of Surface Mining Reclamation and Enforcement.

[FR Doc. 2024–16872 Filed 7–30–24; 8:45 am]

BILLING CODE 4310–05–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–582 and 731–TA–1377 (Review)]

Ripe Olives From Spain

Determinations

On the basis of the record [1] developed in the subject five-year reviews, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the countervailing and antidumping duty orders on ripe olives from Spain would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

Background

The Commission instituted these reviews on July 3, 2023 (88 FR 42751) and determined on October 6, 2023 that it would conduct full reviews (88 FR 73043, October 24, 2023). Notice of the scheduling of the Commission's reviews and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on January 22, 2024 (89 FR 3950). The Commission conducted its hearing on May 30, 2024. All persons who requested the opportunity were permitted to participate.

The Commission made these determinations pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determinations in these reviews on August 5, 2024. The views of the Commission are contained in USITC Publication 5526 (July 2024), entitled *Ripe Olives from Spain: Investigation Nos. 701–TA–582 and 731–TA–1377 (Review).*

By order of the Commission.

Issued: July 25, 2024.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2024–16761 Filed 7–30–24; 8:45 am]

BILLING CODE 7020–02–P

JUDICIAL CONFERENCE OF THE UNITED STATES

Advisory Committees on Appellate, Bankruptcy, and Evidence Rules; Hearings of the Judicial Conference

AGENCY: Judicial Conference of the United States.

ACTION: Advisory Committees on Appellate, Bankruptcy, and Evidence Rules; notice of proposed amendments and open hearings.

DATES: All written comments and suggestions with respect to the proposed amendments may be submitted on or after the opening of the period for public comment on August 15, 2024, but no later than February 17, 2025.

ADDRESSES: Written comments must be submitted electronically, following the instructions provided on the website. Comments will be posted on the website and available to the public.

Public hearings either virtually or in person are scheduled on the proposed amendments as follows:

- Appellate Rules on January 10, 2025, and February 14, 2025;
- Bankruptcy Rules on January 17, 2025, and January 31, 2025; and
- Evidence Rule on January 22, 2025, and February 12, 2025.

Those wishing to testify must contact the Secretary of the Committee on Rules of Practice and Procedure by email at: *RulesCommittee_Secretary@ao.uscourts.gov,* at least 30 days before the hearing.

FOR FURTHER INFORMATION CONTACT: H. Thomas Byron III, Esq., Chief Counsel, Rules Committee Staff, Administrative Office of the U.S. Courts, Thurgood Marshall Federal Judiciary Building, One Columbus Circle NE, Suite 7–300, Washington, DC 20544, Phone (202) 502–1820, *RulesCommittee_Secretary@ao.uscourts.gov.*

SUPPLEMENTARY INFORMATION: The Advisory Committees on Appellate, Bankruptcy, and Evidence Rules have proposed amendments to the following rules:

- Appellate Rules 29 and 32, Appendix on Length Limits, and Form 4;
- Bankruptcy Rules 1007, 3018, 5009, 9006, 9014, 9017, new Rule 7043, and Official Form 410S1; and
- Evidence Rule 801.

The text of the proposals will be posted August 15, 2024, on the Judiciary's website at: *https://www.uscourts.gov/rules-policies/proposed-amendments-published-public-comment.*

(Authority: 28 U.S.C. 2073.)

Dated: July 25, 2024.

Shelly L. Cox,

Management Analyst, Rules Committee Staff.

[FR Doc. 2024–16773 Filed 7–30–24; 8:45 am]

BILLING CODE 2210–55–P

DEPARTMENT OF LABOR

Employment and Training Administration

Workforce Information Advisory Council

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of a virtual WIAC meeting September 9–10, 2024.

SUMMARY: Notice is hereby given that the Workforce Information Advisory Council (WIAC or Advisory Council) will meet in-person September 9–10, 2024. Information for public attendance will be posted at *www.dol.gov/agencies/eta/wioa/wiac/meetings* several days prior to each meeting date. The meetings will be open to the public.

DATES: The meeting will take place September 9–10, 2024. The meeting will begin at 9 a.m. EDT and conclude at approximately 4:30 p.m. EDT on each day. Public statements and requests for special accommodations or to address the Advisory Council must be received by August 26, 2024.

ADDRESSES: The meeting will be held at the Hyatt Regency Crystal City, 2799 Richmond Hwy., Arlington, VA 22202. Any special instructions for attendance will be posted on the WIAC website, *www.dol.gov/agencies/eta/wioa/wiac/meetings.* If problems arise accessing the meeting, please contact Donald Haughton, Unit Chief in the Division of National Programs, Tools, and Technical Assistance, Employment and Training Administration, U.S. Department of Labor, at 202–203–9209.

FOR FURTHER INFORMATION CONTACT: Steven Rietzke, Chief, Division of National Programs, Tools, and Technical Assistance, Employment and Training Administration, U.S. Department of Labor, Room C–4510, 200 Constitution Ave. NW, Washington, DC 20210; Telephone: 202–693–3912; Email: *WIAC@dol.gov.* Mr. Rietzke is the WIAC Designated Federal Officer.

SUPPLEMENTARY INFORMATION:

Background: This meeting is being held pursuant to sec. 308 of the Workforce Innovation and Opportunity Act of 2014 (WIOA) (Pub. L. 113–128), which amends sec. 15 of the Wagner-Peyser Act of 1933 (29 U.S.C. 491–2). The WIAC is an important component of WIOA. The WIAC is a federal advisory committee of workforce and labor market information experts representing a broad range of national, state, and local data and information users and producers. The WIAC was established in accordance with provisions of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. app.) and will act in accordance with the applicable provisions of FACA and its implementing regulation at 41 CFR 102–3. The purpose of the WIAC is to provide recommendations to the Secretary of Labor (Secretary), working jointly through the Assistant Secretary for Employment and Training and the Commissioner of Labor Statistics, to address: (1) the evaluation and improvement of the nationwide workforce and labor market information (WLMI) system and statewide systems that comprise the nationwide system; and (2) how the Department of Labor (Department) and the states will cooperate in the management of those systems. These systems include programs to produce employment-

related statistics and state and local WLMI.

The Department anticipates the WIAC will accomplish its objectives by: (1) studying WLMI issues; (2) seeking and sharing information on innovative approaches, new technologies, and data to inform employment, skills training, and workforce and economic development decision making and policy; and (3) advising the Secretary on how the WLMI system can best support workforce development, planning, and program development. Additional information is available at *www.dol.gov/agencies/eta/wioa/wiac/meetings*.

Purpose: The WIAC is continually identifying and reviewing issues and aspects of the WLMI system and statewide systems that comprise the nationwide system and how the Department and the states will cooperate in the management of those systems. As part of this process, the Advisory Council meets to gather information and to engage in deliberative and planning activities to facilitate the development and provision of its recommendations to the Secretary in a timely manner.

Agenda: The agenda topics for the meeting are: (1) Review, discuss and approve the draft recommendations presented at the Jun 26–27, 2024, virtual meeting, (2) Discuss topics for future consideration of the WIAC, and (3) Determine workplan for developing the next set of WIAC recommendations. A detailed agenda will be available at *www.dol.gov/agencies/eta/wioa/wiac/meetings* shortly before the September 9–10, 2024, meeting commences.

The Advisory Council will open the floor for public comment at approximately 1:15 p.m. EDT for approximately 10 minutes on both meeting dates. However, that time may change at the WIAC chair's discretion.

Attending the meetings: Members of the public who require reasonable accommodations to attend the in-person meeting may submit requests for accommodations via email to the email address indicated in the **FOR FURTHER INFORMATION CONTACT** section with the subject line ''September 2024 WIAC Meeting Accommodations'' by the date indicated in the **DATES** section. Please include a specific description of the accommodations requested and phone number or email address where you may be contacted if additional information is needed to meet your request.

Public statements: Organizations or members of the public wishing to submit written statements may do so by transmitting them as email attachments in PDF format to the email address indicated in the **FOR FURTHER INFORMATION CONTACT** section with the subject line ''September 2024 WIAC Meeting Public Statements'' by the date indicated in the **DATES** section. Submitters may include their name and contact information in the body of the email for statements transmitted electronically. Relevant statements received before the date indicated in the **DATES** section will be included in the record of each meeting. No deletions, modifications, or redactions will be made to statements received, as they are public records. Please do not include personally identifiable information in your public statement.

Requests to Address the Advisory Council: Members of the public or representatives of organizations wishing to address the Advisory Council should forward their requests to the contact indicated in the **FOR FURTHER INFORMATION CONTACT** section, or contact the same by phone, by the date indicated in the **DATES** section. Oral presentations will be limited to 10 minutes, time permitting, and shall proceed at the discretion of the Advisory Council chair. Individuals with disabilities, or others who need special accommodations, should indicate their needs along with their request.

José Javier Rodríguez,

Assistant Secretary for Employment and Training.

[FR Doc. 2024–16825 Filed 7–30–24; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Request To Be Selected as Payee

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Office of Workers' Compensation Programs (OWCP)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before August 30, 2024.

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

FOR FURTHER INFORMATION CONTACT: Michelle Neary by telephone at 202–693–6312, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The CM–910 is used to obtain information about prospective representative payees to determine whether they are qualified to handle monetary benefits on behalf of a beneficiary under part 901 of the Black Lung Benefits Act. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on April 9, 2024 (89 FR 24867).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–OWCP.

Title of Collection: Request to be Selected as Payee.

OMB Control Number: 1240–0010.

Affected Public: Individuals or Households.

Total Estimated Number of Respondents: 350.

Total Estimated Number of Responses: 350.

Total Estimated Annual Time Burden: 88 hours.

Total Estimated Annual Other Costs Burden: $230.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Michelle Neary,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2024–16781 Filed 7–30–24; 8:45 am]

BILLING CODE 4510–CK–P

DEPARTMENT OF LABOR

Office of the Acting Secretary

All Items Consumer Price Index for All Urban Consumers; United States City Average

Pursuant to section 315(c) of the Federal Election Campaign Act of 1971, as amended (Pub. L. 92–225), 52 U.S.C. 30116(c), the Secretary of Labor has certified to the Chair of the Federal Election Commission and publishes this notice in the **Federal Register** that the United States City Average All Items Consumer Price Index for All Urban Consumers (CPI–U) (1967=100) increased 518.0 percent from its 1974 annual average of 147.7 to its 2023 annual average of 912.551 and it increased 72.1 percent from its 2001 annual average of 530.4 to its 2023 annual average of 912.551. Using 1974 as a base (1974=100), I certify that the CPI–U increased 518.0 percent from its 1974 annual average of 100 to its 2023 annual average of 617.976. Using 2001 as a base (2001=100), I certify that the CPI–U increased 72.1 percent from its 2001 annual average of 100 to its 2023 annual average of 172.087. Using 2006 as a base (2006=100), I certify that the CPI–U increased 51.1 percent from its 2006 annual average of 100 to its 2023 annual average of 151.143.

Signed at Washington, DC.

Julie A. Su,

Acting Secretary of Labor.

[FR Doc. 2024–16782 Filed 7–30–24; 8:45 am]

BILLING CODE 4510–24–P

DEPARTMENT OF LABOR

Office of the Acting Secretary

All Items Consumer Price Index for All Urban Consumers; United States City Average

Pursuant to section 33105(c) of title 49, United States Code, and the delegation of the Secretary of Transportation's responsibilities under that Act to the Administrator of the Federal Highway Administration (49 CFR 1.95 (a)), the Secretary of Labor has certified to the Administrator and published this notice in the **Federal Register** that the United States City Average All Items Consumer Price Index for All Urban Consumers (1967=100) increased 193.3 percent from its 1984 annual average of 311.1 to its 2023 annual average of 912.751.

Signed at Washington, DC.

Julie A. Su,

Acting Secretary of Labor.

[FR Doc. 2024–16783 Filed 7–30–24; 8:45 am]

BILLING CODE 4510–24–P

NATIONAL CREDIT UNION ADMINISTRATION

Revision of Agency Information Collections for Comments Request: Proposed Collections

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice and request for comments.

SUMMARY: The National Credit Union Administration (NCUA) will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice.

DATES: Written comments should be received on or before September 30, 2024 to be assured consideration.

ADDRESSES: Interested persons are invited to submit written comments on the information collection to Dacia Rogers, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314, Suite 5067; Fax No. (703) 519–8161; or email at *PRAComments@NCUA.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submission may be obtained by contacting Dacia Rogers at (703) 718–1155.

SUPPLEMENTARY INFORMATION:

OMB Number: 3133–0129.

Title: Corporate Credit Unions, 12 CFR part 704.

Type of Review: Revision of a currently approved collection.

Abstract: Part 704 of NCUA's regulations established the regulatory framework for corporate credit unions. This includes various reporting and recordkeeping requirements as well as safety and soundness standards. NCUA has established and regulates corporate credit unions pursuant to its authority under sections 120, 201, and 209 of the Federal Credit Union Act, 12 U.S.C. 1766(a), 1781, and 1789. The collection of information is necessary to ensure that corporate credit unions operate in a safe and sound manner by limiting risk to their natural person credit union members and the National Credit Union Share Insurance Fund.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated Total Annual Burden Hours: 230.

Request for Comments: Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will become a matter of public record. The public is invited to submit comments concerning: (a) whether the collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of the information on the respondents, including the use of automated collection techniques or other forms of information technology.

By the National Credit Union Administration Board.

Melane Conyers-Ausbrooks,

Secretary of the Board.

[FR Doc. 2024–16790 Filed 7–30–24; 8:45 am]

BILLING CODE 7535–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–456 and 50–457; NRC–2024–0112]

Constellation Energy Generation, LLC; Braidwood Station, Units 1 and 2; Environmental Assessment and Finding of No Significant Impact

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering amending Renewed Facility Operating License Nos. NPF–72 and NPF–77, which authorize Constellation Energy Generation, LLC, (Constellation, the licensee) to operate Braidwood Station

(Braidwood), Units 1 and 2. The proposed amendments would change Technical Specification (TS) Surveillance Requirement (SR) 3.7.9.2 to allow an ultimate heat sink (UHS) temperature of less than or equal to 102.8 degrees Fahrenheit (°F) through September 30, 2024. The NRC staff is issuing an environmental assessment (EA) and finding of no significant impact (FONSI) associated with the proposed amendments.

DATES: The EA and FONSI referenced in this document are available on July 31. 2024.

ADDRESSES: Please refer to Docket ID NRC–2024–0112 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2024–0112. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Joel S. Wiebe, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–6606; email: *Joel.Wiebe@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is considering amending Renewed Facility Operating License Nos. NPF–72 and NPF–77, which authorize Constellation to operate Braidwood, Units 1 and 2, located in Will County, Illinois. Constellation submitted its license amendment request in accordance with section 50.90 of title 10 of the *Code of Federal Regulation* (10 CFR), ''Application for amendment of license, construction permit, or early site permit,'' by letter dated June 4, 2024. If approved, the license amendments would revise TS SR 3.7.9.2 to allow a temporary increase in the allowable UHS average temperature of less than or equal to (≤) 102.8 °F (39.3 degrees Celsius (°C)) through September 30, 2024. In accordance with 10 CFR 51.21, the NRC has determined that an EA is the appropriate form of environmental review for the requested action. Based on the results of the EA that follows, the NRC has determined not to prepare an environmental impact statement for the proposed amendments and is issuing a FONSI.

II. Environmental Assessment

Description of the Proposed Action

The proposed action would allow Constellation to operate Braidwood, Units 1 and 2, at UHS temperatures up to 102.8 °F (39.3 °C) until September 30, 2024. The proposed action is in response to the licensee's license amendment request application dated June 4, 2024. The proposed action would amend the Braidwood, Units 1 and 2, renewed operating licenses TS to allow a temporary increase in the allowable average temperature of water withdrawn from the UHS and supplied to the plant for cooling from ≤102 °F (38.9 °C) to ≤102.8 °F (39.3 °C) through September 30, 2024. Specifically, the proposed action would revise TS SR 3.7.9.2, which currently states, ''Verify average water temperature of UHS is ≤102.8 °F until September 30, 2023. After September 30, 2023, verify average water temperature of UHS is ≤102 °F'' to state ''Verify average water temperature of UHS is ≤102.8 °F until September 30, 2024. After September 30, 2024, verify average water temperature of UHS is ≤102 °F.'' Under the current TS, if the average UHS temperature as measured at the discharge of the operating essential service water system pumps is greater than 102 °F (38.9 °C), TS 3.7.9, Required Actions A.1 and A.2, would be entered concurrently and would require the licensee to place Braidwood in hot standby (Mode 3) within 12 hours and cold shutdown (Mode 5) within 36 hours. The proposed action would allow Braidwood to continue to operate during times when the UHS indicated average water temperature exceeds 102 °F (38.9 °C) but is less than or equal to 102.8 °F (39.3 °C) through September 30, 2024. The current TS's UHS average water temperature limit of 102 °F (38.9 °C) would remain applicable to all other time periods beyond September 30, 2024. The proposed action is nearly identical to previously approved license amendments that allowed for the average water temperature of the UHS to be ≤102.8 °F until September 30, 2020, September 30, 2021, September 30, 2022, and September 30, 2023. The NRC issued EAs for the 2020, 2021, 2022, and 2023, UHS amendments in the **Federal Register** on September 10, 2020 (85 FR 55863), July 7, 2021 (86 FR 35831), July 20, 2022 (87 FR 43301), and June 16, 2023 (88 FR 39487), respectively. The NRC issued the license amendments on September 24, 2020, July 13, 2021, August 10, 2022, and July 13, 2023, respectively. The only difference between the previously approved amendments to TS SR 3.7.9.2 and the proposed action is that the proposed action would replace the year ''2023'' with ''2024.'' It should also be noted that during the past 4 years the temperature of the UHS has not exceeded 102 °F, so no cumulative effects need be considered.

Need for the Proposed Action

The proposed action would allow Constellation to operate Braidwood, Units 1 and 2, during the hot summer months by allowing an UHS temperature of ≤102.8 °F (39.3 °C) until September 30, 2024. The licensee has requested the proposed amendments in connection with historical meteorological and atmospheric conditions that have resulted in the TS UHS temperature being challenged. These conditions included elevated air temperatures, high humidity, and low wind speed. Specifically, from July 4, 2020, through July 9, 2020, northern Illinois experienced high air temperatures and drought conditions, which caused sustained elevated UHS temperatures. In response to these conditions in 2020, the licensee submitted license amendment requests contained in letter dated July 15, 2020, as supplemented by letter dated August 14, 2020. The NRC subsequently granted the licensee's request by letter dated September 24, 2020. The NRC approved similar requests for subsequent years by letters dated July 13, 2021, August 10, 2022, and July 13, 2023. Constellation projects that similar conditions are likely this year. The proposed action

would provide the licensee with operational flexibility until September 30, 2024, so that the plant shutdown criteria specified in the TS are not triggered unless UHS temperature exceeds 102.8 °F (39.3 °C).

Plant Site and Environs

Braidwood Station, in Will County, Illinois, is located approximately 50 miles (mi) or 80 kilometers (km) southwest of the Chicago Metropolitan Area and 20 mi (32 km) south-southwest of Joliet. The Kankakee River is approximately five mi (8 km) east of the eastern site boundary. An onsite 2,540-acre (ac); 1,030-hectare (ha) cooling pond provides condenser cooling. Cooling water is withdrawn from the pond through the lake screen house, which is located at the north end of the pond. Heated water returns to the cooling pond through a discharge canal west of the lake screen house intake that is separated from the intake by a dike. The pond typically holds 22,300 acre-feet (27.5 million cubic meters) of water at any given time. The cooling pond includes both ''essential'' and ''non-essential'' areas. The essential cooling pond is the portion of the cooling pond that serves as the UHS for emergency core cooling, and it consists of a 99 ac (40-ha) excavated area of the pond directly in front of the lake screen house. The essential cooling pond's principal functions are to dissipate residual heat after reactor shutdown and to dissipate heat after an accident. It is capable of supplying Braidwood's cooling system with water for 30 days without additional makeup water. The term ''UHS'' in this EA refers to the 99-ac (40-ha) essential cooling pond, and the term ''cooling pond'' or ''pond'' describes the entire 2,540-ac (1,030-ha) area, which includes both the essential and non-essential areas.

The cooling pond is also part of the Mazonia-Braidwood State Fish and Wildlife Area, which encompasses the majority of the non-UHS area of the cooling pond as well as Illinois Department of Natural Resources (IDNR) owned lands adjacent to the Braidwood site to the south and southwest of the cooling pond. Constellation and the IDNR have jointly managed the cooling pond as part of the Mazonia-Braidwood State Fish and Wildlife Area since 1991 pursuant to a long-term lease agreement. Under the terms of the agreement, the public has access to the pond for fishing, waterfowl hunting, fossil collecting, and other recreational activities.

The cooling pond is also a wastewater treatment works as defined by section 301.415 of title 35 of the Illinois Administrative Code (35 IAC 301.415). Under this definition, the cooling pond is not considered waters of the State under Illinois Administrative Code (35 IAC 301.440) or waters of the United States under the Federal Clean Water Act (40 CFR 230.3(s)), and so the cooling pond is not subject to State water quality standards. In addition, the cooling pond is a managed ecosystem where IDNR fish stocking and other human activities primarily influence species composition and population dynamics.

Since the beginning of the lease agreement, the IDNR has stocked the cooling pond with a variety of game fish, including largemouth bass (Micropterus salmoides), smallmouth bass (M. dolomieu), blue catfish (Ictalurus furcatus), striped bass (Morone saxatilis), crappie (Pomoxis spp.), walleye (Sander vitreum), and tiger muskellunge (Esox masquinongy x lucius). IDNR performs annual surveys to determine which fish to stock based on fishermen preferences, fish abundance, different species' tolerance to warm waters, predator and prey dynamics, and other factors. Because of the warm water temperatures experienced in the summer months, introductions of warm water species, such as largemouth bass and blue catfish, have been more successful than introductions of cool-water species, such as walleye and tiger muskellunge. Since annual surveys began in 1980, IDNR has collected 47 species in the cooling pond. In recent years, bluegill (Lepomis macrochirus), channel catfish (Ictalurus punctatus), threadfin shad (Dorosoma petenense), and common carp (Cyprinus carpio) have been among the most abundant species in the cooling pond. Gizzard shad (Dorosoma cepedianum), one of the most frequently affected species during periods of elevated pond temperatures, have decreased in abundance dramatically in recent years, while bluegills, which can tolerate high temperatures with relatively high survival rates, have noticeably increased in relative abundance. IDNR stocked warm water game species, such as largemouth bass and blue catfish, continue to persist in small numbers, while cooler water stocked species, such as walleye and tiger muskellunge, no longer appear in IDNR survey collections. No Federally listed species or designated critical habitats protected under the Endangered Species Act (ESA) occur within or near the cooling pond.

The Kankakee River serves as the source of makeup water for the cooling pond. The river also receives continuous blowdown from the cooling pond. Water is withdrawn from a small river screen house located on the Kankakee River, and liquid effluents from Braidwood are discharged into the cooling pond blowdown line, which subsequently discharges into the Kankakee River.

The plant site and environs are described in greater detail in Chapter 3 of the NRC's November 2015 ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants: Regarding Braidwood Station, Units 1 and 2, Final Report'' (NUREG 1437, Supplement 55) or ''Braidwood FSEIS'' (Final Supplemental Environment Impact Statement). Figure 3–5 on pages 3–7 in the Braidwood FSEIS depicts the Braidwood Station layout, and Figure 3–4 on pages 3–6 depicts the cooling pond, including the portion of the pond that constitutes the essential cooling pond (or UHS) and the blowdown line to the Kankakee River.

Environmental Impacts of the Proposed Action

The proposed action consists of changing the year ''2023'' to ''2024'' in TS SR 3.7.9.2, allowing a temporary increase in the allowable UHS average temperature of ≤102.8 °F (39.3 °C) until September 30, 2024.

The proposed changes would not increase the probability or consequences of radiological accidents. There would be no change to the types or amounts of radioactive effluents released into the environment and, therefore, no change in occupational or public radiation exposure from the proposed changes. Therefore, there would be no significant radiological environmental impacts associated with the proposed action.

In addition, the proposed action would have no direct impacts on land use or terrestrial biota, as the proposed action involves no new construction or modification of plant operational systems. There would be no changes to the quality or quantity of nonradiological effluents and no changes to the plant's National Pollutant Discharge Elimination System permits would be needed. Overall staffing levels would not increase; therefore, worker vehicle air emissions are not expected to increase. In addition, there would be no noticeable effect on socioeconomic conditions in the region, no environment justice impacts, and no impacts to historic and cultural resources from the proposed action.

Temporarily raising the maximum allowable UHS temperature could increase cooling pond water temperatures until September 30, 2024. Because the proposed action would not affect Braidwood's licensed thermal

power level, the temperature rise across the condensers as cooling water travels through the cooling system would remain unchanged. Thus, if water in the UHS were to rise to 102.8 °F (39.3 °C), heated water returning to the cooling pond through the discharge canal, which lies west of the river screen house, could also experience a corresponding increase. The additional heat load is expected to dissipate across some thermal gradient as discharged water travels down the discharge canal and through the 99-ac (40-ha) UHS.

Fish kills often occur when cooling pond temperatures rise above 95 °F (35 °C), the temperature at which most fish in the cooling pond are thermally stressed. For example, section 3.7.4 of the Braidwood FSEIS describes six fish kill events for the period of 2001 through 2015. The fish kill events, which occurred in July 2001, August 2001, June 2005, August 2007, June 2009, and July 2012, primarily affected threadfin shad and gizzard shad, although bass, catfish, carp, and other game fish were also affected. Reported peak temperatures in the cooling pond during these events ranged from 98.4 °F (36.9 °C) to over 100 °F (37.8 °C), and each event resulted in the death of between 700 to as many as 10,000 fish. During the July 2012 event, cooling pond temperatures exceeded 100 °F (37.8 °C), which resulted in the death of approximately 3,000 gizzard shad and 100 bass, catfish, and carp. This event coincided with the NRC's granting of Enforcement Discretion to allow Braidwood to continue to operate above the TS limit of ≤100 °F (37.8 °C). The IDNR attributed this event, as well as four of the other fish kill events, to Braidwood operation and high cooling pond temperatures. Appendix B, section 4.1, of the Braidwood renewed facility operating licenses, requires Constellation to report unusual or important environmental events, including fish kills, related to plant operation to the NRC. Since November 2015 (issuance of the Braidwood FSEIS), Constellation has not reported any additional fish kill events to the NRC. Although not related to plant operation, several fish kills have occurred since this time, the most recent of which happened in August 2018 and July 2020.

In section 4.7.1.3 of the Braidwood FSEIS, NRC staff concluded that thermal impacts associated with continued operation of Braidwood during the license renewal term would result in SMALL to MODERATE impacts to aquatic resources in the cooling pond. MODERATE impacts would primarily be experienced by gizzard shad and other non-stocked and low-heat tolerant species. As part of its conclusion, NRC staff also noted that because the cooling pond is a highly managed system, any cascading effects that result from the loss of gizzard shad (such as reduction in prey for stocked species, which in turn could affect those stocked species' populations) could be mitigated through IDNR's annual stocking and continual management of the pond. At that time, the UHS TS limit was ≤100 °F (37.8 °C).

In 2016, the NRC granted license amendments that increased the allowable UHS average water temperature TS limit from ≤100 °F (37.8 °C) to ≤102.0 °F (38.9 °C). The NRC staff concluded in its environmental review that increasing the TS limit to ≤102.0 °F (38.9 °C) would have no significant environmental effect, and the NRC issued a FONSI with the EA.

In 2020, 2021, 2022, and 2023 the NRC granted additional license amendments that temporarily increased the allowable UHS average water temperature TS limit from ≤102.0 °F (38.9 °C) to ≤102.8 °F (39.3 °C) until September 30, 2020, September 30, 2021, September 30, 2022, and September 30, 2023, respectively. The NRC staff concluded in their reviews that temporarily increasing the TS limit to ≤102.8 °F (39.3 °C) would have no significant environmental effect, and the NRC issued FONSIs with the EAs.

The NRC staff has also determined that this proposed action would result in no significant impact to aquatic resources in the cooling pond for the same reasons reached in the 2020, 2021, 2022, and 2023, license amendments. The NRC staff's justification for this conclusion is as follows.

The proposed increase in the allowable UHS average water temperature limit by 0.8 °F (0.4 °C) would not increase the likelihood of a fish kill event because the current TS limit for the UHS of 102.0 °F (38.9 °C) already allows cooling pond temperatures above those at which fish species can be thermally stressed (95 °F (35 °C)). In effect, if the UHS temperature rises to the current TS limit, fish within or near the discharge canal, within the flow path between the discharge canal and UHS, or within the UHS itself would have already experienced thermal stress and possibly died. Thus, an incremental increase in the allowable UHS water temperature by 0.8 °F (0.4 °C) and the corresponding temperature increases within and near the discharge canal and within the flow path between the discharge canal and UHS would not significantly affect the number of fish kill events in the cooling pond. Additionally, the proposed action would only increase the allowable UHS average water temperature until September 30, 2024. Thus, any impacts to the aquatic communities in the managed cooling pond, if experienced, would be temporary in nature, and fish populations could recover quickly.

While the proposed action would not affect the likelihood of a fish kill event occurring during periods when the average UHS water temperature approaches the TS limit, the proposed action could increase the number of fish killed per high temperature event. For fish with thermal tolerances at or near 95 °F (35 °C), there would likely be no significant difference in the number of affected fish per high temperature event because, as previously discussed, these fish could have already experienced thermal stress and possibly died, and the additional temperature increase would not measurably affect the mortality rate. For fish with thermal tolerances above 95 °F (35 °C), such as bluegill, increased mortality is possible, as previously explained.

In addition, scientific literature provides conflicting information as to whether incremental temperature increases would cause a subsequent increase in mortality rates of bluegill or other high-temperature-tolerant fish when temperatures exceed 100 °F (37.8 °C). For instance, in laboratory studies, Banner and Van Arman (1973) demonstrated 85 percent survival of juvenile bluegill after 24 hours of exposure to 98.6 °F (37.0 °C) water for stock acclimated to 91.2 °F (32.9 °C). At 100.0 °F (37.8 °C), survival decreased to 25 percent, and at 100.4 °F (38.0 °C) and 102.0 °F (38.9 °C), no individuals survived. Even at 1 hour of exposure to 102.0 °F (38.9 °C) water, average survival was relatively low between 40 to 67.5 percent per replicate. However, in another laboratory study, Cairns (1956 in Banner and Van Arman 1973) demonstrated that if juvenile bluegill were acclimated to higher temperatures at a 3.6 °F (2.0 °C) increase per day, individuals could tolerate water temperatures up to 102.6 °F (39.2 °C) with 80 percent survival after 24 hours of exposure.

Although these studies present inconsistent information on thermal tolerance limits, data from past fish kill events indicate that Cairns' study results more closely describe the cooling pond's bluegill population because the licensee has not reported bluegill as one of the species having been affected by past high temperature events. Thus, bluegills are likely acclimating to temperature rises at rates that allow individuals to remain in high temperature areas until temperatures

decrease or allow individuals time to seek refuge in cooler areas of the pond. Alternately, if Banner and Van Arman's results were more predictive, 75 percent or more of bluegill individuals in high temperature areas of the cooling pond could be expected to die at temperatures approaching or exceeding 100 °F (37.8 °C) for 24 hours, and shorter exposure time would likely result in the death of some reduced percentage of bluegill individuals.

Under the proposed action, fish exposure to temperatures approaching the proposed UHS TS average water temperature limit of 102.8 °F (39.3 °C) and those exposed to the associated discharge for at least 1 hour could result in observable deaths. However, as stated previously, the licensee has not reported bluegill as one of the species that has been affected during past fish kills. Consequently, the NRC staff assumes that bluegill and other high-temperature-tolerant species in the cooling pond would experience effects similar to those observed in Cairn's study. Based on Cairn's results, the proposed action's incremental and short-term temperature increase could result in the death of some additional high-temperature-tolerant individuals, especially in cases where cooling pond temperatures rise dramatically over a short period of time (more than 3.6 °F (2.0 °C) in a 24-hour period).

Nonetheless, the discharge canal, flow path between the discharge canal and the UHS, and the UHS itself is a small portion of the cooling pond. Thus, while the incremental increase would likely increase the area over which cooling pond temperatures would rise, most of the cooling pond would remain at tolerable temperatures, and fish would be able to seek refuge in those cooler areas. Therefore, only fish within or near the discharge canal, within the flow path between the discharge canal and UHS, or within the UHS itself at the time of elevated temperatures would likely be affected, and fish would experience such effects to lessening degrees over the thermal gradient that extends from the discharge canal. This would not result in a significant difference in the number of fish killed per high temperature events for those species with thermal tolerances at or near 95 °F (35 °C) and an insignificant increase in the number of individuals affected for species with thermal tolerances above 95 °F (35 °C), such as bluegill. Additionally, the cooling pond is a managed ecosystem in which fish stocking, fishing pressure, and predator-prey relationships constitute the primary population pressures.

Fish populations affected by fish kills generally recover quickly and, thus, fish kills do not appear to significantly influence the fish community structure. This is demonstrated by the fact that the species that are most often affected by high temperature events (threadfin shad and gizzard shad) are also among the most abundant species in the cooling pond. Managed species would continue to be assessed and stocked by the IDNR on an annual basis in accordance with the lease agreement between Constellation and IDNR. Continued stocking would mitigate any minor effects resulting from the proposed action. As previously stated in this notice, although authorized to operate up to 102.8 °F (39.3 °C), at no time in the past 3 years did the UHS temperature exceed 102 °F (38.9 °C).

Based on the foregoing analysis, the NRC staff concludes that the proposed action would not result in significant impacts to aquatic resources in the cooling pond. Some terrestrial species, such as birds or other wildlife, rely on fish or other aquatic resources from the cooling pond as a source of food. The NRC staff does not expect any significant impacts to birds or other wildlife because, if a fish kill occurs, the number of dead fish would be a small proportion of the total population of fish in the cooling pond. Furthermore, during fish kills, birds and other wildlife could consume many of the floating, dead fish. Additionally, and as described previously, the NRC staff does not expect that the proposed action would result in a significant difference in the number or intensity of fish kill events or otherwise result in significant impacts on aquatic resources in the cooling pond.

With respect to water resources and ecological resources along and within the Kankakee River, the Illinois Environmental Protection Agency imposes regulatory controls on Braidwood's thermal effluent through title 35, Environmental Protection, section 302, ''Water Quality Standards,'' of the Illinois Administrative Code (35 IAC 302) and through the National Pollutant Discharge Elimination System (NPDES) permitting process pursuant to the Clean Water Act. Section 302 of the Illinois Administrative Code stipulates that ''[t]he maximum temperature rise shall not exceed 2.8 °C (5 °F) above natural receiving water body temperatures,'' (35 IAC 302.211(d)) and that ''[w]ater temperature at representative locations in the main river shall at no time exceed 33.7 °C (93 °F) from April through November and 17.7 °C (63 °F) in other months'' (35 IAC 302.211(e)). Additional stipulations pertaining to the mixing zone further protect water resources and biota from thermal effluents. The Braidwood NPDES permit contains special conditions that mirror these temperature requirements and that stipulate more detailed temperature requirements at the edge of the mixing zone. Under the proposed action, Braidwood thermal effluent would continue to be limited by the Illinois Administrative Code and the Braidwood NPDES permit to ensure that Braidwood operations do not create adverse effects on water or ecological resources along or within the Kankakee River. Occasionally, the licensee has applied for a provisional variance to allow higher-than-permitted temperatures at the edge of the discharge mixing zone. For instance, Exelon, the license holder at the time, applied for and the Illinois Environmental Protection Agency (IEPA) granted one provisional variance in 2012 during a period of extremely warm weather and little to no precipitation. Constellation reported no fish kills or other events to the IEPA and the NRC that would indicate adverse environmental effects resulting from the provisional variance. The details of this provisional variance are described in section 4.7.1.3 of the Braidwood FSEIS.

Under the proposed action, Constellation would remain subject to the regulatory controls described in this notice. The NRC staff finds it reasonable to assume that Constellation's continued compliance with, and the State's continued enforcement of, the Illinois Administrative Code and the Braidwood NPDES permit would ensure that Kankakee River water and ecological resources are protected. Further, the proposed action would not alter the types or amounts of effluents being discharged to the river as blowdown. Therefore, the NRC staff does not expect any significant impacts to water or ecological resources within and along the Kankakee River from temporarily increasing the allowable UHS average water temperature TS limit.

With respect to Federally listed species, the NRC staff consulted with the U.S. Fish and Wildlife Service (FWS) pursuant to section 7 of the ESA during its license renewal environmental review for Braidwood. During that consultation, the NRC staff found that the sheepnose (Plethobasus cyphyus) and snuffbox (Epioblasma triquetra) mussels had the potential to occur in the areas that would be directly or indirectly affected by license renewal (*i.e.,* the action area). In September 2015, Exelon transmitted the results of a mussel survey to the NRC and the FWS. The survey documented the

absence of Federally listed mussels near the Braidwood discharge site in the Kankakee River. Based on this survey and other information described in the Braidwood FSEIS, the NRC concluded that license renewal may affect, but is not likely to adversely affect the sheepnose mussel, and the NRC determined that license renewal would have no effect on the snuffbox mussel. The FWS concurred with the NRC's ''not likely to adversely affect'' determination in a letter dated October 20, 2015. The results of the consultation are further summarized in the Record of Decision for Braidwood license renewal.

As previously described, the impacts of the proposed action would be confined to the UHS cooling pond and would not affect water or ecological resources along and within the Kankakee River. The NRC's previous ESA, section 7, consultation confirmed that no Federally listed aquatic species occur within or near the cooling pond. The NRC has not identified any information indicating the presence of Federally listed species in the area since consultation was concluded, and the FWS has not listed any new aquatic species that may occur in the area since that time. The proposed action would not result in any disturbance or other impacts to terrestrial habitats and, thus, no Federally listed terrestrial species would be affected. Accordingly, the NRC staff concludes that the proposed action would have no effect on Federally listed species or designated critical habitat. Consultation with the FWS regarding the proposed action is not necessary because the NRC staff has determined that the proposed action will have no effect on listed species or critical habitat.

The NRC staff has identified no foreseeable land use, visual resource, noise, or waste management impacts given that the proposed action would not result in any physical changes to Braidwood facilities or equipment or changes any land uses on or off site. The NRC staff has identified no air quality impacts given that the proposed action would not result in air emissions beyond what would be experienced during current operations. Additionally, there would be no socioeconomic, environmental justice, or historic and cultural resource impacts associated with the proposed action since no physical changes would occur beyond the site boundaries and any impacts would be limited to the cooling pond.

Based on the discussion and findings previously described in this EA, the NRC concludes that the proposed action would not significantly affect plant safety and would not have a significant adverse effect on the probability of an accident occurring. In addition, there would be no significant nonradiological environmental impacts associated with the proposed action. Accordingly, the NRC concludes that the proposed action would have no significant environmental effect on the quality of the human environment.

Environmental Impacts of the Alternatives to the Proposed Action

As an alternative to the proposed action, the NRC staff considered the denial of the proposed action (*i.e.,* the ''no-action'' alternative). Denial of the proposed action would result in no changes to the current TS. Therefore, the licensee would continue to be required to place Braidwood in hot standby (Mode 3) if average UHS water temperatures exceed 102 °F (38.9 °C). The no-action alternative would result in no change in current environmental conditions or impacts at Braidwood beyond those considered in the Braidwood FSEIS.

Alternative Use of Resources

There are no unresolved conflicts concerning alternative uses of available resources under the proposed action.

Agencies and Persons Consulted

No additional agencies or persons were consulted regarding the environmental impact of the proposed action.

III. Finding of No Significant Impact

Constellation submitted a license amendment request in accordance with 10 CFR 50.90. The request seeks to amend Renewed Facility Operating License Nos. NPF–72 and NPF–77, issued to Constellation for operation of Braidwood. The amendments would revise TS SR in TS 3.7.9.2 to allow a temporary increase in the allowable UHS average temperature of less than or equal to (≤) 102.8 °F (39.3 degrees Celsius (°C)) through September 30, 2024. The NRC is considering the requested amendments.

In addition, the NRC staff conducted an environmental review of the proposed action, and prepared an EA, which is provided in Section II of this notice and is incorporated by reference in this FONSI. The NRC determined the proposed action would not significantly affect plant safety, would not have a significant adverse effect on the probability of an accident occurring, and would not have any significant radiological or nonradiological impacts. Based on the EA, the NRC staff has concluded that the proposed action will not have a significant impact on the quality of the human environment. Based on its finding, the NRC has decided not to prepare an environmental impact statement for the proposed action.

As required by 10 CFR 51.32(a)(5), the related environmental document is the ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants: Regarding Braidwood Station, Units 1 and 2, Final Report,'' NUREG–1437, Supplement 55, which provides the latest environmental review of current operations and description of environmental conditions at Braidwood.

Section IV lists the environmental documents related to the proposed action and includes information on the availability of these documents.

This FONSI and other related environmental documents are available for public inspection and are accessible online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC's PDR reference staff by telephone at 1–800–397–4209 or 301–415–4737, or by email to *PDR.Resource@nrc.gov.*

IV. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document description	ADAMS accession No.
Amendment Request	
Constellation Energy Generation, LLC. License Amendment to Braidwood Station, Units 1 and 2, Technical Specification 3.7.9, ''Ultimate Heat Sink,'' dated June 4, 2024.	ML24156A245.

Document description	ADAMS accession No.
Similar Amendments	
Braidwood Station, Units 1 and 2—Issuance of Amendments Nos. 218 and 218 Re: Revision of Technical Specifications for the Ultimate Heat Sink (EPID L–2020–LLA–0159), dated September 24, 2020.	ML20245E419.
Braidwood Station, Units 1 and 2—Issuance of Amendments Nos. 222 and 222 Re: Revision of Technical Specifications for the Ultimate Heat Sink (EPID L–2020–LLA–0095), dated July 13, 2021.	ML21154A046.
Braidwood Station, Units 1 and 2—Issuance of Amendments Nos. 228 and 228 Re: Revision of Technical Specifications for the Ultimate Heat Sink (EPID L–2022–LLA–0082), dated August 10, 2022.	ML22173A214.
Braidwood Station, Units 1 and 2—Issuance of Amendment Nos. 232 and 232 Re: Revision of Technical Specifications for the Ultimate Heat Sink (EPID L–2022–LLA–0042), dated July 13, 2023.	ML23087A076.
Other Referenced Documents	
Cairns J. 1956. Effects of heat on fish. *Industrial Wastes,* 1:180–183	n/a.[1]
Banner A, Van Arman JA. 1973. Thermal effects on eggs, larvae and juveniles of bluegill sunfish. Washington, DC: U.S. Environmental Protection Agency. EPA–R3–73–041.	n/a.[1]
Ecological Specialists, Inc. Final Report: Five Year Post-Construction Monitoring of the Unionid Community Near the Braidwood Station Kankakee River Discharge, dated September 29, 2015.	ML15274A093 (Package).
Exelon Generation Company, LLC. Byron and Braidwood Stations, Units 1 and 2, License Renewal Application, Braidwood Station Applicant's Environmental Report, Responses to Requests for Additional Information, Environmental RAIs AQ–11 to AQ–15, dated April 30, 2014, as modified by letter dated October 8, 2014 (ML14281A019).	ML14339A044.
U.S. Fish and Wildlife Service. Concurrence Letter Concluding Informal Consultation with the NRC for Braidwood License Renewal, dated October 20, 2015.	ML15299A013.
Exelon Generation Company, LLC. License Amendment to Braidwood Station, Units 1 and 2, Technical Specification 3.7.9, ''Ultimate Heat Sink,'' dated July 15, 2020.	ML20197A434.
Exelon Generation Company, LLC Supplement to License Amendment to Braidwood Station, Unit 1 and 2, Technical Specification 3.7.9, ''Ultimate Heat Sink,'' dated August 14, 2020.	ML20227A375.
U.S. Nuclear Regulatory Commission. Generic Environmental Impact Statement for License Renewal of Nuclear Plants: Regarding Braidwood Station, Units 1 and 2, Final Report (NUREG–1437, Supplement 55), dated November 30, 2015.	ML15314A814.
U.S. Nuclear Regulatory Commission. Constellation Energy Generation, LLC; Docket No. STN 50–456; Braidwood Station, Unit 1 Renewed Facility Operating License, issued on January 27, 2016, as amended through amendment number 234.	ML053040362.
U.S. Nuclear Regulatory Commission. Constellation Energy Generation, LLC; Docket No. STN 50–457; Braidwood Station, Unit 2 Renewed Facility Operating License, issued on January 27, 2016, as amended through amendment number 234.	ML053040366.
U.S. Nuclear Regulatory Commission. Record of Decision; U.S. Nuclear Regulatory Commission; Docket Nos. 50–456 and 560–457; License Renewal Application for Braidwood Station, Units 1 and 2, dated January 27, 2016.	ML15322A317.
U.S. Nuclear Regulatory Commission. Environmental Assessment and Finding of No Significant Impact Related to Ultimate Heat Sink Modification, dated July 18, 2016.	ML16181A007.
U.S. Nuclear Regulatory Commission. Braidwood Station, Units 1 and 2—Issuance of Amendments Re: Ultimate Heat Sink Temperature Increase, dated July 26, 2016.	ML16133A438.
U.S. Nuclear Regulatory Commission. Environmental Assessment and Finding of No Significant Impact Related to Temporary Revision of Technical Specifications for the Ultimate Heat Sink, dated September 3, 2020.	ML20231A469.
U.S. Nuclear Regulatory Commission. Environmental Assessment and Finding of No Significant Impact Related to Temporary Revision of Technical Specifications for the Ultimate Heat Sink, dated June 30, 2021.	ML21165A041.
U.S. Nuclear Regulatory Commission. **Federal Register** Notice, Environmental Assessment and Finding of No Significant Impact Related to Temporary Revision of Technical Specifications for the Ultimate Heat Sink, dated July 15, 2022.	ML22159A176.
U.S. Nuclear Regulatory Commission. **Federal Register** Notice, Environmental Assessment and Finding of No Significant Impact Related to Temporary Revision of Technical Specifications for the Ultimate Heat Sink, dated June 12, 2023.	ML23110A122.

[1] These references are subject to copyright laws and are, therefore, not reproduced in ADAMS.

Dated: July 26, 2024.

For the Nuclear Regulatory Commission.

Joel S. Wiebe,

Senior Project Manager, Licensing Projects Branch III, Division of Operating Reactors, Office of Nuclear Reactor Regulation.

[FR Doc. 2024–16895 Filed 7–30–24; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–338 and 50–339; NRC–2020–0201]

Virginia Electric and Power Company; North Anna Power Station, Unit Nos. 1 and 2; Final Site-Specific Environmental Impact Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has published a final site-specific environmental impact statement (EIS), issued as NUREG–1437, Supplement 7a, Second Renewal, ''Site-Specific Environmental Impact Statement for License Renewal of Nuclear Plants Regarding Subsequent License Renewal for North Anna Power Station Units 1 and 2, Final Report.'' This EIS evaluates, on a site-specific basis, the environmental impacts of subsequent license renewal of Facility Operating License Nos. NPF–4 and NPF–7 for an additional 20 years of operation for North Anna Power Station (NAPS), Unit Nos. 1 and 2, respectively.

NAPS is located in Louisa County, Virginia. Alternatives to the proposed action of subsequent license renewal for NAPS include the no-action alternative and reasonable replacement power alternatives.

DATES: NUREG–1437, Supplement 7a, Second Renewal is available as of July 22, 2024.

ADDRESSES: Please refer to Docket ID NRC–2020–0201 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0201. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* NUREG–1437, Supplement 7a, Second Renewal is available in ADAMS under Accession No. ML24204A104.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.
- *Public Library:* A copy of the final EIS will be available for public inspection at the Louisa County Library, 881 Davis Highway, Mineral, VA 23117. The NRC staff encourages those addressees with mailing addresses listed in Chapter 7 of the final EIS, to visit the NRC's NUREG-Series Publication website (*https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff.html*) or the NAPS project website (*https://www.nrc.gov/reactors/operating/licensing/renewal/applications/north-anna-1-2-subsequent.html*) to download an electronic copy. You may also obtain an electronic copy by contacting Tam Tran via email at *Tam.Tran@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Tam Tran, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3617; email: *Tam.Tran@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 51.118 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Final environmental impact statement—notice of availability,'' the NRC is making available for public inspection NUREG–1437, Supplement 7a, Second Renewal, regarding the subsequent license renewal of Virginia Electric and Power Company's (Dominion), renewed Facility Operating License Nos. NPF–4 and NPF–7 for an additional 20 years of operation for NAPS. A notice of availability of the site-specific draft EIS (DEIS) (NUREG–1437, Supplement 7a, Second Renewal) was published in the **Federal Register** on January 8, 2024, (89 FR 960) by the NRC, and on January 5, 2024 (89 FR 781) as amended January 19, 2024 (89 FR 3653), by the Environmental Protection Agency. The public comment period on the site-specific DEIS (NUREG–1437, Supplement 7a, Second Renewal) ended on February 22, 2024, and the comments received on the site-specific DEIS are addressed in the final EIS (NUREG–1437, Supplement 7a, Second Renewal).

II. Discussion

The site-specific draft EIS (NUREG–1437, Supplement 7a, Second Renewal) superseded a draft Supplemental EIS (SEIS) (NUREG–1437, Supplement 7, Second Renewal), that the NRC had issued for public comment on August 25, 2021 (86 FR 47525). The site-specific final EIS addresses the comments received on both the site-specific draft EIS (NUREG–1437, Supplement 7a, Second Renewal) and the previous draft SEIS (NUREG–1437, Supplement 7, Second Renewal). As discussed in Chapter 4 of the final EIS (NUREG–1437, Supplement 7a, Second Renewal), the NRC staff has determined that the adverse environmental impacts of subsequent license renewal for NAPS for an additional 20 years beyond the expiration dates of the initial renewed licenses are not so great that preserving the option of subsequent license renewal for energy-planning decisionmakers would be unreasonable. This recommendation is based on: (1) information provided in the environmental report, as supplemented, and other documents submitted by Dominion; (2) consultation with Federal, State, Tribal, and local governmental agencies; (3) the NRC staff's independent environmental review; and (4) consideration of public comments received during the scoping process, on the site-specific DEIS (NUREG–1437, Supplement 7a, Second Renewal), and on the previous draft SEIS (NUREG–1437, Supplement 7, Second Renewal).

Dated: July 26, 2024.

For the Nuclear Regulatory Commission.

John Moses,

Deputy Director, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Material Safety, and Safeguards.

[FR Doc. 2024–16886 Filed 7–30–24; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2024–142; CP2024–167; MC2024–448 and CP2024–455; MC2024–450 and CP2024–457; MC2024–453 and CP2024–460; MC2024–454 and CP2024–461]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* August 2, 2024.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or

removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* CP2024–142; *Filing Title:* USPS Notice of Amendment to USPS Ground Advantage & Parcel Select Contract 1, Filed Under Seal; *Filing Acceptance Date:* July 25, 2024; *Filing Authority:* 39 CFR 3035.105; *Public Representative:* Arif Hafiz; *Comments Due:* August 2, 2024.

2. *Docket No(s).:* CP2024–167; *Filing Title:* USPS Notice of Amendment to Priority Mail, USPS Ground Advantage & Parcel Select Contract 3, Filed Under Seal; *Filing Acceptance Date:* July 25, 2024; *Filing Authority:* 39 CFR 3035.105; *Public Representative:* Arif Hafiz; *Comments Due:* August 2, 2024.

3. *Docket No(s).:* MC2024–448 and CP2024–455; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 289 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 25, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Alireza Motameni; *Comments Due:* August 2, 2024.

4. *Docket No(s).:* MC2024–450 and CP2024–457; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 179 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 25, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* August 2, 2024.

5. *Docket No(s).:* MC2024–453 and CP2024–460; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 181 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 25, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Samuel Robinson; *Comments Due:* August 2, 2024.

6. *Docket No(s).:* MC2024–454 and CP2024–461; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 291 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 25, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Samuel Robinson; *Comments Due:* August 2, 2024.

This Notice will be published in the **Federal Register**.

Mallory S. Richards,

Federal Register Liaison.

[FR Doc. 2024–16833 Filed 7–30–24; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100595; File No. SR–ISE–2024–30]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish Fees for Its Expanded Co-Location Services

July 25, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 15, 2024, Nasdaq ISE, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to establish fees for its expanded co-location services, as described further below.

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on August 15, 2024.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/ise/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange filed a proposal to expand its co-location services by offering new cabinet, power, and power distribution unit options in the Exchange's expanded data center.[3] As described in that filing, the Exchange's current data center (''NY11'') in Carteret, NJ is undergoing an expansion (''NY11–4'') in response to demand for power and cabinets. The purpose of this proposed rule change is to establish fees for the expanded co-location services. Specifically, the Exchange proposes to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* SR–ISE–2024–28 (not yet published).

establish (i) a monthly fee for Ultra High Density Cabinets, (ii) an installation fee for cabinets in NY11–4, (iii) fees for power installation in NY11–4, and (iv) fees for power distribution unit options in NY11–4.

Ultra High Density Cabinet

Currently, co-location customers have the option of obtaining cabinets of various sizes and power densities. Co-location customers may obtain a Half Cabinet,[4] a Low Density Cabinet with power density less than or equal to 2.88 kilowatts (''kW''), a Medium Density Cabinet with power density greater than 2.88 kW and less than or equal to 5 kW, a Medium-High Density Cabinet with power density greater than 5 kW and less than or equal to 7 kW, a High Density Cabinet with power density greater than 7 kW and less than 10 kW, and a Super High Density Cabinet with power density greater than 10 kW and less than or equal to 17.3 kW.

The Exchange filed a proposal to introduce a new cabinet choice in NY11–4, an ''Ultra High Density Cabinet,'' with power density greater than 10 kW and less than or equal to 15 kW.[5] The Ultra High Density Cabinet option will only be offered in NY11–4 because of the power configuration necessary for such cabinets, which is not possible or available in other portions of the data center due to different power distribution.[6] In addition to the Ultra High Density Cabinet, the Exchange will offer the other, existing cabinet options in NY11–4, with the exception of the Low Density Cabinet and Half Cabinet due to a lack of demand for such cabinets. The ongoing monthly fees for the Super High Density Cabinet, High Density Cabinet, Medium-High Density Cabinet, and Medium Density Cabinet are the same in NY11 and NY11–4 and the Exchange is not proposing to modify such fees.

The Exchange proposes to establish an ongoing monthly fee of $7,230 for the Ultra High Density Cabinets. To effectuate this change, the Exchange proposes to add the $7,230 ongoing monthly fee for Ultra High Density Cabinets to its fee schedule in General 8, Section 1(a). The Exchange notes that the proposed fee amount falls between the $4,748 ongoing monthly fee charged for High Density Cabinets and the $8,440 ongoing monthly fee charged for Super High Density Cabinets. Furthermore, the proposed fee is consistent with the existing ongoing monthly cabinet fees on a per kW basis. The existing monthly cabinet fees range from approximately $475 per kW to $916 per kW, while the proposed ongoing monthly cabinet fee for the Ultra High Density Cabinet ranges from approximately $482 per kW (at the high end of the power density range for Ultra High Density Cabinets) to $723 per kW (at the low end of the power density range for Ultra High Density Cabinets).

Installation Fee for Cabinets in NY11–4

The Exchange proposes to establish a cabinet installation fee of $5,940 for all cabinets in NY11–4. To effectuate this change, the Exchange proposes to add the proposed $5,940 installation fee to its fee schedule in General 8, Section 1(a) for Super High Density Cabinets, Ultra High Density Cabinets, High Density Cabinets, Medium-High Density Cabinets, and Medium Density Cabinets in NY11–4. In the existing data halls, customers may bring their own cabinets or use Exchange-provided cabinets. In NY11–4, because of the cooling system (hot aisle containment),[7] all cabinets must be uniform and therefore, the Exchange will provide all cabinets, the cost of which is included in the $5,940 installation fee.[8] The cabinets in NY11–4 include certain features not included in cabinets provided by the Exchange in the existing data halls. Specifically, the cabinets in NY11–4 include uniform, wider cabinets (32′ W x 48′ D x 91′ H), cable management, and a rear split door and combo lock. In addition, the proposed installation fee of $5,940 is comparable to fees charged for similar products.[9]

Installation Fee for Cabinet Power in NY11–4

The cabinet power options for NY11–4 include: Phase 1 20 amp 240 volt, Phase 1 32 amp 240 volt, Phase 1 40 amp 240 volt, Phase 3 20 amp 415 volt, and Phase 3 32 amp 415 volt. These cabinet power options are specific to NY11–4 and one of these options must be selected for cabinets in NY11–4. The Exchange proposes to establish an installation fee of $3,600 for Phase 1 cabinet power options in NY11–4 and an installation fee of $4,560 for Phase 3 cabinet power options in NY11–4. To effectuate this change, the Exchange proposes to add the proposed fees to its fee schedule in General 8, Section 1(c). The Exchange also proposes not to charge an ongoing monthly fee for the cabinet power options in NY11–4 and update the fee schedule accordingly. For NY11–4, the data center operator is bringing in these higher voltage power options and is likely to experience increased power distribution efficiencies across the data center. The proposed power installation fees are higher in NY11–4 as compared to the existing data halls as the installation of the higher voltage power options costs more to the Exchange and is considered a premium product due to anticipated operational efficiencies.[10] As between the Phase 1 and Phase 3 power options, the Phase 3 options provide a more efficient power source.

Fees for Power Distribution Unit Options

The Exchange will offer power distribution units (''PDUs'')[11] in NY11–4 as a convenience to customers. Rather than sourcing PDUs on a customer-by-customer basis, as the Exchange does for customers in NY11, the Exchange will offer Phase 1 and Phase 3[12] power distribution units in NY11–4. The Exchange proposes to establish a fee of $4,100 for a Phase 1 PDU and $5,260 for a Phase 3 PDU. This service is optional and customers may choose to provide their own PDUs appropriate for their power installation choices. The Exchange notes that, as part of such proposed fees, the Exchange would provide a primary and redundant PDU. As such, the proposed PDU fees covers a pair of PDUs. In addition, customers utilizing a Phase 1 or Phase 3 PDU provided by the Exchange have the ability to upgrade or downgrade between amperage levels without replacing the PDU, by a simple upgrade of the facility cord and a receptacle

[4] Half cabinets are not available to new subscribers. *See* General 8, Section 1(a).

[5] *Supra* note 3.

[6] Because of the addition of the Ultra High Density Cabinet option in NY11–4, the Super High Density Cabinet in NY11–4 will have power density greater than 15 kW and less than or equal to 17.3 kW.

[7] The existing data halls utilize cold aisle containment to manage temperatures. Hot aisle containment is a more effective way to manage heat in the data center.

[8] In contrast, to the extent customers provide their own cabinets in NY11, there is an additional out-of-pocket cost for such cabinets.

[9] For example, NYSE charges an initial $5,000 fee for dedicated cabinets. *See https://www.nyse.com/publicdocs/Wireless_Connectivity_Fees_and_Charges.pdf.*

[10] Benefits include future proofing the data hall to allow for increasing power density in the future, requiring less whips to deliver the same amount of amperage, less circuits need to be installed to reach the same power supply, and safety improvements.

[11] PDUs are devices fitted with multiple outputs designed to distribute electric power. The standardized PDUs would only be offered for NY11–4.

[12] Phase 1 PDUs are compatible with the following power options: Phase 1 20 amp 240 volt, Phase 1 32 amp 240 volt, and Phase 1 40 amp 240 volt. Phase 3 PDUs are compatible with the following power options: Phase 3 20 amp 415 volt and Phase 3 32 amp 415 volt. Phase 1 and Phase 3 are available in NY11 and NY11–4. Phase 3 PDUs provide greater power density than Phase 1 PDUs by delivering power over three wires as opposed to one wire.

update.[13] A PDU replacement is required when switching between phases/voltage.

The Exchange will also offer a switch monitored PDU add on in NY11–4, which would allow customers to connect remotely to their PDU and control the power sockets. With the switch monitored PDU option, customers would be able to power cycle or shut off power remotely. The Exchange proposes to establish a $2,000 fee for the switch monitored PDU option. This option is optional as well and customers may choose to provide their own switch monitored PDU, if desired.

Implementation

Although the timing is subject to change,[14] the Exchange anticipates opening NY11–4 Exchange access on October 21, 2024 and providing customers access in advance of this date. The proposed fees are designated to be operative on August 15, 2024. However, customer orders will not be fee liable until customers are provided access to the space.[15]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[16] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[17] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposal to establish a monthly fee for Ultra High Density Cabinets, an installation fee for cabinets in NY11–4, installation fees for power installation in NY11–4, and fees for power distribution unit options in NY11–4 is reasonable. First, the Exchange's proposal to establish a $7,230 ongoing monthly fee for Ultra High Density Cabinets in NY11–4 is reasonable because it is comparable to the Exchange's current ongoing monthly fees for cabinets. The proposed fee amount falls between the $4,748 ongoing monthly fee charged for High Density Cabinets and the $8,440 ongoing monthly fee charged for Super High Density Cabinets. Furthermore, the proposed fee is consistent with the existing ongoing monthly cabinet fees on a per kW basis. The existing monthly cabinet fees range from approximately $475 per kW to $916 per kW, while the proposed ongoing monthly cabinet fee for the Ultra High Density Cabinet ranges from approximately $482 per kW (at the high end of the power density range for Ultra High Density Cabinets) to $723 per kW (at the low end of the power density range for Ultra High Density Cabinets). Second, the Exchange believes that the proposed cabinet installation fee of $5,940 is reasonable as compared to the installation fees in NY11 (of $3,693–$4,748) because the proposed installation fee includes the cabinet itself, which includes certain enhanced features in NY11–4, including uniform, wider cabinets (32″ W × 48″ D × 91″ H), cable management, and a rear split door and combo lock. In contrast, in NY11, customers may choose to provide their own cabinets, incurring an additional cost. Furthermore, the proposed installation fee is comparable to the rate charged by NYSE for a similar product, as described above. Third, the Exchange believes that the power installation fees of $3,600 for Phase 1 power options and $4,560 for Phase 3 power options in NY11–4 are reasonable. As compared to power installation fees in NY11, the proposed rates for NY11–4 are higher because the Exchange will incur increased costs for installation of the higher voltage power options. In addition, the higher voltage power options will provide operational efficiencies for the data hall, as discussed above,[18] warranting a higher fee. Finally, the Exchange believes that the proposed fees for PDUs and the PDU add on are reasonable because such fees are consistent with market rates. Furthermore, the Exchange is providing the PDU options as a convenience to customers. No customer is required to purchase any PDU options from the Exchange. Customers may choose to provide their own PDUs and PDU add ons.

The Exchange believes substitutable products and services are available to market participants, including, among other things, other options exchanges that a market participant may connect to in lieu of the Exchange,[19] connectivity to the Exchange via a third-party reseller of connectivity, and/or trading of options products within markets which do not require connectivity to the Exchange, such as the Over-the-Counter (OTC) markets. Market participants that wish to connect to the Exchange will continue to choose the method of connectivity based on their specific needs. Market participants that wish to connect to the Exchange but want to avoid or mitigate the effect of these proposed fees can choose to connect to the Exchange through a vendor.

In summary, the proposal represents an equitable allocation of reasonable dues, fees and other charges because customers have choices in how they connect to the Exchange, the proposed monthly fee for Ultra High Density Cabinets is comparable to current fees charged by the Exchange for other cabinets, the Exchange will provide uniform cabinets in NY11–4 with special features, the proposed cabinet installation fee is consistent with that of comparable products offered by other providers, the Exchange will incur increased costs for new power installation in NY11–4, higher voltage power options will provide operational efficiencies for the data hall, and PDU options are provided as a convenience to customers and customers may choose to provide their own PDUs.

The Exchange believes that the proposed fee changes are not unfairly discriminatory because the cabinet, power, and PDU fees for NY11–4 are available to and assessed uniformly across all market participants. In addition, all customers have the choice of whether and how to connect to the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal burdens inter-market competition because approval of the proposal does not impose any burden on the ability of other exchanges to compete. The

[13] This functionality may be available with customer-provided PDUs as well and depends on the PDU provided by the customer.

[14] The Exchange will announce modifications to the proposed timing via the Nasdaq Customer Portal, which is the web portal used for order and inventory management of colocation services, and email communication to all colocation customers.

[15] Charging customers once access is provided is consistent with current practice and allows customers to set up equipment and begin using power.

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(4) and (5).

[18] *Supra* note 10.

[19] There are currently 17 exchanges offering options trading services. No single options exchange trades more than 15% of the options market by volume and only one of the 17 options exchanges has a market share over 10 percent. *See* Nasdaq, Options Market Statistics (Last updated July 3, 2024), available at *https://www.nasdaqtrader.com/Trader.aspx?id=OptionsVolumeSummary*. This broad dispersion of market share demonstrates that market participants can and do exercise choice in trading venues. Further, low barriers to entry mean that new exchanges may rapidly enter the market and offer additional substitute platforms to further compete with the Exchange and the products it offers.

Exchange operates in a highly competitive market in which market participants can determine whether or not to connect to the Exchange based on the value received compared to the cost of doing so. Indeed, market participants have numerous alternative exchanges that they may participate on and direct their order flow, as well as off-exchange venues, where competitive products are available for trading.

Nothing in the proposal burdens intra-market competition because the Ultra High Density Cabinets, cabinet power options, and PDU optionality in NY11–4 are available to any customer under the same fees as any other customer, and any customer that wishes to order cabinets, power and PDUs in NY11–4 can do so on a non-discriminatory basis.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[20] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–ISE–2024–30 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–ISE–2024–30. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–ISE–2024–30 and should be submitted on or before August 21, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–16802 Filed 7–30–24; 8:45 am]

BILLING CODE 8011–01–P

[20] 15 U.S.C. 78s(b)(3)(A)(ii).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100587; File No. SR–CboeBZX–2024–068]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fees Schedule

July 25, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 9, 2024, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') proposes to amend its Fees Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/BZX/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fees Schedule.[3]

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 17 options venues to which market participants may direct their order flow. Based on publicly available information, no single options exchange has more than 13% of the market share.[4] Thus, in such a low-concentrated and highly competitive market, no single options exchange, including the Exchange, possesses significant pricing power in the execution of option order flow. The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue to reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain the Exchange's transaction fees, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable. In response to competitive pricing, the Exchange, like other options exchanges, offers rebates and assesses fees for certain order types executed on or routed through the Exchange.

The Exchange's fee schedule sets forth standard rebates and rates applied per contract. For example, the Exchange provides a rebate of $0.25 per contract for Firm,[5] Broker Dealer[6] and Joint Back Office[7] (''Firm/BD/JBO'') orders that add liquidity in Penny Securities, yielding fee code PF. Additionally, in response to the competitive environment, the Exchange also offers tiered pricing, which provides Members opportunities to qualify for higher rebates or reduced fees where certain volume criteria and thresholds are met.[8] Tiered pricing provides an incremental incentive for Members to strive for higher tier levels, which provides increasingly higher benefits or discounts for satisfying increasingly more stringent criteria.

First, the Exchange proposes to increase the standard rebate for Firm/BD/JBO orders (*i.e.,* yield fee code PF) that add liquidity in Penny Securities, from $0.25 to $0.26.[9]

Second, the Exchange proposes to update the Firm, Broker Dealer, and Joint Back Office Penny Add Volume Tiers (*i.e.,* applicable to orders yielding fee code PF) set forth in Footnote 2. The Exchange currently provides opportunities for rebates per contract to add liquidity in Penny Securities as follows:

Tier	Rebate per contract to add	Required criteria
Tier 1	($0.38)	Member has an ADAV* in Firm/BD/JBO orders ≥0.20% of average OCV.**
Tier 2	($0.46)	(1) Member has an ADAV in Away MM/Firm/BD/JBO orders ≥1.05% of average OCV; and (2) Member has an ADV*** ≥1.95% of average OCV.

* ''ADAV'' means average daily added volume calculated as the number of contracts added.
** ''OCC Customer Volume'' or ''OCV'' means the total equity and ETF options volume that clears in the Customer range at the Options Clearing Corporation (''OCC'') for the month for which the fees apply, excluding volume on any day that the Exchange experiences an Exchange System Disruption and on any day with a scheduled early market close.
*** ''ADV'' means average daily volume calculated as the number of contracts added or removed, combined, per day.

The Exchange proposes to amend these tiers as follows:

- modify Tier 1 to require the Member to have an ADAV in Firm/BD/JBO orders greater than or equal to 15,000 contracts and an ADAV in Customer orders greater than or equal to 0.20% of average OCV, to qualify for the rebate; and
- modify Tier 2 to reduce the rebate from $0.46 to $0.42 per contract[10] and require the Member to have an ADAV in Firm/BD/JBO orders greater than or equal to 30,000 contracts and an ADAV in Customer orders greater than or equal to 0.20% of average OCV, to qualify for the rebate.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[11] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[12] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[13] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(4) of the Act,[14] which requires that Exchange rules provide for the equitable allocation of reasonable

[3] The Exchange initially filed the proposed fee changes on July 1, 2024 (SR–CboeBZX–2024–063). On July 9, 2024, the Exchange withdrew that filing and submitted this proposal.

[4] *See* Cboe Global Markets U.S. Options Market Volume Summary by Month (June 27, 2024), available at *https://markets.cboe.com/us/options/market_statistics/.*

[5] ''Firm'' applies to any order for the proprietary account of an OCC clearing member.

[6] ''Broker Dealer'' applies to any order for the account of a broker dealer, including a foreign broker dealer.

[7] ''Joint Back Office'' applies to any order for a joint back office account.

[8] As part of the proposed rule change, the Exchange proposes a clarifying change to remove the duplicative reference to a rebate of $0.39 for fee code PM in the Standard Rates table.

[9] In connection with the proposed fee changes, the Exchange also proposes to update the corresponding listed rebate of $0.25 for fee codes PF in the Fee Codes and Associated Fees table to the proposed new rebate of $0.26.

[10] In connection with the proposed fee changes, the Exchange also proposes to update the corresponding listed rebate of $0.46 for fee codes PF in the Fee Codes and Associated Fees table to the proposed new rebate of $0.42.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *Id.*

[14] 15 U.S.C. 78f(b)(4).

dues, fees, and other charges among its Members and other persons using its facilities.

As described above, the Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. The proposed rule change reflects a competitive pricing structure designed to incentivize market participants to direct their order flow to the Exchange, which the Exchange believes would enhance market quality to the benefit of all Members. Additionally, competing exchanges offer similar tiered pricing structures, including schedules of rebates and fees that apply based upon similarly situated members achieving certain volume and/or growth thresholds, as well as assess similar fees or rebates for similar types of orders, to that of the Exchange.

The Exchange believes the proposed rule change to increase the standard rebate for Firm/BD/JBO orders that add liquidity in Penny Securities is reasonable because it is a modest increase in this rebate rate for these orders and it continues to be in line with the standard rebate for orders of other market participants that remove liquidity in Penny Securities on the Exchange.[15] Additionally, the proposed rebate is in line with rebates for similar transactions at other exchanges.[16] The Exchange believes the proposed change is equitable and not unfairly discriminatory because it applies uniformly to all Members and, as previously noted, the increased rebate is in line with the standard rebate for orders submitted for other market participants that add liquidity in Penny Securities on the Exchange.

The Exchange believes the proposed changes to the Firm/BD/JBO Penny Add Volume Tiers are reasonable because they continue to provide opportunities for Members to receive higher rebates by providing for incrementally increasing volume-based criteria they can reach for. The Exchange believes the tiers, as modified, continue to serve as a reasonable means to encourage Members to increase their liquidity on the Exchange, particularly in connection with additional Firm/BD/JBO order flow to the Exchange in order to benefit from the proposed enhanced rebates.

The Exchange believes the proposed criteria remain commensurate with the corresponding enhanced rebates, including as amended for Tier 2. The Exchange believes the revised criteria will continue to encourage Members to send additional Firm/BD/JBO orders to the Exchange. Greater remove volume order flow may increase transactions on the Exchange, which the Exchange believes incentivizes liquidity providers to submit additional liquidity and execution opportunities. An overall increase in activity deepens the Exchange's liquidity pool, offers additional cost savings, supports the quality of price discovery, promotes market transparency and improves market quality for all investors.

Further, the Exchange believes the proposed reduced rebate offered under revised Firm/BD/JBO Penny Add Volume Tier 2 is reasonable because Members are still eligible to receive a rebate for meeting the corresponding criteria, albeit at a lower amount then before. While Firm/BD/JBO Penny Add Volume Tier 2, as proposed, will provide a lower rebate than that currently offered (from $0.46 to $0.42), the Exchange still believes that the changes are reasonable as the tier, even as amended, will continue to incentivize Members to send additional Firm/BD/JBO orders to the Exchange. As noted above, an overall increase in add activity may provide for deeper, more liquid markets and execution opportunities at improved prices, which ultimately offers additional cost savings, supports the quality of price discovery, promotes market transparency and improves market quality for all investors. Moreover, the Exchange is not required to maintain these tiers nor provide rebates. The Exchange believes the proposed changes to the rebates offered under these tiers still remain commensurate with the corresponding criteria under the respective tiers.

The Exchange believes the proposed change is also equitable and not unfairly discriminatory because it applies uniformly to all Members, who will have the opportunity to meet the tiers' criteria and receive the corresponding enhanced rebate for each tier if such criteria is met. Without having a view of activity on other markets and off-exchange venues, the Exchange has no way of knowing whether these proposed changes would definitely result in any Members qualifying for the proposed rebates. While the Exchange has no way of predicting with certainty how the proposed changes will impact Member activity, based on trading activity from the prior months, the Exchange anticipates that up to two Members will achieve Tier 1 and up to two Members will achieve Tier 2. Additionally, all Members are able to increase their Firm/BD/JBO order flow to attempt to achieve these tiers. Should a Member not meet the proposed new criteria, the Member will merely not receive that corresponding enhanced rebate.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the Exchange believes the proposal to increase the standard rebate for Firm/BD/JBO orders that add liquidity in Penny Securities will not impose any burden on intramarket competition because it will apply uniformly to all Members. All Members that submit orders yielding fee code PF will receive this same rebate. The Exchange believes the proposal to amend the Firm/BD/JBO Penny Add Volume Tiers will also not impose any burden on intramarket competition, as the changes will also apply to all Members. All Members will continue to have an opportunity to receive rebates under various tiers in the program. The Firm/BD/JBO Penny Add Volume Tiers are generally designed to increase the competitiveness of BZX and incentivize participants to increase their order flow on the Exchange, providing for additional execution opportunities for market participants and improved price transparency. An overall increase in add activity may provide for deeper, more liquid markets and execution opportunities at improved prices. Furthermore, greater overall order flow, trading opportunities, and pricing transparency benefit all market participants on the Exchange by enhancing market quality and continuing to encourage Members to send orders, thereby contributing towards a robust and well-balanced market ecosystem.

The Exchange does not believe that the proposed changes represent a significant departure from pricing currently offered by the Exchange. Members may opt to disfavor the Exchange's pricing if they believe that alternatives offer them better value. Accordingly, the Exchange does not believe that the proposed changes will impair the ability of Members or competing venues to maintain their

[15] As set forth in the Fees Schedule, the standard rebate for orders that add liquidity in Penny Securities is between $0.25 and $0.29 for Professional, Customer, Market Maker, and Away MM orders.

[16] *See, e.g.,* MIAX Emerald Options Exchange Fee Schedule, Transaction Fees, which provides that Firm Proprietary and Broker Dealer orders that add liquidity are provided a rebate of $0.25 per contract in Penny Classes. *See also* MEMX Options Fee Schedule, which provides Firms and Broker Dealers that add liquidity are provided a rebate of $0.45 per contract in Penny Securities.

competitive standing in the financial markets.

The Exchange does not believe that the proposed rule changes will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As previously discussed, the Exchange operates in a highly competitive market. Members have numerous alternative venues that they may participate on and direct their order flow, including 16 other options exchanges and off-exchange venues. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single options exchange has more than 13% of the market share.[17] Therefore, no exchange possesses significant pricing power in the execution of option order flow. Indeed, participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [18] The fact that this market is competitive has also long been recognized by the courts. In NetCoalition v. Securities and Exchange Commission, the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers' . . . .''.[19] Accordingly, the Exchange does not believe its proposed fee change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [20] and paragraph (f) of Rule 19b–4 [21] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeBZX–2024–068 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CboeBZX–2024–068. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeBZX–2024–068 and should be submitted on or before August 21, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Sherry R. Haywood,

Assistant Secretary.

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[17] *See supra* note 4.

[18] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[19] *NetCoalition* v. *SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[20] 15 U.S.C. 78s(b)(3)(A).

[21] 17 CFR 240.19b–4(f).

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100594; File No. SR–FINRA–2024–004]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Partial Amendment No. 1 to Proposed Rule Change To Amend FINRA Rule 6730 To Reduce the 15-Minute TRACE Reporting Timeframe to One Minute

July 25, 2024.

I. Introduction

On January 11, 2024, the Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change (SR–FINRA–2024–004) to amend FINRA Rule 6730 to reduce the 15-minute reporting timeframe for transactions reported to FINRA's Trade

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Reporting and Compliance Engine (''TRACE'') system to one minute, with exceptions for FINRA member firms with de minimis reporting activity and for manual trades. The proposed rule change was published for comment in the **Federal Register** on January 25, 2024.[3]

On February 29, 2024, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On April 22, 2024, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act[6] to determine whether to approve or disapprove the proposed rule change.[7] On July 18, 2024, the Commission, pursuant to Section 19(b)(2) of the Act,[8] designated September 20, 2024, as the date by which the Commission shall either approve or disapprove the proposed rule change.[9] On July 18, 2024, FINRA responded to comments[10] and filed a partial amendment to the proposed rule change in response to certain comments on the proposed rule change (''Partial Amendment No. 1''). Partial Amendment No. 1 is described in Item II below, which has been substantially prepared by FINRA.[11] The Commission is publishing this notice to solicit comments on Partial Amendment No. 1 from interested persons.[12]

[3] *See* Securities Exchange Act Release No. 99404 (Jan. 19, 2024), 89 FR 5034 (Jan. 25, 2024) (''Notice''). Comments received on the proposed rule change are available at: *https://www.sec.gov/comments/sr-finra-2024-004/srfinra2024004.htm.*

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 99640 (Feb. 29, 2024), 89 FR 16042 (Mar. 6, 2024). The Commission designated April 24, 2024, as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 100006 (Apr. 22, 2024), 89 FR 32475 (Apr. 26, 2024).

[8] 15 U.S.C. 78s(b)(2).

[9] *See* Securities Exchange Act Release No. 100555 (July 18, 2024), 89 FR 59948 (July 24, 2024) (''Extension'').

[10] *See* Letter from Racquel L. Russell, Senior Vice President, Director of Capital Markets Policy, Office of General Counsel, FINRA, dated July 18, 2024, available at *https://www.sec.gov/comments/sr-finra-2024-004/srfinra2024004.htm.*

[11] The Commission has reformatted FINRA's presentation of its proposed modifications to, and descriptions of, the proposed rule change.

[12] Partial Amendment No. 1 is also available on FINRA's website at *https://www.finra.org/sites/default/files/2024-07/SR-FINRA-2024-004-Partial-A-1.pdf.*

II. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Partial Amendment

FINRA is proposing the following amendments to the filing:

1. FINRA Proposes To Amend the Proposed Manual Trades Exception To Provide FINRA Members With an Additional Year To Transition to Five-Minute Reporting for Manual Trades

As discussed in the original filing, the proposed rule change would create an exception from the proposed one-minute reporting requirement for manual trades.[13] As originally proposed, manual trades would have been subject to reporting as soon as practicable with a five-minute outer-limit reporting timeframe, phased in after two years.[14] Specifically, where a trade qualified for the manual trades exception, a 15-minute outer limit would have applied for the first year following implementation; a 10-minute outer limit would have applied for the second year; and a five-minute outer limit would have applied thereafter.[15] Some commenters raised various concerns regarding the feasibility of five-minute reporting for manual trades, and some commenters recommended that FINRA study and assess (and provide an opportunity for public comment on) the feasibility of five-minute reporting for manual trades prior to its implementation or maintain a 15-minute reporting requirement for manual trades.[16]

In response to these comments, FINRA is amending the proposed rule change to extend the phase-in period for five-minute reporting by one year so that FINRA members would have three years to transition to five-minute reporting for manual trades.[17]

Accordingly, the proposed rule change, as amended, would provide that a FINRA member relying on the manual trades exception will be required to report the manual trade as soon as practicable and no later than within 15 minutes of the time of execution (for up to one calendar year from the effectiveness of the proposed amendments), within 10 minutes of the time of execution (for up to three calendar years from the effectiveness of the proposed amendments), and within five minutes of the time of execution (three or more calendar years from the effectiveness of the proposed amendments).[18] Partial Amendment No. 1 will provide FINRA with additional time to assess FINRA members' trade reporting times in connection with manual trades and request comment on the operation of the manual trades exception—and FINRA will be prepared to make adjustments, as necessary, prior to the effectiveness of the five-minute reporting timeframe.[19]

Following are the changes proposed in Partial Amendment No. 1, with the proposed changes in the original filing shown as if adopted. Proposed new language in Partial Amendment No. 1 is italicized; proposed deletions in Partial Amendment No. 1 are in brackets:

6730. Transaction Reporting

(a) through (f) No Change.

• • • **Supplementary Material:**

.01 through **.08** No Change.

.09 Exception for Manual Trades

(a) No Change.

(b) Except as otherwise specifically provided in paragraph (a)(2) of this Rule with respect to List or Fixed Offering Price Transactions and Takedown Transactions, a member relying on the exception for manual trades in this Supplementary Material .09 must report the transaction as soon as practicable but no later than within: 15 minutes of the Time of Execution (this 15-minute outer timeframe is available for up to one calendar year from the effectiveness of this Supplementary Material .09); within 10 minutes of the Time of Execution (this 10-minute outer timeframe is available for up to *three*[two] calendar years from the effectiveness of this Supplementary Material .09); or within 5 minutes of the Time of Execution (this 5-minute outer timeframe is applicable *three*[two] or more calendars years from the effectiveness of this Supplementary Material .09), as further provided in this paragraph.

(1) No Change.

(2) Transactions Executed During TRACE System Hours

Transactions executed on a business day at or after 8:00:00 a.m. Eastern Time through 6:29:59 p.m. Eastern Time (standard TRACE System Hours) must be reported as soon as practicable, but no later than within 15, 10, or 5 minutes *of the Time of Execution*[after the TRACE system opens] (the 15-, 10-, or 5-minute outer timeframe is available for up to one year, up to *three*[two]

[13] *See* Notice, *supra* note 3.

[14] *Id.*

[15] *Id.*

[16] *See* Partial Amendment No. 1 at 4.

[17] *Id.*

[18] *See* proposed Rule 6730.09(b).

[19] *See* Partial Amendment No. 1 at 5.

years, or *three*[two] or more years, respectively, from the effectiveness of this Supplementary Material .09), except as provided in paragraph (b)(3) of this Supplementary Material .09.

(3) Transactions Executed Less Than 5 Minutes Before TRACE System Closes

Transactions executed on a business day less than 15, 10, or 5 minutes (the 15-, 10-, or 5-minute timeframe is available for up to one year, up to *three*[two] years, or *three*[two] or more years, respectively, from the effectiveness of this Supplementary Material .09) before 6:30:00 p.m. Eastern Time must be reported as soon as practicable after the TRACE system opens the next business day (T + 1), but no later than within 15 minutes after the TRACE system opens the next business day, and if reported on T + 1, designated ''as/of'' and include the date of execution.

(4) No Change.

2. FINRA Proposes To Make a Correction to the Text of Proposed Rule 6730.09(b)(2)

Additionally, Partial Amendment No. 1 would make a correction to the proposed rule text such that proposed Rule 6730.09(b)(2) would require reporting within the prescribed timeframe from ''the Time of Execution'' rather than ''after the TRACE system opens.'' [20] As originally proposed, for transactions subject to the manual trades exception that were executed on a business day at or after 8:00:00 a.m. Eastern Time (''ET'') through 6:29:59 p.m. ET (*i.e.,* during TRACE system hours), the rule text erroneously would have required reporting ''. . . as soon as practicable, but no later than within 15, 10, or 5 minutes after the TRACE system opens. . . .'' [21] Partial Amendment No. 1 would correct the text of proposed Rule 6730.09(b)(2) so that it requires reporting of these transactions ''. . . as soon as practicable, but no later than within 15, 10, or 5 minutes of the Time of Execution. . . .'' [22]

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended by Partial Amendment No. 1, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–FINRA–2024–004 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–FINRA–2024–004. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of FINRA. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.

All submissions should refer to File Number SR–FINRA–2024–004 and should be submitted on or before August 21, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–16801 Filed 7–30–24; 8:45 am]

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[20] *See* Partial Amendment No. 1 at 5.

[21] *See* proposed Rule 6730.09(b)(2).

[22] *See* Partial Amendment No. 1 at 5.

[23] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100589; File No. SR–MSRB–2024–01]

Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Notice of Filing of Amendment No. 1 to Proposed Rule Change Consisting of Amendments to MSRB Rule G–14 To Shorten the Timeframe for Reporting Trades in Municipal Securities to the MSRB

July 25, 2024.

I. Introduction

On January 12, 2024, the Municipal Securities Rulemaking Board (''MSRB'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to (1) amend MSRB Rule G–14 (''Rule G–14''), on reports of sales or purchases, to (i) shorten the amount of time within which brokers, dealers, and municipal securities dealers (collectively, ''dealers,'' and each individually, a ''dealer'') must report most transactions to the MSRB; and (ii) require dealers to report certain transactions with a new trade indicator, and make certain clarifying amendments, and (2) make conforming amendments to MSRB Rule G–12, on uniform practice (''Rule G–12''), and the MSRB's Real-Time Transaction Reporting System (''RTRS'') Information Facility (''IF–1'') to reflect the shortened reporting timeframe (collectively, the ''proposed rule change'').[3] The proposed rule change was published for comment in the **Federal Register** on January 26, 2024.[4]

The Commission received comments in response to the proposed rule change.[5] On April 22, 2024, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act [6] to determine whether to approve or disapprove the proposed rule change.

On July 18, 2024, the Commission, pursuant to Section 19(b)(2) of the Act,[7] designated September 20, 2024, as the date by which the Commission shall either approve or disapprove the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Exchange Act Release No. 99402 (Jan. 19, 2024), 89 FR 5384 (Jan. 26, 2024) (''Notice'').

[4] *Id.* at 5384.

[5] Comment letters received by the Commission are available on our website at *https://www.sec.gov/comments/sr-msrb-2024-01/srmsrb202401.htm.*

[6] 15 U.S.C. 78s(b)(2)(B).

[7] 15 U.S.C. 78s(b)(2).

proposed rule change.[8] On July 18, 2024, the MSRB responded to comments[9] and filed Amendment No. 1 to the original proposed rule change (''Amendment No. 1''). The text of Amendment No. 1 is available on the MSRB's website.[10]

II. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Amendment

As described further below, the MSRB filed Amendment No. 1 to amend the proposed rule change to (i) revise the definition of a ''dealer with limited trading activity'' in proposed subsection (d)(xi) of Rule G–14 RTRS Procedures[11] and (ii) modify the pace of phasing-in the shortened reporting timeframe for a ''trade with a manual component'' in proposed Supplementary Material .02(b).

A. Exception for Dealers With Limited Trading Activity

The MSRB noted that upon further review of the methodology used for proposing a 1,800-trade threshold for qualifying for the dealer with limited trading activity exception in the original proposed rule change, the MSRB had determined to increase the threshold to 2,500 trades in connection with a modification of its methodology.[12]

In establishing the original proposed threshold of 1,800 trades, the MSRB explained that it had used an approach, consistent with other instances where MSRB rules and related transparency activities had been based on inter-dealer trade activity, that relied solely on the sell-side inter dealer trade reports to avoid, for those specific purposes, potential double counting if both the sell-side and buy-side were used.[13] The MSRB stated that the calculations discussed in the Notice underlying the 1,800-trade threshold in the proposed definition of ''dealer with limited trading activity'' resulted in a lower threshold and did not fully account for inter-dealer trade reports since only the sell-side inter-dealer trade reports were taken into account.[14] In order to maintain comparability with the threshold used by the Financial Industry Regulatory Authority, Inc. (''FINRA'') in its proposed definition of ''member with limited trading activity'' [15] and in light of the plain meaning of the language of the MRSB's proposed definition of ''dealer with limited trading activity,'' the MSRB explained that it had recalculated the appropriate threshold for such definition to be 2,500 trades, taking into account both sell-side and buy-side inter-dealer trade reports together with reports of dealer trades with customers, regardless of whether the dealer bought or sold in the customer transaction.[16] The MSRB also stated that Amendment No. 1 would add clarifying language to reflect that the threshold is based on both sell-side and buy-side inter-dealer and customer trade reports.[17] Thus, proposed subparagraph (d)(xi) of Rule G–14 RTRS Procedures would define a dealer with limited trading activity as a dealer that, during at least one of the two prior consecutive calendar years, reported to an RTRS Portal fewer than 2,500 purchase or sale transactions with customers or other dealers, excluding certain exempted transactions as specified therein.[18] The MSRB further noted that the proposed new threshold would continue to account for only a very small portion of the market volume and therefore would have minimal impact on overall trading.[19]

B. Exception for Trades With a Manual Component

The MSRB noted concerns expressed by commenters regarding potential difficulties in achieving dramatically shortened reporting timeframes for at least some trades with a manual component and whether dealers would have sufficient time to make the necessary changes to processes and technology to achieve such shortened timeframes, and determined to modify the pace of phasing-in the shortened reporting timeframe for trades with a manual component to extend the period during which such trades would be reportable by no later than 10 minutes after the Time of Trade from one year to two years.[20]

The MSRB explained that Amendment No. 1 would, in part, amend proposed Supplementary Material .02(b) to provide in clause (ii) that a trade with a manual component must be reported no later than 10 minutes after the Time of Trade for the second and third calendar years (rather than only the second year) from the effective date of the proposed rule change and to provide in clause (iii) that a trade with a manual component would become reportable no later than five minutes after the Time of Trade after the conclusion of the third calendar year (rather than the second calendar year) from the effective date of the proposed rule change.[21]

The MSRB further explained that the proposed rule change sets out a phased-in implementation of the exception for manual trades that would provide for an ultimate five-minute timeframe for the reporting of such trades. The MSRB also noted that no further reductions in such timeframe, and no elimination of the manual trade exception, could be possible without additional formal rulemaking by the MSRB that would be filed with the Commission, and that any such change would be subject to the required notice and comment process under Section 19 of the Exchange Act.[22]

Furthermore, the MSRB stated that it would monitor the implementation of the proposed rule change and, going forward, would analyze trade data related to the operation of the proposed two new exceptions to, among other things, determine whether the eventual five-minute trade reporting timeframe that would become applicable after two years continues to be feasible and appropriate in light of the empirical data collected through the earlier phases of implementation.[23] The MSRB further explained that it would be prepared to take action to provide appropriate guidance or undertake appropriate modifications in connection with the phase-in of the manual trade exception should circumstances warrant any such action, including, but not limited to

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[8] *See* Exchange Act Release No. 100557 (July 18, 2024), 89 FR 59951 (July 24, 2024) (''Extension'').

[9] *See* Letter from Ernesto A. Lanza, Chief Regulatory and Policy Officer, MSRB, to Secretary, Commission, dated July 18, 2024, available at *https://www.sec.gov/comments/sr-msrb-2024-01/srmsrb202401-491663-1411646.pdf.*

[10] Amendment No. 1 is available at *https://www.msrb.org/sites/default/files/2024-07/MSRB-2024-01-A-1.pdf.*

[11] The MSRB stated that the revision to the proposed definition of dealer with limited trading activity does not have a material impact on the MSRB's economic analysis included in the original proposed rule change. *See* Amendment No. 1 at 9.

[12] *See* Amendment No. 1 at 7.

[13] *Id.* at 7–8.

[14] *Id.* at 8.

[15] *See* Exchange Act Release No. 99404 (Jan. 19, 2024), 89 FR 5034 (Jan. 24, 2024) (''FINRA Notice'').

[16] *See* Amendment No. 1 at 8. The MSRB explained that reports of dealer trades with customers, regardless of whether the dealer bought or sold in the transaction, were included in the original methodology and continue to be included in the revised methodology. Based on this change in methodology, the total number of trade reports in 2022 has changed to 16.8 million when counting both the buy-side and the sell-side trades for inter-dealer trades. Previously, when only counting the sell side trades for inter-dealer trades, the total number of reported trades in 2022 was 12.1 million. *See* Amendment No. 1 n. 21.

[17] *See* Amendment No. 1 at 8.

[18] *Id.*

[19] *See* Amendment No. 1 at 9. The MSRB stated that the revised number of transactions under Amendment No. 1 would be expected to continue to capture approximately 1.5 percent of the trades in the municipal securities markets in a given calendar year, based on transaction data from calendar year 2022.

[20] *See* Amendment No. 1 at 9.

[21] *Id.*

[22] 15 U.S.C. 78s. *See* Amendment No. 1 at 9.

[23] *See* Amendment No. 1 at 9.

potentially filing a proposed rule change to extend the implementation period for the eventual five-minute timeframe for trades with a manual component.[24]

As noted by the MSRB, Amendment No. 1 would provide for a modified phase-in of the shortened reporting timeframe for trades with a manual component that the MSRB believes would foster a more orderly transition to more rapid reporting of manual trades.[25] Additionally, the MSRB explained that Amendment No. 1 would allow the MSRB to undertake a more meaningful and timely analysis of potential impacts of the intermediate 10-minute reporting stage in the phase-in process.[26] Specifically, the MSRB observed the extended timeframe would provide more time and data for the MSRB to understand whether any adverse impacts have developed as a result of the shortened reporting timeframe to 10 minutes so that the MSRB can determine whether it should undertake additional rulemaking to modify implementation or phase-in of the final step to a five-minute timeframe.[27]

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the filing as amended by Amendment No. 1 is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MSRB–2024–01 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–MSRB–2024–01. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the MSRB. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.

All submissions should refer to File Number SR–MSRB–2024–01 and should be submitted on or before August 21, 2024.

For the Commission, pursuant to delegated authority.[28]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–16796 Filed 7–30–24; 8:45 am]

BILLING CODE 8011–01–P

[24] *Id.*

[25] *Id.* at 10.

[26] *Id.*

[27] *Id.*

[28] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100601; File No. SR–NYSEAMER–2024–44]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Change To Establish Fees for the NYSE American Aggregated Lite Data Feed

July 25, 2024.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 11, 2024, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to establish fees for the NYSE American Aggregated Lite data feed. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the NYSE American LLC Equities Proprietary Market Data Fees Schedule (''Fee Schedule'') and establish fees for the NYSE American Aggregated Lite (''NYSE American Agg Lite'') data feed,[4] effective July 11, 2024.[5]

In summary, the NYSE American Agg Lite is a NYSE American-only frequency-based depth of book market data feed of the NYSE American's limit order book for up to ten (10) price levels on both the bid and offer sides of the order book for securities traded on the Exchange and for which the Exchange reports quotes and trades under the Consolidated Tape Association (''CTA'') Plan or the Nasdaq/UTP Plan. The NYSE American Agg Lite is a compilation of limit order data that the

[4] The proposed rule change establishing the NYSE American Agg Lite data feed was immediately effective on February 27, 2024. *See* Securities Exchange Act Release No. 99690 (March 7, 2024), 89 FR 18445 (March 13, 2024) (SR–NYSEAMER–2024–14) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish the NYSE American Aggregated Lite Market Data Feed).

[5] The Exchange originally filed to amend the Fee Schedule on May 13, 2024 (SR–NYSEAMER–2024–31). SR–NYSEAMER–2024–31 was subsequently withdrawn and replaced by this filing.

Exchange provides to vendors and subscribers. The NYSE American Agg Lite includes depth of book order data as well as security status messages. The security status message informs subscribers of changes in the status of a specific security, such as trading halts, short sale restriction, etc. In addition, the NYSE American Agg Lite includes order imbalance information prior to the opening and closing of trading.

Background

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [6]

While Regulation NMS has enhanced competition, it has also fostered a ''fragmented'' market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that ''such competition can lead to the fragmentation of order flow in that stock.'' [7] Indeed, cash equity trading is currently dispersed across 16 exchanges,[8] numerous alternative trading systems,[9] and broker-dealer internalizers and wholesalers, all competing for order flow. Based on publicly-available information, no single exchange currently has more than 20% market share (whether including or excluding auction volume).[10]

Proposed NYSE American Agg Lite Data Feed Fees

To reflect the value of NYSE American's market data, the Exchange proposes to establish the fees listed below for the NYSE American Agg Lite data feed. The Exchange proposes to charge fees for the same categories of market data use as its affiliated exchanges (namely, NYSE, NYSE Arca and NYSE National) currently charge. The Exchange believes that adopting the same fee structure as its affiliated exchanges would reduce administrative burdens on market data subscribers that also currently subscribe to market data feeds from the Exchange's affiliates.

1. *Access Fee.* For the receipt of access to the NYSE American Agg Lite data feed, the Exchange proposes to charge $500 per month. This proposed Access Fee would be charged to any data recipient that receives the NYSE American Agg Lite data feed. Data recipients that only use display devices to view NYSE American Agg Lite market data and do not separately receive a data feed would not be charged an Access Fee. The proposed Access Fee would be charged only once per firm.

2. *User Fees.* The Exchange proposes to charge a Professional User Fee (Per User) of $1 per month. The Exchange does not propose a fee for Non-Professional Users. The Professional User Fee would apply to each display device that has access to the NYSE American Agg Lite data feed.

3. *Redistribution Fee.* For redistribution of the NYSE American Agg Lite data feed, the Exchange proposes to establish a fee of $250 per month. The proposed Redistribution Fee would be charged to any Redistributor of the NYSE American Agg Lite data feed, which is defined to mean a vendor or any person that provides a real-time NYSE American market data product externally to a data recipient that is not its affiliate or wholly-owned subsidiary, or to any system that an external data recipient uses, irrespective of the means of transmission or access. The proposed Redistribution Fee would be charged only once per Redistributor account. As an incentive to potential Redistributors to subscribe to the NYSE American Agg Lite data feed, the Exchange proposes to waive the Access Fee and Redistribution Fee for a Redistributor if the Redistributor provides NYSE American Agg Lite externally to at least one data feed recipient and reports such data feed recipient or recipients to the Exchange. For example, a Redistributor that subscribes to the NYSE American Agg Lite data feed will have the Access Fee and Redistribution Fee waived if such Redistributor provides NYSE American Agg Lite externally to at least one data feed recipient and reports such data feed recipient to the Exchange.

By targeting this proposed fee waiver to Redistributors that provide external distribution of NYSE American Agg Lite, the Exchange believes that this would provide an incentive for Redistributors to make the NYSE American Agg Lite market data product available to its customers. Specifically, if a data recipient is interested in subscribing to NYSE American Agg Lite and relies on a Redistributor to obtain market data products from the Exchange, that data recipient would need its Redistributor to subscribe to and redistribute NYSE American Agg Lite. The Exchange believes that this proposed fee waiver for Redistributors of NYSE American Agg Lite would provide an incentive for Redistributors to make NYSE American Agg Lite available to their customers, which will increase the availability of the Exchange's market data products to a larger potential population of data recipients.

Further, the Exchange proposes to adopt a credit that would be applicable to Redistributors that provide external distribution of NYSE American Agg Lite to Professional and Non-Professional Users. As proposed, such Redistributors would receive a credit equal to the amount of the monthly Professional User and Non-Professional User Fees for such external distribution, up to a maximum of the combination of the Access Fee and Redistribution Fee for NYSE American Agg Lite that the Redistributor would otherwise be required to pay to the Exchange. For example, a Redistributor that reports external Professional Users in a month totaling $750 or more would receive a maximum credit of $750 for that month, which could effectively reduce its monthly fee for access and redistribution to zero. If that same Redistributor were to report external User quantities in a month totaling $600 of monthly usage, that Redistributor would receive a credit of $600. The Exchange believes the proposed credit would provide Redistributors with an incentive to increase their redistribution of NYSE American Agg Lite because the credit they would be eligible to receive would increase if they report additional external User quantities.

4. *Enterprise Fees.* The Exchange proposes to establish an enterprise license that will reduce Exchange fees and administrative costs for subscribers that disseminate NYSE American Agg Lite. Subscribers that are broker-dealers

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[6] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (File No. S7–10–04) (Final Rule) (''Regulation NMS'').

[7] *See* Securities Exchange Act Release No. 61358, 75 FR 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

[8] *See* Cboe U.S. Equities Market Volume Summary, available at *https://markets.cboe.com/us/equities/market_share. See generally https://www.sec.gov/fastanswers/divisionsmarketregmrexchangesshtml.html.*

[9] *See* FINRA ATS Transparency Data, available at *https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is available at *https://www.sec.gov/foia/docs/atslist.htm.*

[10] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

will be able to distribute the NYSE American Agg Lite data feed for display usage to an unlimited number of recipients (professional users and non-professional users) for a monthly fee of $550, with an opportunity to lower that fee to $500 per month if they contract for twelve months of service in advance.

As proposed, the NYSE American Agg Lite data feed may be distributed pursuant to the proposed market data enterprise license only for display usage and in the context of a brokerage relationship with a broker-dealer through such broker-dealer's own devices. Purchase of an enterprise license would eliminate per User subscriber fees for NYSE American Agg Lite. Further, the Exchange proposes to waive the Access Fee and the Redistribution Fee for NYSE American Agg lite for Redistributors that pay the Professional and Non-Professional Enterprise Fee. The Exchange believes the proposed fee waiver would provide an incentive for Redistributors to subscribe to the NYSE American Agg Lite market data product at the enterprise level to reduce the fees it would pay to the Exchange and without having to report the number of users that receive the data feed from the Redistributor.

Subscribers that intend to purchase a market data enterprise license for at least twelve months may elect to purchase this product in advance for a monthly fee of $500 per month for distribution to an unlimited number of professional users and non-professional users. This feature is intended to simplify cost projections and budgeting for both subscribers and the Exchange. Subscribers that elect not to purchase this particular feature will nevertheless be able to obtain all of the market data information offered by NYSE American Agg Lite by paying the standard fee of $550 per month for distribution to an unlimited number of professional users and non-professional users. Subscribers that elect to pay the monthly fee will be able to switch to the annual fee at any time, and those that elect to purchase the annual contract would be able to change to the monthly contract, with notice, at the end of the twelve-month period.

The Exchange believes that the proposed market data enterprise license will reduce exchange fees, lower administrative costs for subscribers, and help expand the availability of market information to investors, and thereby increase participation in financial markets.

5. *Non-Display Use Fees.* The Exchange proposes to establish non-display fees for the NYSE American Agg Lite data feed that are based on the non-display use categories charged by NYSE, NYSE Arca, NYSE National, the CTA, and the UTP Plan for non-display use.[11] Non-display use would mean accessing, processing, or consuming the NYSE American Agg Lite data feed delivered directly or through a Redistributor, for a purpose other than in support of a data recipient's display or further internal or external redistribution (''Non-Display Use''). Non-Display Use would include trading uses such as high frequency or algorithmic trading as well as any trading in any asset class, automated order or quote generation and/or order pegging, price referencing for algorithmic trading or smart order routing, operations control programs, investment analysis, order verification, surveillance programs, risk management, compliance, and portfolio management.

Under the proposal, for Non-Display Use of NYSE American Agg Lite, there would be three categories of, and fees applicable, to data recipients. One, two, or three categories of Non-Display Use may apply to a data recipient.

- As proposed, the Category 1 Fee would be $1,000 per month and would apply when a data recipient's Non-Display Use of the NYSE American Agg Lite data feed is on its own behalf, not on behalf of its clients.
- As proposed, Category 2 Fees would be $1,000 per month and would apply to a data recipient's Non-Display Use of the NYSE American Agg Lite data feed on behalf of its clients.
- As proposed, Category 3 Fees would be $1,000 per month and would apply to a data recipient's Non-Display Use of the NYSE American Agg Lite data feed for the purpose of internally matching buy and sell orders within an organization, including matching customer orders for a data recipient's own behalf and/or on behalf of its clients. This category would apply to Non-Display Use in trading platforms, such as, but not restricted to, alternative trading systems (''ATSs''), broker crossing networks, broker crossing systems not filed as ATSs, dark pools, multilateral trading facilities, exchanges and systematic internalization systems. A data recipient will be charged $1,000 per month for each platform on which it uses the Non-Display data internally to match buy and sell orders, up to a cap of $3,000 per month; even if the data recipient uses the NYSE American Agg Lite data feed for more than three platforms, it will not pay more than $3,000 for such Category 3 use per month.

The description of the three non-display use categories is set forth in the Fee Schedule in endnote 1 and that endnote would be referenced in the NYSE American Agg Lite data feed fees on the Fee Schedule. The text in the endnote would remain unchanged.

Data recipients that receive the NYSE American Agg Lite data feed for Non-Display Use would be required to complete and submit a Non-Display Use Declaration before they would be authorized to receive the feed. A firm subject to Category 3 Fees would be required to identify each platform that uses the NYSE American Agg Lite data feed for a Category 3 Non-Display Use basis, such as ATSs and broker crossing systems not registered as ATSs, as part of the Non-Display Use Declaration.

6. *Non-Display Use Declaration Late Fee.* Data recipients that receive the NYSE American Agg Lite data feed for Non-Display Use would be required to complete and submit a Non-Display Use Declaration before they would be authorized to receive the feed. Beginning in 2025, NYSE American Agg Lite data feed recipients would be required to submit, by January 31 of each year, the Non-Display Use Declaration. The requirement to submit a Non-Display Use Declaration applies to all real-time NYSE American data feed product recipients. The Exchange proposes to charge a Non-Display Use Declaration Late Fee of $1,000 per month to any data recipient that pays an Access Fee for the NYSE American Agg Lite data feed that has failed to timely complete and submit a Non-Display Use Declaration. Specifically, with respect to the Non-Display Use Declaration due by January 31 of each year, the Non-Display Use Declaration Late Fee would apply to data recipients that fail to complete and submit the Non-Display Use Declaration by the January 31 due date, and would apply beginning February 1 and for each month

[11] *See* Endnote 1 to the NYSE Proprietary Market Data Fees, available here: *https://www.nyse.com/publicdocs/nyse/data/NYSE_Market_Data_Fee_Schedule.pdf;* Endnote 1 to the NYSE Arca Equities Proprietary Market Data Fees, available here: *https://www.nyse.com/publicdocs/nyse/data/NYSE_Arca_Equities_Proprietary_Data_Fee_Schedule.pdf;* Endnote 1 to the NYSE National Equities Proprietary Market Data Fees, available here: *https://www.nyse.com/publicdocs/nyse/data/NYSE_National_Market_Data_Fee_Schedule.pdf;* Endnote 8 to the Schedule of Market Data Charges for the CTA, available here: *https://www.ctaplan.com/publicdocs/ctaplan/notifications/trader-update/ScheduleOfMarketDataCharges-January1,2015.pdf;* and Non-Display Usage Fees as set forth in the UTP Plan Fee Schedule and Non-Display Policy, available here: *http://utpplan.com/DOC/Datapolicies.pdf. See, e.g.,* Securities Exchange Act Release Nos. 69285 (April 3, 2013), 78 FR 21172 (April 9, 2013) (SR–NYSEMKT–2013–32) and 72020 (September 9, 2014), 79 FR 55040 (September 15, 2014) (SR–NYSEMKT–2014–72).

thereafter until the data recipient has completed and submitted the annual Non-Display Use Declaration.

The proposed Non-Display Use Declaration Late Fee applicable to NYSE American Agg Lite data feed would be set forth in endnote 2 on the Fee Schedule. As proposed, endnote 2 would be amended with the proposed addition of the following new text: ''The Non-Display Declaration Late Fee will apply, beginning in 2025, to NYSE American Aggregated Lite data recipients that fail to complete and submit the annual Non-Display Use Declaration by the January 31st due date, and applies beginning February 1st and for each month thereafter until the data recipient has completed and submitted the annual Non-Display use Declaration.''

In addition, if a data recipient's use of the NYSE American Agg Lite data feed changes at any time after the data recipient submits a Non-Display Use Declaration, the data recipient must inform the Exchange of the change by completing and submitting at the time of the change an updated declaration reflecting the change of use.

7. *Multiple Data Feed Fee.* The Exchange proposes to establish a monthly fee, the ''Multiple Data Feed Fee,'' that would apply to data recipients that take a data feed for a market data product in more than two locations. Data recipients taking the NYSE American Agg Lite data feed in more than two locations would be charged $200 per additional location per month. No new reporting would be required.[12]

8. *Three-Month Fee Waiver.* The Exchange currently provides a one-month free trial to any firm that subscribes to a particular NYSE American market data product for the first time. Under the current one-month trial, a first-time subscriber is not charged the Access Fee, Non-Display Fee, any applicable Professional and Non-Professional User Fee and Redistribution Fee for one calendar month.[13] The Exchange now proposes an additional three-month fee waiver for any Redistributor that subscribes to a particular NYSE American market data product for the first time for external redistribution. As proposed, a first-time Redistributor would be any firm that has not previously subscribed to and externally redistributed a particular NYSE American market data product listed on the Fee Schedule. As proposed, a first-time Redistributor that subscribes to a particular NYSE American market data product would not be charged the Access Fee and the Redistribution Fee for that product for three calendar months. Any other fees, including but not limited to, Non-Display Fee, any applicable Professional and Non-Professional User Fee, and Enterprise Fee would be billable after the first calendar month after a first-time Redistributor subscribes to a particular NYSE American market data product. For example, a first-time Redistributor that chooses to subscribe to NYSE American Agg Lite on July 24, 2024 would not be charged the Access Fee and the Redistribution Fee for the months of August, September, and October 2024. The proposed fee waiver would be for the three calendar months following the date a Redistributor is approved to receive access to the particular NYSE American market data product. The Exchange would provide the three-month fee waiver for each particular product to each Redistributor once.

The Exchange believes that providing a three-month fee waiver to NYSE American market data products listed on the Fee Schedule would enable potential Redistributors to determine whether a particular NYSE American market data product provides value to their business models before fully committing to expend development and implementation costs related to the receipt of that product, and is intended to encourage increased use of the Exchange's market data products by defraying some of the development and implementation costs Redistributors would ordinarily have to expend before using a product. The proposed three-month fee waiver would also provide Redistributors with time to begin onboarding new clients prior to being liable to the Access Fee and the Redistribution Fee, allowing time to choose how to allocate costs and increase revenues to defray costs associated with providing a new feed to its customers.

Application of Proposed Fees

The Exchange is not required to make the NYSE American Agg Lite data feed available or to offer any specific pricing alternatives to any customers, nor is any firm required to purchase the NYSE American Agg Lite data feed. Firms that choose to purchase the NYSE American Agg Lite data feed do so for the primary goals of using it to increase their revenues, reduce their expenses, and in some instances to compete directly with the Exchange (including for order flow). Those firms are able to determine for themselves whether or not the NYSE American Agg Lite data feed or any other similar products are attractively priced.

The Exchange believes the proposed rule change would provide an incentive both for data subscribers to subscribe to NYSE American Agg Lite and for Redistributors to subscribe to the product for purposes of providing external distribution of NYSE American Agg Lite. The Exchange believes that this proposed rule change also has the potential to attract new Redistributors for NYSE American Agg Lite.

The proposed fee structure is not novel as it is based on the fee structure currently in place for the NYSE American OpenBook feed. The Exchange is proposing fees for the NYSE American Agg Lite data feed that are based on the existing fee structure and rates that data recipients already pay for the NYSE American OpenBook feed. Specifically, the fees for the NYSE American OpenBook feed—which like the NYSE American Agg Lite data feed, includes depth of book and security status messages—consist of an Access Fee of $1,000 per month, a Professional User Fee (Per User) of $5 per month, a Non-Professional User Fee (Per User) of $1 per month, Non-Display Fees of $2,000 per month for each of Categories 1, 2 and 3. The Exchange does not currently charge a Redistribution Fee for NYSE American OpenBook. The Exchange also charges a Non-Display Use Declaration Late Fee of $1,000 per month and a Multiple Data Feed Fee of $200 per month for NYSE American OpenBook.[14]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[15] in general, and Sections 6(b)(4) and 6(b)(5) of the Act,[16] in particular, in that it provides an equitable allocation of reasonable fees among users and recipients of the data and is not designed to permit unfair discrimination among customers, issuers, and brokers.

[12] Data vendors currently report a unique Vendor Account Number for each location at which they provide a data feed to a data recipient. The Exchange considers each Vendor Account Number a location. For example, if a data recipient has five Vendor Account Numbers, representing five locations, for the receipt of the NYSE American Agg Lite data feed, that data recipient will pay the Multiple Data Feed fee with respect to three of the five locations.

[13] *See* Fee Schedule.

[14] *See* NYSE American LLC Equities Proprietary Market Data Fees at *https://www.nyse.com/publicdocs/nyse/data/NYSE_American_Equities_Market_Data_Fee_Schedule.pdf.*

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(4), (5).

The Proposed Rule Change Is Reasonable

In adopting Regulation NMS, the Commission granted SROs and broker-dealers increased authority and flexibility to offer new and unique market data to the public. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues, and also recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [17]

With respect to market data, the decision of the United States Court of Appeals for the District of Columbia Circuit in *NetCoalition* v. *SEC* upheld the Commission's reliance on the existence of competitive market mechanisms to evaluate the reasonableness and fairness of fees for proprietary market data:

> In fact, the legislative history indicates that the Congress intended that the market system ''evolve through the interplay of competitive forces as unnecessary regulatory restrictions are removed'' and that the SEC wield its regulatory power ''in those situations where competition may not be sufficient,'' such as in the creation of a ''consolidated transactional reporting system.'' [18]

The court agreed with the Commission's conclusion that ''Congress intended that 'competitive forces should dictate the services and practices that constitute the U.S. national market system for trading equity securities.' '' [19]

More recently, the Commission confirmed that it applies a ''market-based'' test in its assessment of market data fees, and that under that test:

> the Commission considers whether the exchange was subject to significant competitive forces in setting the terms of its proposal for [market data], including the level of any fees. If an exchange meets this burden, the Commission will find that its fee rule is consistent with the Act unless there is a substantial countervailing basis to find that the terms of the rule violate the Act or the rules thereunder.[20]

As discussed below, the Exchange believes that its proposed fees are constrained by competitive forces.

As the D.C. Circuit recognized in *NetCoalition I,* ''[n]o one disputes that competition for order flow is fierce.'' [21] The court further noted that ''no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers,'' and that an exchange ''must compete vigorously for order flow to maintain its share of trading volume.'' [22]

As noted above, while Regulation NMS has enhanced competition, it has also fostered a ''fragmented'' market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that ''such competition can lead to the fragmentation of order flow in that stock.'' [23] Indeed, today, equity trading is currently dispersed across 16 exchanges,[24] numerous alternative trading systems,[25] broker-dealer internalizers and wholesalers, all competing for order flow. Based on publicly-available information, no single exchange currently has more than 20% market share.[26]

Further, low barriers to entry mean that new exchanges may rapidly and inexpensively enter the market to compete with the Exchange. For example, since 2020, three new ones have entered the market: Long Term Stock Exchange (LTSE), which began operations as an exchange on August 28, 2020; [27] Members Exchange (MEMX), which began operations as an exchange on September 29, 2020; [28] and Miami International Holdings (MIAX), which began operations of its first equities exchange on September 29, 2020.[29]

These low barriers enable existing exchange customers to disintermediate and start their own exchanges if they think the prices charged for exchange proprietary market data products are too high. This is precisely the rationale behind the creation of MEMX, which was formed by some of the largest and most well capitalized financial firms that are also Exchange customers (including Bank of America, BlackRock, Charles Schwab, Citadel, Citi, E*Trade, Fidelity, Goldman Sachs, J.P. Morgan, Jane Street, Morgan Stanley, TD Ameritrade, and others).[30]

For example, one of MEMX's founding principles is that exchange proprietary market data prices are too high, and that MEMX will benefit its members by offering ''[l]ower pricing on market data.'' [31] Nor is this a new phenomenon: exchange customers formed BATS to compete with incumbent exchanges and once registered as an exchange in 2008, BATS did not initially charge for market data. The BATS venture was a financial success for its founders, first through recouping their investment in its initial public offering and then in the subsequent sale of BATS to Cboe, which now charges for market data from those exchanges. Notably, MEMX has some of the same founding broker-dealer customers, leading some to dub MEMX ''BATS 2.0.'' [32]

The fact that this cycle is viable and repeatable by entities that both trade on and compete with existing exchanges confirms that barriers to entry are low and that these markets are competitive

[17] *See* Regulation NMS Adopting Release, 70 FR 37495, at 37499.

[18] *NetCoalition* v. *SEC,* 615 F.3d 525, 535 (D.C. Cir. 2010) (''*NetCoalition I*'') (quoting H.R. Rep. No. 94–229 at 92 (1975), *as reprinted in* 1975 U.S.C.C.A.N. 323).

[19] *Id.* at 535.

[20] *See* Securities Exchange Act Release No. 34–90217 (October 16, 2020), 85 FR 67392 (October 22, 2020) (SR–NYSENAT–2020–05) (''National IF Approval Order'') (internal quotation marks omitted), quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74781 (December 9, 2008).

[21] *NetCoalition I,* 615 F.3d at 544 (internal quotation omitted).

[22] *Id.*

[23] *See* Securities Exchange Act Release No. 61358, 75 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

[24] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[25] *See* FINRA ATS Transparency Data, *available at https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is *available at https://www.sec.gov/foia/docs/atslist.htm.*

[26] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[27] *See* LTSE Market Announcement: MA–2020–020, dated August 14, 2020, announcing LTSE production securities phase-in planned for August 28, available here: *https://assets-global.website-files.com/6462417e8db99f8baa06952c/6462417e8db99f8baa0698e7_MA-2020-020__Production_Securities_Launching_August_28_-_Google_Docs.pdf* and LTSE Market Announcement: MA–2020–025, available here: *https://assets-global.website-files.com/6462417e8db99f8baa06952c/6462417e8db99f8baa069873_MA-2020-025.pdf.*

[28] As of October 29, 2020, MEMX is trading all NMS symbols. *See https://info.memxtrading.com/trader-alert-20-10-memx-trading-symbols-update/.*

[29] *See* MIAX Pearl Press release, dated September 29, 2020, available here: *https://www.miaxoptions.com/sites/default/files/alert-files/MIAX_Press_Release_09292020.pdf.*

[30] MEMX Home Page (''Founded by members and investors, MEMX aims to drive simplicity, efficiency, and competition in equity markets.''), available at *https://memx.com/.*

[31] MEMX home page, available at *https://memx.com/.*

[32] *See* ''MEMX turns up the heat on US stock exchanges,'' Financial Times, January 9, 2019, available at *https://www.ft.com/content/4908c8b0-1418-11e9-a581-4ff78404524e; see also* ''US equities exchanges: If you can't beat them, join them,'' Euromoney, February 13, 2019, available at *https://www.euromoney.com/article/b1d3tfby4p3y4v/us-equities-exchanges-if-you-cant-beat-them-join-them.*

and contestable.[33] And low barriers to entry act as a market check on high prices.[34]

In sum, the fierce competition thus constrains any exchange from pricing its market data at a supracompetitive price and constrains the Exchange in setting its fees at issue here.

More specifically, in setting fees for the NYSE American Agg Lite data feed, the Exchange is constrained by the fact that, if its pricing is unattractive to customers, customers have their pick of an increasing number of alternatives to purchase similar data from instead of purchasing it from the Exchange. The existence of alternatives to the Exchange's data product ensures that the Exchange cannot set unreasonable market data fees without suffering the negative effects of that decision in the fiercely competitive market for proprietary market data.

The Exchange notes that the NYSE American Agg Lite is entirely optional. The Exchange is not required to make the NYSE American Agg Lite available to any customers, nor is any customer required to purchase the NYSE American Agg Lite market data feed. Unlike some other data products (*e.g.,* the consolidated quotation and last-sale information feeds) that firms are required to purchase in order to fulfil regulatory obligations,[35] a customer's decision whether to purchase any of the Exchange's proprietary market data feeds, including the NYSE American Agg Lite, is entirely discretionary. Most firms that choose to subscribe to the proprietary market data feeds from the Exchange, including NYSE American Agg Lite, would do so for the primary goals of using it to increase their revenues, reduce their expenses, and in some instances to compete directly with the Exchange for order flow. Such firms are able to determine for themselves whether the NYSE American Agg Lite data feed is necessary for their business needs, and if so, whether or not it is attractively priced. If the NYSE American Agg Lite data feed does not provide sufficient value to firms based on the uses those firms may have for it, such firms may simply choose to conduct their business operations in ways that do not use the NYSE American Agg Lite data feed.

Further, in the case of products that are also redistributed through market data vendors such as Bloomberg and Refinitiv, the vendors themselves provide additional price discipline for proprietary data products because they control the primary means of access to certain end users. These vendors impose price discipline based upon their business models. For example, vendors that assess a surcharge on data they sell are able to refuse to offer proprietary products that their end users do not or will not purchase in sufficient numbers. Vendors may elect not to make NYSE American Agg Lite available to its customers unless their customers request it, and customers will not elect to pay the proposed fees unless NYSE American Agg Lite can provide value by sufficiently increasing revenues or reducing costs in the customer's business in a manner that will offset the fees. All of these factors operate as constraints on pricing proprietary data products.

In setting the proposed fees for the NYSE American Agg Lite data feed, the Exchange considered the competitiveness of the market for proprietary data and all of the implications of that competition. The Exchange believes that it has considered all relevant factors and has not considered irrelevant factors in order to establish reasonable fees. The proposed fees are therefore reasonable because in setting them, the Exchange is constrained by the availability of numerous substitute market data products. The Commission has been clear that substitute products need not be identical, but only substantially similar to the product at hand.[36]

The NYSE American Aggregated Lite market data feed is subject to significant competitive forces that constrain its pricing. Specifically, the NYSE American Agg Lite data feed competes head-to-head with similar market data products currently offered by the four U.S. equities exchanges operated by Cboe Exchange, Inc.—Cboe BZX Exchange, Inc. (''BZX''), Cboe BYX Exchange, Inc. (''BYX''), Cboe EDGA Exchange, Inc. (''EDGA''), and Cboe EDGX Exchange, Inc. (''EDGX''), each of which offers a market data product called BZX Summary Depth, BYX Summary Depth, EDGA Summary Depth and EDGX Summary Depth, respectively (collectively, the ''Cboe Summary Depth'').[37] Similar to Cboe Summary Depth, NYSE American Agg Lite can be utilized by vendors and subscribers to quickly access and distribute aggregated order book data. As noted above, NYSE American Agg Lite, similar to Cboe Summary Depth, would provide aggregated depth per security, including the bid, ask and share quantity for orders received by NYSE American, except unlike Cboe Summary Depth, which provides aggregated depth per security for up to five price levels, NYSE American Agg Lite would provide aggregated depth per security for up to ten price levels on both the bid and offer sides of the NYSE American limit order book as well as auction imbalance data.

The specific fees that the Exchange proposes for the NYSE American Agg Lite data feed are reasonable for the following additional reasons.

Overall. The Exchange believes that the proposed fees for the NYSE American Agg Lite data feed are reasonable because they represent the value of receiving the data on an aggregated basis. The Exchange believes

[33] *United States* v. *SunGard Data Sys.,* 172 F. Supp. 2d 172, 186 (D.D.C. 2001) (recognizing that ''[a]s a matter of law, courts have generally recognized that when a customer can replace the services of an external product with an internally-created system, this captive output (*i.e.* the self-production of all or part of the relevant product) should be included in the same market.''). In *SunGard,* the court rejected the Antitrust Division's attempt to block SunGuard's acquisition of the disaster recovery assets of Comdisco on the basis that the acquisition would ''substantially lessen competition in the market for shared hotsite disaster recovery services,'' when the evidence showed that ''internal hotsites'' created by customers competed with the ''external shared hotsite business'' engaged in by the merging parties. *Id.* at 173–74, 187.

[34] *United States* v. *Baker Hughes,* 908 F.2d 981, 987 (1990) (''In the absence of significant barriers [to entry], a company probably cannot maintain supracompetitive pricing for any length of time.''); *see also* David S. Evans and Richard Schmalensee, Markets with Two-Sided Platforms, in 1 Issues In Competition Law And Policy 667, 685 (ABA Section of Antitrust Law 2008) (noting that exchange mergers in 2005 and 2006 were approved by competition authorities in part in reliance on planned and likely entry of other firms).

[35] The Exchange notes that broker-dealers are not required to purchase proprietary market data to comply with their best execution obligations. *See In the Matter of the Application of Securities Industry and Financial Markets Association for Review of Actions Taken by Self-Regulatory Organizations,* Release Nos. 34–72182; AP–3–15350; AP–3–15351 (May 16, 2014). Similarly, there is no requirement in Regulation NMS or any other rule that proprietary data be utilized for order routing decisions, and some broker-dealers and ATSs have chosen not to do so.

[36] For example, in the National IF Approval Order, the Commission recognized that for some customers, the best bid and offer information from consolidated data feeds may function as a substitute for the NYSE National Integrated Feed product, which contains order by order information. *See* National IF Approval Order, *supra* note 20, at 67397 [release p. 21] (''[I]nformation provided by NYSE National demonstrates that a number of executing broker-dealers do not subscribe to the NYSE National Integrated Feed and executing broker-dealers can otherwise obtain NYSE National best bid and offer information from the consolidated data feeds.'' (internal quotations omitted)).

[37] *See* BZX Rule 11.22(m) BZX Summary Depth; BYX Rule 11.22(k) BYX Summary Depth; EDGA Rule 13.8(f) EDGA Summary Depth; and EDGX Rule 13.8(f) EDGX Summary Depth. The Cboe Summary Depth offered by BZX, BYX, EDGA and EDGX are each a data feed that offers aggregated two-sided quotations for all displayed orders for up to five (5) price levels and contains the individual last sale information, market status, trading status and trade break messages.

that providing vendors and subscribers with the option to subscribe to a market data product that integrates a subset of data from existing products and where such aggregated data is published at a pre-defined interval, thus lowering bandwidth, infrastructure and operational requirements, would allow vendors and subscribers to choose the best solution for their specific business needs.

The Exchange believes the proposed fees for the NYSE American Agg Lite data feed are also reasonable when compared to fees for comparable products, such as the Cboe Summary Depth.[38] Additionally, the Exchange is proposing fees for the NYSE American Agg Lite data feed that are based on the existing fee structure that data recipients already pay for the NYSE American's other market data products. The Exchange believes that adopting the same fee structure would reduce administrative burdens on NYSE American data subscribers that also currently subscribe to market data feeds from NYSE American.

Access Fee. The Exchange believes that the proposed monthly Access Fee of $500 for the NYSE American Aggregated Lite data feed is reasonable because it is lower than the fees charged by BZX, BYX, EDGA, and EDGX, each of which charges between $2,500 per month to $5,000 per month for both Internal Distribution and External Distribution of the Cboe Summary Depth market data product.[39]

User Fees. The Exchange believes that having separate Professional and Non-Professional User fees for the NYSE American Agg Lite data feed is reasonable because it will make the product more affordable and result in greater availability to Professional and Non-Professional Users. Not charging a Non-Professional User fee is reasonable because it provides a cost-effective method for Non-Professional Users to access the NYSE American Agg Lite data feed by providing the same data that is available to Professional Users. The proposed monthly Professional User Fee (Per User) of $1 and monthly Non-Professional User Fee (Per User) of $0 are reasonable because they are comparable to user fees generally charged by exchanges. For example, NYSE American charges a monthly Professional User Fee (Per User) of $5 and a monthly Non-Professional User Fee (Per User) of $1 for the NYSE American OpenBook feed.[40] Although the proposed User Fees for Professional and Non-Professional Users are higher than those charged by BZX, BYX, EDGA and EDGX, the Exchange notes that User fees are only a subset of the total fees that vendors and subscribers pay and the lower fees proposed to access and redistribute NYSE American Agg Lite would provide such market data recipients with a more affordable alternative to existing substitutes offered by the Exchange and its competitors.

Redistribution Fees. The Exchange believes that it is reasonable to charge redistribution fees because vendors receive value from redistributing the data in their business products for their customers. The Exchange believes that charging a Redistribution Fee is reasonable because the vendors that would be charged such a fee profit by re-transmitting the Exchange's market data to their customers. This fee would be charged only once per month to each vendor account that redistributes the NYSE American Agg Lite data feed, regardless of the number of customers to which that vendor redistributes the data. The Exchange believes the proposed monthly Redistribution Fee of $250 for the NYSE American Agg Lite data feed is reasonable because it is nominal and lower than the fees charged by BZX, BYX, EDGA and EDGX, each of which charges considerably more for both Internal Distribution and External Distribution of the Cboe Summary Depth market data feed.[41]

Enterprise Fees. The Exchange believes the proposed enterprise license is reasonable because it would reduce exchange fees, lower administrative costs for subscribers that are broker-dealers and help expand the availability of market information to investors, and thereby increase participation in financial markets. Subscribers that are broker-dealers would be able to disseminate the NYSE American Agg Lite data feed for display usage to an unlimited number of professional users and non-professional users for a monthly fee of $550, or $500 if they contract for twelve months of service in advance. The proposed enterprise license would result in lower fees for subscribers able to reach the largest audience of investors, including retail investors. Discounts for broader dissemination of market data information have routinely been adopted by exchanges and permitted by the Commission as equitable allocations of reasonable dues, fees and charges.[42]

Non-Display Use Fees. The Exchange believes that the proposed Non-Display Use fees reflect the value of the non-display data use to data recipients, which purchase such data on an entirely voluntary basis. Non-display data can be used by data recipients for a wide variety of uses, including proprietary and agency trading and smart order routing, as well as by data recipients that operate order matching and execution platforms. Non-display data also can be used for a variety of non-trading purposes that indirectly support trading, such as risk management and compliance. Although some of these non-trading uses do not directly generate revenues, they can nonetheless substantially reduce a recipient's costs by automating such functions so that they can be carried out in a more efficient and accurate manner and reduce errors and labor costs, thereby benefiting recipients. The Exchange believes that charging for non-trading uses is reasonable because data recipients can derive substantial value from such uses, for example, by automating tasks so that they can be performed more quickly and accurately and less expensively than if they were performed manually.

Previously, the non-display use data pricing policies of many exchanges required customers to count, and the exchanges to audit the count of, the number of non-display devices used by a customer. As non-display use grew more prevalent and varied, however, exchanges received an increasing number of complaints about the impracticality and administrative burden associated with that approach. In response, the Exchange and its affiliated exchanges developed a non-display use pricing structure that does not require non-display devices to be counted or those counts to be audited, and instead looks merely at the three following categories of potential use of non-display data: use of the data on the customer's own behalf (Category 1), use on behalf of clients (Category 2), and use to internally match buy and sell orders within an organization (Category 3).

The Exchange believes that it is reasonable to segment the fee for non-display use into these three categories. As noted above, the uses to which customers can put the NYSE American

[38] *See https://cdn.cboe.com/resources/membership/US_Market_Data_Product_Price_List.pdf.*

[39] *Id.*

[40] *See* Fee Schedule.

[41] *See supra,* note 38.

[42] For example, the Commission has permitted pricing discounts for market data under Nasdaq Rules 7023(c) and 7047(b). *See also* Securities Exchange Act Release No. 82182 (November 30, 2017), 82 FR 57627 (December 6, 2017) (SR–NYSE–2017–60) (changing an enterprise fee for NYSE BBO and NYSE Trades).

Agg Lite data feed are numerous and varied, and the Exchange believes that charging separate fees for these separate categories of use is reasonable because it reflects the actual value the customer derives from the data, based upon how many categories of use the customer makes of the data. Segmenting the fees for non-display data in this way avoids the unreasonable result of customers that make only limited non-display use of the data paying the same fees as customers that use the data for numerous different purposes.

The Exchange believes that the proposed fees of $1,000 per month for each of Categories 1, 2, and 3 is reasonable. These fees are comparable to non-display use fees generally charged by exchanges. For example, the fees for Non-Display Use of NYSE American OpenBook for Categories 1, 2 and 3 is $2,000 per month.[43] The Exchange believes that the proposed fees directly and appropriately reflect the value of using non-display data in a wide range of computer-automated functions relating to both trading and non-trading activities and that the number and range of these functions continue to grow through innovation and technology developments.

The Exchange believes that it is reasonable to cap non-display use fees for Category 3 at $3,000 per month per data recipient, because a higher monthly fee may potentially dissuade competitors from buying the NYSE American Agg Lite data feed.

The proposed Non-Display Use fees for the NYSE American Agg Lite data feed are also reasonable because they take into account the value of receiving the data for Non-Display Use on an integrated basis. The Exchange believes that the proposed fees directly and appropriately reflect the value of using the NYSE American Agg Lite data feed on a non-display basis in a wide range of computer-automated functions relating to both trading and non-trading activities and that the number and range of these functions continue to grow through innovation and technology developments.[44]

Non-Display Use Declaration Late Fee. The Exchange believes that it is reasonable to require annual submissions of the Non-Display Use Declaration so that the Exchange will have current and accurate information about the use of the NYSE American Agg Lite data feed and can correctly assess fees for the uses of the NYSE American Agg Lite data feed. Requiring annual submissions of such declarations is reasonable because it also allows users to re-assess their own usage each year.

The Exchange believes that it is reasonable to impose a late fee in connection with the submission of the Non-Display Use Declaration. In order to correctly assess fees for the non-display use of the NYSE American Agg Lite data feed, the Exchange needs to have current and accurate information about the use of the NYSE American Agg Lite data feed. The failure of data recipients to submit the Non-Display Use Declaration on time leads to potentially incorrect billing and administrative burdens, including tracking and obtaining late Non-Display Use Declarations and correcting and following up on payments owed in connection with late Non-Display Use Declarations. The purpose of the late fee is to incent data recipients to submit the Non-Display Use Declaration promptly to avoid the administrative burdens associated with the late submission of Non-Display Use Declarations.

Multiple Data Feed Fee. The Exchange believes that it is reasonable to require data recipients to pay a modest fee for taking a data feed for a market data product in more than two locations, because such data recipients can derive substantial value from being able to consume the product in as many locations as they want. In addition, there are administrative burdens associated with tracking each location at which a data recipient receives the product. The Multiple Data Feed Fee is designed to encourage data recipients to better manage their requests for additional data feeds and to monitor their usage of data feeds. The proposed fee is designed to apply to data feeds received in more than two locations so that each data recipient can have one primary and one backup data location before having to pay a multiple data feed fee.

Three-Month Fee Waiver. The Exchange believes the proposal to waive the Access Fee and the Redistribution Fee for the NYSE American Agg Lite data feed to new Redistributors for three calendar months is reasonable because it would enable potential Redistributors to determine whether a particular NYSE American market data product provides value to their business models before fully committing to expend development and implementation costs related to the receipt of that product, and is intended to encourage increased use of the Exchange's market data products by defraying some of the development and implementation costs Redistributors would ordinarily have to expend before using a product. The proposed fee waiver would also allow Redistributors to become familiar with the feed and determine whether it suits their needs without incurring fees. Making a new market data product available without charging a fee for three months is consistent with offerings of other exchanges. For example, BZX offers subscribers of BZX Summary Depth a three-month credit for external distribution, which is akin to the three-month fee waiver proposed by the Exchange.[45]

For all of the foregoing reasons, the Exchange believes that the proposed fees for the NYSE American Agg Lite data feed are reasonable.

The Proposed Fees Are Equitably Allocated

The Exchange believes the proposed fees for the NYSE American Agg Lite data feed are allocated fairly and equitably among the various categories of users of the feed, and any differences among categories of users are justified.

Overall. The Exchange believes that the proposed fees are equitably allocated because they will apply to all data recipients that choose to subscribe to the NYSE American Agg Lite data feed. Any subscriber or vendor that chooses to subscribe to the NYSE American Agg Lite data feed is subject to the same Fee Schedule, regardless of what type of business they operate or the use they plan to make of the data feed. Subscribers and vendors are not required to purchase the NYSE American Agg Lite data feed and may choose to receive the data on the NYSE American Agg Lite data feed regardless of what type of business they operate or the use they plan to make of the data feed.

Access Fee. The Exchange believes the proposed monthly Access Fee of $500 for the NYSE American Agg Lite data feed is equitably allocated because it would be charged on an equal basis to all data recipients that receive a data feed of the NYSE American Agg Lite

[43] *See* Fee Schedule.

[44] *See also* Exchange Act Release No. 69157, March 18, 2013, 78 FR 17946, 17949 (March 25, 2013) (SR–CTA/CQ–2013–01) (''[D]ata feeds have become more valuable, as recipients now use them to perform a far larger array of non-display functions. Some firms even base their business models on the incorporation of data feeds into black boxes and application programming interfaces that apply trading algorithms to the data, but that do not require widespread data access by the firm's employees. As a result, these firms pay little for data usage beyond access fees, yet their data access and usage is critical to their businesses.'').

[45] *See e.g.,* Securities Exchange Act Release No. 94432 (March 16, 2022), 87 FR 16277 (March 22, 2022) (SR–CboeBZX–2022–015) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fees Applicable to Various Market Data Products).

data feed, regardless of what type of business they operate or the use they plan to make of the data feed.

User Fees. The Exchange believes that the fee structure differentiating Professional User fees ($1 per month per user) from Non-Professional User fees ($0 per month per user) for display device access to the NYSE American Agg Lite data feed is equitable. This structure has long been used by the Exchange to reduce the price of data to Non-Professional Users and make it more broadly available.[46] Offering the NYSE American Agg Lite data feed to Non-Professional Users with the same data as is available to Professional Users results in greater equity among data recipients. These user fees would be charged uniformly to all display devices that have access to the NYSE American Agg Lite data feed.

Redistribution Fees. The Exchange believes the proposed monthly fee of $250 for redistributing the NYSE American Agg Lite data feed is equitably allocated because it would be charged on an equal basis to those Redistributors that choose to redistribute the feed.

Enterprise Fees. The Exchange believes the proposed enterprise license is equitably allocated because it would be available on an equal basis to all subscribers that are broker-dealers, each of whom would benefit from reduced exchange fees and from lower administrative costs. Moreover, the specific feature of the proposed enterprise license that will allow subscribers to lower fees by subscribing to a twelve-month contract is also an equitable allocation because all subscribers will have the same option of choosing between the stability of a fixed, lower rate, and the more flexible option of maintaining the ability to change market data products after a month of service. Subscribers will be free to move from the monthly to the annual rate at any time, or from annual to a monthly fee, with notice, at the expiration of the twelve-month period.

Non-Display Use Fees. The Exchange believes the proposed Non-Display Use fees are equitably allocated because they would require subscribers to pay fees only for the uses they actually make of the data. As noted above, non-display data can be used by data recipients for a wide variety of purposes (including trading, risk management, and compliance) as well as purposes that reduce the recipient's costs by automating certain functions. The Exchange believes that it is equitable to charge non-display data subscribers a $1,000 fee for each category of use they make of such data—namely, using the data on their own behalf (Category 1), on behalf of their clients (Category 2), and to internally match buy and sell orders within an organization (Category 3)—because this fee structure results in subscribers with greater uses of the data paying higher fees, and subscribers with fewer uses of the data paying lower fees. This segmented fee structure is also equitable because no subscriber of non-display data would be charged a fee for a category of use in which it did not actually engage.

The Exchange believes that it is equitable to cap non-display use fees for Category 3 at $3,000 per month per data recipient, because a higher monthly fee may potentially dissuade competitors from buying the NYSE American Agg Lite data feed.

Non-Display Use Declaration Late Fee. The Exchange believes that the proposed fee of $1,000 per month for a late Non-Display Use Declaration is equitably allocated because it applies to any data recipient that pays an Access Fee for the NYSE American Agg Lite data feed but has failed to complete and submit a Non-Display Use Declaration. In addition, the Exchange believes that it is equitable to charge a late fee to subscribers who fail to timely submit their Non-Display Use Declarations because their failure to do so leads to potentially incorrect billing and administrative burdens on the part of the Exchange. The Exchange believes it is equitable to defray these administrative costs by imposing a late fee only on subscribers' whose declarations were late, as opposed to all subscribers.

Multiple Data Feed Fee. The Exchange believes that the $200 per month per location fee to data recipients taking the NYSE American Agg Lite data feed in more than two locations is equitable because it would apply to all such customers, regardless of what type of business they operate or the use they make of the data feed. In addition, the Exchange believes that it is equitable to charge a fee to subscribers for taking a data feed in more than two locations because there are administrative burdens on the part of the Exchange associated with tracking each location at which a data recipient receives the product. The Exchange believes that it is equitable for it to defray these administrative costs by imposing a modest fee only on subscribers who seek to take the feed in more than two locations, as opposed to all subscribers.

Three-Month Fee Waiver. The Exchange believes the proposal to waive the Access Fee and the Redistribution Fee for the NYSE American Agg Lite data feed to new Redistributors for three calendar months is equitable because it would apply to any first-time Redistributor, regardless of the use they plan to make of the feed. As proposed, any first-time Redistributor of the NYSE American Agg Lite data feed would not be charged the Access Fee and the Redistribution Fee for three calendar months. The Exchange believes it is equitable to restrict the availability of this three-month fee waiver to Redistributors that have not previously subscribed to and redistributed the NYSE American Agg Lite data feed, since customers who are current or previous subscribers of the feed are already familiar with it and are able to determine whether it suits their needs.

For all of the foregoing reasons, the Exchange believes that the proposed fees for the NYSE American Agg Lite data feed are equitably allocated.

The Proposed Fees Are Not Unfairly Discriminatory

The Exchange believes the proposed fees for the NYSE American Agg Lite data feed are not unfairly discriminatory because any differences in the application of the fees are based on meaningful distinctions between customers, and those meaningful distinctions are not unfairly discriminatory between customers.

Overall. The Exchange believes that the proposed fees are not unfairly discriminatory because they would apply to all data recipients that choose to subscribe to the NYSE American Agg Lite data feed. Any subscriber, including Redistributor, that chooses to subscribe to the NYSE American Agg Lite data feed is subject to the same Fee Schedule, regardless of what type of business they operate or the use they plan to make of the data feed. Subscribers, including Redistributors, may choose to receive the data on the NYSE American Agg Lite data feed regardless of what type of business they operate or the use they plan to make of the data feed.

Access Fee. The Exchange believes the proposed monthly Access Fee of $500 for the NYSE American Agg Lite data feed is not unfairly discriminatory because it would be charged on an equal basis to all data recipients that receive a data feed of the NYSE American Agg Lite, regardless of what type of business

[46] *See, e.g.,* Securities Exchange Act Release No. 70212 (August 15, 2013), 78 FR 51775 (August 21, 2013) (SR–NYSEMKT–2013–69) (lowering the Non-Professional User Fee (Per User) for NYSE MKT BBO and Trades); Securities Exchange Act Release No. 20002, File No. S7–433 (July 22, 1983), 48 FR 34552 (July 29, 1983) (establishing Non-Professional fees for CTA data); NASDAQ BX Equity 7 Pricing Schedule, Section 123.

they operate or the use they plan to make of the data feed.

User Fees. The Exchange believes that the fee structure differentiating Professional User fees ($1 per month per user) from Non-Professional User fees ($0 per month per user) for display device access to the NYSE American Agg Lite data feed is not unfairly discriminatory. This structure has long been used by the Exchange to reduce the price of data to Non-Professional Users and make it more broadly available.[47] Offering the NYSE American Agg Lite data feed to Non-Professional Users with the same data as is available to Professional Users results in greater equity among data recipients. These user fees would be charged uniformly to all display devices that have access to the NYSE American Agg Lite data feed.

Redistribution Fees. The Exchange believes the proposed monthly fee of $250 for redistributing the NYSE American Agg Lite data feed is not unfairly discriminatory because it would be charged on an equal basis to those Redistributors that choose to redistribute the feed.

Enterprise Fees. The Exchange believes the proposed enterprise license will not unfairly discriminate between customers, issuers, brokers or dealers. The Act does not prohibit all distinctions among customers, but only discrimination that is unfair, and it is not unfair discrimination to charge those subscribers that are able to reach the largest audiences of investors, including retail investors, a lower fee for incremental investors in order to encourage the widespread distribution of market data. This principle has been repeatedly endorsed by the Commission, as evidenced by the approval of enterprise licenses for other market data products.[48] Moreover, the proposed enterprise license will be subject to significant competition, and that competition will ensure that there is no unfair discrimination. Each subscriber will be able to accept or reject the license depending on whether it will or will not lower costs for that particular subscriber, and, if the license is not sufficiently competitive, the Exchange may lose market share. The proposed enterprise license will compete with other enterprise licenses of the Exchange, underlying fee schedules promulgated by the Exchange, and enterprise licenses and fee structures implemented by other exchanges. As such, it is a voluntary product for which market participants can readily find substitutes. Accordingly, the Exchange is constrained from introducing a fee that would be inequitable or unfairly discriminatory.

Non-Display Use Fees. The Exchange believes the proposed Non-Display Use fees are not unfairly discriminatory because they would require subscribers for non-display use to pay fees only for the categories of use they actually make of the data. As noted above, non-display data can be used by data recipients for a wide variety of purposes (including trading, risk management, and compliance) as well as purposes that reduce the recipient's costs by automating certain functions. The Exchange believes that it is not unfairly discriminatory to charge non-display data subscribers a $1,000 per month fee for each category of use they make of such data—namely, using the data on their own behalf (Category 1), on behalf of their clients (Category 2), and to internally match buy and sell orders within an organization (Category 3)—because this fee structure results in subscribers with greater uses for the data paying higher fees, while subscribers with fewer uses of the data pay lower fees. This segmented fee structure is not unfairly discriminatory because no subscriber of non-display data would be charged a fee for a category of use in which it did not actually engage.

The Exchange believes that it is not unreasonably discriminatory to cap non-display use fees for Category 3 at $3,000 per month per data recipient, because a higher monthly fee may potentially dissuade competitors from buying the NYSE American Agg Lite data feed.

Non-Display Use Declaration Late Fee. The Exchange believes that the proposed fee of $1,000 per month for a late Non-Display Use Declaration is not unfairly discriminatory because it applies to any data recipient that pays an Access Fee for the NYSE American Agg Lite data feed but has failed to complete and submit a Non-Display Use Declaration. In addition, the Exchange believes that it is not unfairly discriminatory to charge a late fee to subscribers who fail to timely submit their Non-Display Use Declarations because their failure to do so leads to potentially incorrect billing and administrative burdens on the part of the Exchange. Nor is it unfairly discriminatory for the Exchange to defray these administrative costs by imposing a late fee only on subscribers' whose declarations were late, as opposed to all subscribers.

Multiple Data Feed Fee. The Exchange believes that the $200 per month per location fee to data recipients taking the NYSE American Agg Lite data feed in more than two locations is not unfairly discriminatory because it would apply to all such customers, regardless of what type of business they operate or the use they make of the data feed. In addition, the Exchange believes that it is not unfairly discriminatory to charge a fee to subscribers for taking a data feed in more than two locations because there are administrative burdens on the part of the Exchange associated with tracking each location at which a data recipient receives the product. The Exchange believes that it is not unfairly discriminatory for it to defray these administrative costs by imposing a modest fee only on subscribers who seek to take the feed in more than two locations, as opposed to all subscribers.

Three-Month Fee Waiver. The Exchange believes the proposal to waive the Access Fee and the Redistribution Fee for the NYSE American Agg Lite data feed to new Redistributors for three months is not unfairly discriminatory because it would apply to any first-time Redistributor, regardless of the use they plan to make of the feed. As proposed, any first-time Redistributor of the NYSE American Agg Lite data feed would not be charged the Access Fee and the Redistribution Fee for three calendar months. The Exchange believes it is not unfairly discriminatory to restrict the availability of this three-month fee waiver to Redistributors that have not previously subscribed to the NYSE American Agg Lite data feed, since Redistributors who are current or previous subscribers of the feed are already familiar with it and are able to determine whether it suits their needs.

For all of the foregoing reasons, the Exchange believes that the proposed fees for the NYSE American Agg Lite data feed are not unfairly discriminatory.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed fees will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intramarket Competition. The Exchange believes that the proposed fees do not put any market participants at a relative disadvantage compared to other market participants. As noted above, the proposed fees would apply to all subscribers, including Redistributors,

[47] *Id.*

[48] *See e.g.,* Securities Exchange Act Release No. 83751 (July 31, 2018), 83 FR 38428 (August 6, 2018) (SR–NASDAQ–2018–058) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Lower Fees and Administrative Costs for Distributors of Nasdaq Basic, Nasdaq Last Sale, NLS Plus and the Nasdaq Depth-of-Book Products Through a Consolidated Enterprise License).

of the NYSE American Agg Lite data feed, and customers may not only choose whether to subscribe to the feed at all, but also may tailor their subscription to include only the products offered by the Exchange that they deem suitable for their business needs. The Exchange also believes that the proposed fees neither favor nor penalize one or more categories of market participants in a manner that would impose an undue market on competition. As shown above, to the extent that particular proposed fees apply to only a subset of subscribers (*e.g.,* Category 2 fees apply only to those making non-display use on behalf of clients; late fees apply only to customers who fail to timely submit their declarations), those distinctions are not unfairly discriminatory and do not unfairly burden one set of customers over another. To the contrary, by tailoring the proposed fees in this manner, the Exchange believes that it has eliminated the potential burden on competition that might result from unfairly asking subscribers to pay fees for services they did not use, or late fees they did not actually incur.

Intermarket Competition. The Exchange believes that the proposed fees do not impose a burden on competition or on other SROs that is not necessary or appropriate. In setting the proposed fees, the Exchange is constrained by the availability of numerous substitute platforms also offering market data products, and low barriers to entry mean new exchanges are frequently introduced. In setting fees for the NYSE American Agg Lite data feed, the Exchange is constrained by the fact that if its pricing for the NYSE American Agg Lite data feed is unattractive to customers, customers will have their pick of an increasing number of alternative market data products to purchase instead of purchasing the Exchange's products.

In addition, the Exchange believes that the proposed fees do not impose a burden on competition or on other exchanges that is not necessary or appropriate because of the availability of numerous substitute market data products. Many other exchanges offer proprietary data feeds like the NYSE American Agg Lite data feed, supplying depth of book order data, security status updates, stock summary messages, and the exchange's best bid and offer at any given time, on a real-time basis. Because market data users can find suitable substitute feeds, an exchange that overprices its market data products stands a high risk that users may purchase another market's market data product. These competitive pressures ensure that no one exchange's market data fees can impose an unnecessary burden on competition, and the Exchange's proposed fees do not do so here.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective upon filing pursuant to Section 19(b)(3)(A)[49] of the Act and paragraph (f) thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSEAMER–2024–44 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSEAMER–2024–44. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSEAMER–2024–44 and should be submitted on or before August 21, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[50]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–16806 Filed 7–30–24; 8:45 am]

BILLING CODE 8011–01–P

[49] 15 U.S.C. 78s(b)(3)(A).

[50] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100603; File No. SR–NYSE–2024–39]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NYSE Proprietary Market Data Fee Schedule To Establish an Access Fee for the NYSE Pillar Depth Data Feed

July 25, 2024.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 11, 2024, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Proprietary Market Data Fee Schedule to establish an Access Fee for the NYSE Pillar Depth data feed. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the NYSE Proprietary Market Data Fee Schedule (''Fee Schedule''). Specifically, the Exchange proposes to establish an Access Fee for the NYSE Pillar Depth (''Pillar Depth'') data feed, effective July 11, 2024.[4]

The proposed fee for Pillar Depth would be $250 per month, provided that the market data recipient separately pays the applicable fees for the five existing market data products underlying the Pillar Depth data feed, consistent with the existing fee structures for those market data products.

The Pillar Depth data feed is a frequency-based depth of book market data feed that provides a consolidated view of the ten (10) best price levels on both the bid and offer sides across the NYSE Group's combined limit order books for securities traded on the NYSE Group equities markets, *i.e.,* NYSE, NYSE American LLC (''NYSE American''), NYSE Arca, Inc. (''NYSE Arca''), NYSE Chicago, Inc. (''NYSE Chicago'') and NYSE National, Inc. (''NYSE National''), for which the NYSE Group equities markets report quotes and trades under the Consolidated Tape Association (''CTA'') Plan or the Nasdaq/UTP Plan.[5] In other words, Pillar Depth would be a compilation of limit order data that the Exchange provides to vendors and subscribers, updated no less frequently than once per second. Specifically, the Pillar Depth data feed consists of certain data elements from five market data feeds[6]—NYSE Aggregated Lite,[7] NYSE American Aggregated Lite,[8] NYSE Arca Aggregated Lite,[9] NYSE Chicago Aggregated Lite[10] and NYSE National Aggregated Lite.[11]

The Exchange, NYSE American, NYSE Arca, NYSE Chicago and NYSE National are the exclusive distributors of the five Aggregated Lite feeds from which certain data elements are taken to create the Pillar Depth data feed. By contrast, the Exchange would not be the exclusive distributor of the aggregated and consolidated information that comprises the Pillar Depth data feed. Any entity that receives, or elects to receive, the five underlying Aggregated Lite data feeds would be able, if it so chooses, to create a data feed with the same information included in Pillar Depth and sell and distribute it to its clients so that it could be received by those clients as quickly as the Pillar Depth data feed would be received by those same clients.[12]

As proposed, the Exchange would charge a $250 per month Access Fee for Pillar Depth, which reflects the value of the aggregation and consolidation function that the Exchange performs in creating Pillar Depth. To obtain Pillar Depth, a market data recipient would need to pay any applicable fees for the five data feeds underlying Pillar Depth, consistent with the existing fee schedules for those market data products as previously filed with the Commission and which may be amended from time to time, including any applicable Access, Redistribution, Professional User, Non-Professional User, Non-Display or Enterprise fees. The Exchange proposes to denote the requirement for market data recipients to pay the applicable fees for the five data feeds underlying Pillar Depth in proposed footnote 3 on the Fee Schedule.

When subscribing to Pillar Depth, the underlying data feeds would be delivered in the Pillar Depth consolidated format, as described above, but charged for as if the recipient were receiving the underlying feeds directly. The Exchange notes that if a subscriber chooses to receive the five underlying feeds both separately and in the Pillar Depth format, such subscriber may be subject to additional Professional User or Non-Professional User fees to reflect the distribution of both Pillar Depth (which incorporates the five underlying data feeds) and any separate dissemination of the underlying data feeds. The Exchange believes that the proposed fees for Pillar Depth would not be lower than the cost to a vendor of creating a comparable product, including the cost of receiving the underlying data feeds.

The Exchange notes that another market participant seeking to distribute a competing product to Pillar Depth might engage in a different analysis of assessing the cost of a competing product, which may incorporate passing through fees associated with co-location at the Mahwah, New Jersey data center. However, the incremental co-location cost to a particular vendor might be inconsequential if such vendor is already co-located and is able to allocate its co-location costs over numerous product and customer relationships.

[4] The Exchange originally filed to amend the Fee Schedule on May 13, 2024 (SR–NYSE–2024–30). SR–NYSE–2024–30 was subsequently withdrawn and replaced by this filing.

[5] *See* Securities Exchange Act Release No. 100030 (April 25, 2024), 89 FR 35260 (May 1, 2024) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish the NYSE Pillar Depth Data Feed) (SR–NYSE–2024–24) (''Pillar Depth Product Filing'').

[6] Each of these data feeds are offered pursuant to preexisting and effective rules and fees filed with the Commission. This filing does not affect those rules, or the fees associated with these underlying data feeds or the ability for the Exchange, NYSE American, NYSE Arca, NYSE Chicago or NYSE National to amend the data feeds or fees associated with those data feeds pursuant to a separate rule filing.

[7] *See* Securities Exchange Act Release No. 99689 (March 7, 2024) 89 FR 18466 (March 13, 2024) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish the NYSE Aggregated Lite Market Data Feed) (SR–NYSE–2024–12).

[8] *See* Securities Exchange Act Release No. 99690 (March 7, 2024) 89 FR 18445 (March 13, 2024) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish the NYSE American Aggregated Lite Market Data Feed) (SR–NYSEAMER–2024–14).

[9] *See* Securities Exchange Act Release No. 99713 (March 12, 2024) 89 FR 19381 (March 18, 2024) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish the NYSE Arca Aggregated Lite Market Data Feed) (SR–NYSEARCA–2024–22).

[10] *See* Securities Exchange Act Release No. 99691 (March 7, 2024) 89 FR 18468 (March 13, 2024) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish the NYSE Chicago Aggregated Lite Market Data Feed) (SR–NYSECHX–2024–08).

[11] *See* Securities Exchange Act Release No. 99715 (March 12, 2024) 89 FR 19383 (March 18, 2024) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish the NYSE National Aggregated Lite Market Data Feed) (SR–NYSENAT–2024–06).

[12] *See* Pillar Depth Product Filing, *supra* note 5.

The Exchange therefore believes that a vendor could create and offer a product similar to Pillar Depth on a cost-competitive basis.

The proposed rule change is intended to encourage market participants to subscribe to Pillar Depth by making it more affordable for prospective customers. The proposed fee change would allow the Exchange to compete more effectively with the Cboe One Premium Feed, which as described below, is a comparable market data offering to Pillar Depth.

The Exchange notes that the proposed change is not otherwise intended to address any other issues, and the Exchange is not aware of any problems that member organizations or others would have in complying with the proposed rule change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[13] in general, and Sections 6(b)(4) and 6(b)(5) of the Act,[14] in particular, in that it provides an equitable allocation of reasonable fees among users and recipients of the data and is not designed to permit unfair discrimination among customers, issuers, and brokers. The Exchange also believes that the proposed rule change is consistent with Section 11(A) of the Act [15] in that it is consistent with (i) fair competition among brokers and dealers, among exchange markets, and between exchange markets and markets other than exchange markets; and (ii) the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities. Furthermore, the proposed rule change is consistent with Rule 603 of Regulation NMS,[16] which provides that any national securities exchange that distributes information with respect to quotations for or transactions in an NMS stock do so on terms that are not unreasonably discriminatory.

The Proposed Rule Change Is Reasonable

In adopting Regulation NMS, the Commission granted SROs and broker-dealers increased authority and flexibility to offer new and unique market data to the public. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues, and also recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [17]

With respect to market data, the decision of the United States Court of Appeals for the District of Columbia Circuit in *NetCoalition* v. *SEC* upheld the Commission's reliance on the existence of competitive market mechanisms to evaluate the reasonableness and fairness of fees for proprietary market data:

> In fact, the legislative history indicates that the Congress intended that the market system ''evolve through the interplay of competitive forces as unnecessary regulatory restrictions are removed'' and that the SEC wield its regulatory power ''in those situations where competition may not be sufficient,'' such as in the creation of a ''consolidated transactional reporting system.'' [18]

The court agreed with the Commission's conclusion that ''Congress intended that 'competitive forces should dictate the services and practices that constitute the U.S. national market system for trading equity securities.' '' [19]

More recently, the Commission confirmed that it applies a ''market-based'' test in its assessment of market data fees, and that under that test:

> the Commission considers whether the exchange was subject to significant competitive forces in setting the terms of its proposal for [market data], including the level of any fees. If an exchange meets this burden, the Commission will find that its fee rule is consistent with the Act unless there is a substantial countervailing basis to find that the terms of the rule violate the Act or the rules thereunder.[20]

As discussed below, the Exchange believes that its proposed fees are constrained by competitive forces.

As the D.C. Circuit recognized in *NetCoalition I,* ''[n]o one disputes that competition for order flow is fierce.'' [21] The court further noted that ''no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers,'' and that an exchange ''must compete vigorously for order flow to maintain its share of trading volume.'' [22]

As noted above, while Regulation NMS has enhanced competition, it has also fostered a ''fragmented'' market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that ''such competition can lead to the fragmentation of order flow in that stock.'' [23] Indeed, today, equity trading is currently dispersed across 16 exchanges,[24] numerous alternative trading systems,[25] broker-dealer internalizers and wholesalers, all competing for order flow. Based on publicly-available information, no single exchange currently has more than 20% market share.[26]

Further, low barriers to entry mean that new exchanges may rapidly and inexpensively enter the market to compete with the Exchange. For example, since 2020, three new ones have entered the market: Long Term Stock Exchange (LTSE), which began operations as an exchange on August 28, 2020; [27] Members Exchange (MEMX), which began operations as an exchange on September 29, 2020; [28] and Miami International Holdings (MIAX), which

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(4), (5).

[15] 15 U.S.C. 78k–1.

[16] 17 CFR 242.603.

[17] *See* Regulation NMS Adopting Release, 70 FR 37495, at 37499.

[18] *NetCoalition* v. *SEC,* 615 F.3d 525, 535 (D.C. Cir. 2010) (''*NetCoalition I*'') (quoting H.R. Rep. No. 94–229 at 92 (1975), *as reprinted in* 1975 U.S.C.C.A.N. 323).

[19] *Id.* at 535.

[20] *See* Securities Exchange Act Release No. 34–90217 (October 16, 2020), 85 FR 67392 (October 22, 2020) (SR–NYSENAT–2020–05) (''National IF Approval Order'') (internal quotation marks omitted), quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74781 (December 9, 2008) (''2008 ArcaBook Approval Order'').

[21] *NetCoalition I,* 615 F.3d at 544 (internal quotation omitted).

[22] *Id.*

[23] *See* Securities Exchange Act Release No. 61358, 75 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

[24] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[25] *See* FINRA ATS Transparency Data, *available at https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is *available at https://www.sec.gov/foia/docs/atslist.htm.*

[26] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[27] *See* LTSE Market Announcement: MA–2020–020, dated August 14, 2020, announcing LTSE production securities phase-in planned for August 28, available here: *https://assets-global.website-files.com/6462417e8db99f8baa06952c/6462417e8db99f8baa0698e7_MA-2020-020__Production_Securities_Launching_August_28_-_Google_Docs.pdf* and LTSE Market Announcement: MA–2020–025, available here: *https://assets-global.website-files.com/6462417e8db99f8baa06952c/6462417e8db99f8baa069873_MA-2020-025.pdf.*

[28] As of October 29, 2020, MEMX is trading all NMS symbols. *See https://info.memxtrading.com/trader-alert-20-10-memx-trading-symbols-update/.*

began operations of its first equities exchange on September 29, 2020.[29]

These low barriers enable existing exchange customers to disintermediate and start their own exchanges if they think the prices charged for exchange proprietary market data products are too high. This is precisely the rationale behind the creation of MEMX, which was formed by some of the largest and most well capitalized financial firms that are also Exchange customers (including Bank of America, BlackRock, Charles Schwab, Citadel, Citi, E*Trade, Fidelity, Goldman Sachs, J.P. Morgan, Jane Street, Morgan Stanley, TD Ameritrade, and others).[30]

For example, one of MEMX's founding principles is that exchange proprietary market data prices are too high, and that MEMX will benefit its members by offering ''[l]ower pricing on market data.'' [31] Nor is this a new phenomenon: exchange customers formed BATS to compete with incumbent exchanges and once registered as an exchange in 2008, BATS did not initially charge for market data. The BATS venture was a financial success for its founders, first through recouping their investment in its initial public offering and then in the subsequent sale of BATS to Cboe, which now charges for market data from those exchanges. Notably, MEMX has some of the same founding broker-dealer customers, leading some to dub MEMX ''BATS 2.0.'' [32]

The fact that this cycle is viable and repeatable by entities that both trade on and compete with existing exchanges confirms that barriers to entry are low and that these markets are competitive and contestable.[33] And low barriers to entry act as a market check on high prices.[34]

In sum, the fierce competition thus constrains any exchange from pricing its market data at a supracompetitive price and constrains the Exchange in setting its fees at issue here.

More specifically, in setting fees for the Pillar Depth data feed, the Exchange is constrained by the fact that, if its pricing is unattractive to customers, customers have their pick of an increasing number of alternatives to purchase similar data from instead of purchasing it from the Exchange. The existence of alternatives to the Exchange's data product ensures that the Exchange cannot set unreasonable market data fees without suffering the negative effects of that decision in the fiercely competitive market for proprietary market data.

More specifically, the Exchange believes that the proposed $250 per month Access Fee for Pillar Depth is reasonable because it represents the value for the data aggregation and consolidation function that the Exchange performs. The Exchange further believes that requiring market data recipients to separately pay for the five underlying data feeds to Pillar Depth is reasonable because by design, Pillar Depth represents an aggregated and consolidated version of those existing five data feeds. The Exchange notes that it is not seeking with this filing to establish fees relating to the underlying five Aggregated Lite data feeds, as those fees have been established consistent with Section 19(b)(3)(A) of the Act [35] and Rule 19b–4(f)(2) [36] thereunder, and which may be amended from time to time. However, the Exchange believes it would be unfair if it did not require Pillar Depth data feed recipients to separately pay for those five feeds because otherwise, Pillar Depth data feed recipients would be receiving a data product that includes such underlying data at a lower cost than separately subscribing to the underlying data feeds. Similarly, the Exchange believes that it would be reasonable to charge separate Professional User or Non-Professional User fees if a market data recipient chooses to receive both Pillar Depth and a separate dissemination of the five underlying data feeds in a non-consolidated form. The Exchange believes that such delivery would constitute two separate uses of the underlying data feeds and thus should be charged accordingly, consistent with the existing fee schedule for those market data products. The Exchange therefore believes that the proposed fee structure for Pillar Depth would not be lower than the cost to another party to create a comparable product, including the cost of receiving the underlying data feeds.

The Exchange notes that its proposed fee structure is similar to the fee structure for the NYSE BQT data feed.[37] The NYSE BQT data feed provides best bid and offer (''BBO'') and last sale information (''Trades'') for the Exchange and its affiliates, NYSE Arca, NYSE American, NYSE Chicago and NYSE National. NYSE BQT consists of certain data elements from ten market data feeds—NYSE Trades, NYSE BBO, NYSE Arca Trades, NYSE Arca BBO, NYSE American Trades, NYSE American BBO, NYSE Chicago Trades, NYSE Chicago BBO, NYSE National Trades and NYSE National BBO.[38] To receive NYSE BQT, a market data recipient must pay the applicable fee for the ten data feeds underlying NYSE BQT, and an Access Fee of $250 per month.[39]

The Exchange notes that Pillar Depth is entirely optional. The Exchange is not required to make Pillar Depth available

[29] *See* MIAX Pearl Press release, dated September 29, 2020, available here: *https://www.miaxoptions.com/sites/default/files/alert-files/MIAX_Press_Release_09292020.pdf.*

[30] MEMX Home Page (''Founded by members and investors, MEMX aims to drive simplicity, efficiency, and competition in equity markets.''), available at *https://memx.com/.*

[31] MEMX home page, available at *https://memx.com/.*

[32] *See* ''MEMX turns up the heat on US stock exchanges,'' Financial Times, January 9, 2019, available at *https://www.ft.com/content/4908c8b0-1418-11e9-a581-4ff78404524e; see also* ''US equities exchanges: If you can't beat them, join them,'' Euromoney, February 13, 2019, available at *https://www.euromoney.com/article/b1d3tfby4p3y4v/us-equities-exchanges-if-you-cant-beat-them-join-them.*

[33] *United States* v. *SunGard Data Sys.,* 172 F. Supp. 2d 172, 186 (D.D.C. 2001) (recognizing that ''[a]s a matter of law, courts have generally recognized that when a customer can replace the services of an external product with an internally-created system, this captive output (*i.e.* the self-production of all or part of the relevant product) should be included in the same market.''). In *SunGard,* the court rejected the Antitrust Division's attempt to block SunGuard's acquisition of the disaster recovery assets of Comdisco on the basis that the acquisition would ''substantially lessen competition in the market for shared hotsite disaster recovery services,'' when the evidence showed that ''internal hotsites'' created by customers competed with the ''external shared hotsite business'' engaged in by the merging parties. *Id.* at 173–74, 187.

[34] *United States* v. *Baker Hughes,* 908 F.2d 981, 987 (1990) (''In the absence of significant barriers [to entry], a company probably cannot maintain supracompetitive pricing for any length of time.''); *see also* David S. Evans and Richard Schmalensee, Markets with Two-Sided Platforms, in 1 Issues In Competition Law And Policy 667, 685 (ABA Section of Antitrust Law 2008) (noting that exchange mergers in 2005 and 2006 were approved by competition authorities in part in reliance on planned and likely entry of other firms).

[35] 15 U.S.C. 78s(b)(3)(A).

[36] 17 CFR 240.19b–4(f)(2).

[37] *See* Securities Exchange Act Release No. 73816 (December 11, 2014), 79 FR 75200 (December 17, 2014) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish an Access Fee for the NYSE Best Quote & Trades Data Feed) (SR–NYSE–2014–64).

[38] *See* Securities Exchange Act Release Nos. 72750 (August 4, 2014), 79 FR 46494 (August 8, 2014) (notice—NYSE BQT); and 73553 (November 6, 2014), 79 FR 67491 (November 13, 2014) (approval order—NYSE BQT) (SR–NYSE–2014–40) (''NYSE BQT Filing''). In 2018, NYSE BQT was amended to include NYSE National BBO and NYSE National Trades. *See* Securities Exchange Act Release No. 83359 (June 1, 2018), 83 FR 26507 (June 7, 2018) (SR–NYSE–2018–22). In 2019, NYSE BQT was amended to include NYSE Chicago BBO and NYSE Chicago Trades. *See* Securities Exchange Act Release No. 87511 (November 12, 2019), 84 FR 63689 (November 18, 2019) (SR–NYSE–2019–60).

[39] *See* Securities Exchange Act Release No. 82121 (November 30, 2017), 82 FR 57627 (December 6, 22017) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Fees for NYSE BBO and NYSE Trades To Lower the Enterprise Fee, and for NYSE BQT To Lower the Access Fee) (SR–NYSE–2017–60).

to any customers, nor is any customer required to purchase the Pillar Depth data feed. Unlike some other data products (*e.g.,* the consolidated quotation and last-sale information feeds) that firms are required to purchase in order to fulfil regulatory obligations,[40] a customer's decision whether to purchase any of the Exchange's proprietary market data feed, including Pillar Depth, is entirely discretionary. Most firms that choose to subscribe to proprietary market data feeds from the Exchange, including Pillar Depth, would do so for the primary goals of using it to increase their revenues, reduce their expenses, and in some instances compete directly with the Exchange's order flow. Such firms are able to determine for themselves whether Pillar Depth is necessary for their business needs, and if so, whether or not it is attractively priced. If Pillar Depth does not provide sufficient value to firms based on the uses those firms may have for it, such firms may simply choose to conduct their business operations in ways that do not use Pillar Depth.

Further, in the case of products that are also redistributed through market data vendors such as Bloomberg and Refinitiv, the vendors themselves provide additional price discipline for proprietary data products because they control the primary means of access to certain end users. These vendors impose price discipline based upon their business models. For example, vendors that assess a surcharge on data they sell are able to refuse to offer proprietary products that their end users do not or will not purchase in sufficient numbers. Vendors may elect not to make Pillar Depth available to its customers unless their customers request it, and customers will not elect to pay the proposed fees unless Pillar Depth can provide value by sufficiently increasing revenues or reducing costs in the customer's business in a manner that will offset the fees. All of these factors operate as constraints on pricing proprietary data products.

In setting the proposed fees for Pillar Depth, the Exchange considered the competitiveness of the market for proprietary data and all of the implications of that competition. The Exchange believes that it has considered all relevant factors and has not considered irrelevant factors in order to establish reasonable fees. The proposed fees are therefore reasonable because in setting them, the Exchange is constrained by the availability of numerous substitute market data products. The Commission has been clear that such substitutes need not be identical, but only substantially similar to the product at hand.[41]

The four U.S. equities exchanges operated by Cboe Exchange, Inc.—Cboe BZX Exchange, Inc. (''BZX''), Cboe BYX Exchange, Inc. (''BYX''), Cboe EDGA Exchange, Inc. (''EDGA''), and Cboe EDGX Exchange, Inc. (''EDGX''), currently offer a market data product called the Cboe One Premium Feed,[42] which competes with the Pillar Depth data feed. Similar to the Cboe One Premium Feed, Pillar Depth can be utilized by vendors and subscribers to quickly access and distribute aggregated order book data. As noted above, Pillar Depth, similar to Cboe One Premium Feed, would provide aggregated depth per security, including the bid, ask and share quantity for orders received by the NYSE Group markets. The Exchange believes that Pillar Depth will offer a competitive alternative to the Cboe One Premium Feed.[43]

The fees that are the subject of this rule filing are constrained by competition. As explained below in the Exchange's Statement on Burden on Competition, the existence of alternatives to these data products further ensures that the Exchange cannot set unreasonable fees, or fees that are unreasonably discriminatory, when vendors and subscribers can elect such alternatives. That is, the Exchange competes with other exchanges (and their affiliates) that provide similar market data products. If another exchange (or its affiliate) were to charge less to consolidate and distribute its similar product than the Exchange charges to consolidate and distribute Pillar Depth, prospective users likely would not subscribe to, or would cease subscribing to, Pillar Depth. In addition, the Exchange would compete with unaffiliated market data vendors who would be in a position to consolidate and distribute the same data that comprises the Pillar Depth data feed into the vendor's own comparable market data product. If the third-party vendor is able to provide the exact same data for a lower cost, prospective users would avail themselves of that lower cost and elect not to take Pillar Depth.

The Proposed Fees Are Equitably Allocated and Are Not Unfairly Discriminatory

The Exchange believes that the proposed fee is equitable and non-discriminatory in that it would apply uniformly to all recipients of Exchange data. The Exchange also believes the proposed fee is competitive with those charged by other venues and, therefore, reasonable and equitably allocated to recipients. The Exchange also notes that the proposed fee is not designed to permit unfair discrimination because all market data recipients that subscribe to Pillar Depth would be charged the same fee. The Exchange further believes that the proposed Pillar Depth fee structure is equitable and not unfairly discriminatory because all vendors and subscribers that elect to purchase Pillar Depth would be charged the same fees. In addition, vendors and subscribers that do not wish to purchase Pillar Depth may separately purchase the five individual underlying products, and if they so choose, perform a similar aggregation and consolidation function that the Exchange performs in creating Pillar Depth. To enable such competition, the Exchange is offering Pillar Depth on terms that a subscriber of those five feeds could offer a competing product if it so chooses.

For these reasons, the Exchange believes that the proposed fees are reasonable, equitable, and not unfairly discriminatory.

[40] The Exchange notes that broker-dealers are not required to purchase proprietary market data to comply with their best execution obligations. *See In the Matter of the Application of Securities Industry and Financial Markets Association for Review of Actions Taken by Self-Regulatory Organizations,* Release Nos. 34–72182; AP–3–15350; AP–3–15351 (May 16, 2014). Similarly, there is no requirement in Regulation NMS or any other rule that proprietary data be utilized for order routing decisions, and some broker-dealers and ATSs have chosen not to do so.

[41] For example, in the National IF Approval Order, the Commission recognized that for some customers, the best bid and offer information from consolidated data feeds may function as a substitute for the NYSE National Integrated Feed product, which contains order by order information. *See* National IF Approval Order, *supra* note 20, at 67397 [release p. 21] (''[I]nformation provided by NYSE National demonstrates that a number of executing broker-dealers do not subscribe to the NYSE National Integrated Feed and executing broker-dealers can otherwise obtain NYSE National best bid and offer information from the consolidated data feeds.'' (internal quotations omitted)).

[42] *See* BZX Rule 11.22(j); BYX Rule 11.22(i); EDGA Rule 13.8(b); and EDGX Rule 13.8(b). The Cboe One Feed offered by BZX, BYX, EDGA and EDGX is a data feed that contains the aggregate best bid and offer of all displayed orders for securities traded on the Cboe exchanges. The Cboe One Feed also contains the individual last sale information, consolidated volume, the primary listing market's official opening and closing price, and the current day consolidated high and low price for all listed equity securities. Cboe One Feed recipients may also elect to receive aggregated two-sided quotations from the Cboe exchanges for five (5) price levels (''Cboe One Premium Feed'').

[43] Fees for the Cboe One Premium Feed are available at *https://www.cboe.com/market_data_services/us/equities/cboe_one/.*

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) [44] of the Act, the Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. As noted above, the Pillar Depth data feed represents aggregated and consolidated information from five existing market data feeds. Although the Exchange, NYSE American, NYSE Arca, NYSE Chicago and NYSE National are the exclusive distributors of the five Aggregated Lite data feeds from which certain data elements are taken to create Pillar Depth, the Exchange may not be the exclusive distributor of the aggregated and consolidated information that comprises the Pillar Depth data feed. Any other market participant recipient of the five Aggregated Lite feeds would be able, if it chose, to create a data feed with the same information as Pillar Depth and distribute it to their clients on a level-playing field with respect to latency and cost as compared to the Exchange's product.[45]

Intramarket Competition. The Exchange believes that the proposed fees do not put any market participant at a relative disadvantage compared to other market participant. As noted above, the proposed fees would apply equally to all subscribers of Pillar Depth, and subscribers may not only choose whether to subscribe to Pillar Depth at all, but also may tailor their subscription to include only the products offered by the Exchange that they deem suitable for their business needs. The Exchange also believes that the proposed fees neither favor nor penalize one or more categories of market participants in a manner that would impose an undue market on competition.

Intermarket Competition. The Exchange believes that the proposed monthly Access Fee the Exchange proposes to charge subscribers for Pillar Depth would be pro-competitive because another market data recipient could perform a similar aggregating and consolidating function and similarly charge for such service. The Exchange notes that a competing vendor might engage in a different analysis of assessing the cost of a competing product, which may incorporate passing through fees associated with co-location at the Mahwah, New Jersey data center. However, the incremental co-location costs to a particular vendor may be inconsequential if such vendor is already co-located and is able to allocate its co-location costs over numerous product and customer relationships. The Exchange therefore believes that a competing vendor could create and offer a product similar to the Pillar Depth data feed at a similar cost. For these reasons, the Exchange believes that vendors could readily offer a product similar to Pillar Depth on a competitive basis.

In addition, the Exchange believes that the proposed fees do not impose a burden on competition or on other exchanges that is not necessary or appropriate because of the availability of numerous substitute market data products. Specifically, as described above, Pillar Depth would compete with the Cboe One Premium Feed.[46] These products each serve as reasonable substitutes for one another as they are each designed to provide investors with a unified view of quotes in all Tape A, B, and C securities. Each product provides subscribers with aggregated and consolidated quotes from multiple U.S. equities markets. Pillar Depth provides depth of book data from five NYSE-affiliated U.S. equities exchanges, while Cboe One Premium Feed similarly provides depth of book data from Cboe's four U.S. equities exchanges. Pillar Depth and Cboe One Premium Feed are intended to provide indicative pricing and therefore, are reasonable substitutes for one another. Additionally, market data vendors are also able to offer close substitutes to Pillar Depth. Because market data users can find suitable substitute feeds, an exchange that overprices its market data products stands a high risk that users may substitute another source of market data information for its own. These competitive pressures ensure that no one exchange's market data fees can impose an unnecessary burden on competition, and the Exchange's proposed fees do not do so here.

As such, in establishing the proposed fees, the Exchange considered the competitiveness of the market for proprietary data and all of the implications of that competition. The Exchange believes that it has considered all relevant factors and has not considered irrelevant factors in order to establish fair, reasonable, and not unreasonably discriminatory fees and an equitable allocation of fees among all users. The existence of alternatives to Pillar Depth, including the five underlying feeds, consolidated data, and proprietary data from other sources, ensures that the Exchange cannot set unreasonable fees, or fees that are unreasonably discriminatory, when vendors and subscribers can elect these alternatives or choose not to purchase a specific proprietary data product if its cost to purchase is not justified by the returns any particular vendor or subscriber would achieve through the purchase.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective upon filing pursuant to Section 19(b)(3)(A) [47] of the Act and paragraph (f) thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSE–2024–39 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSE–2024–39. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the

[44] 78 U.S.C. 78f(b)(8).

[45] *See* Pillar Depth Product Filing, *supra* note 5.

[46] *See supra,* note 42.

[47] 15 U.S.C. 78s(b)(3)(A).

submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSE–2024–39 and should be submitted on or before August 21, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[48]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–16808 Filed 7–30–24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100602; File No. SR–NYSE–2024–38]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish Fees for the NYSE Aggregated Lite Data Feed

July 25, 2024.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 11, 2024, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to establish fees for the NYSE Aggregated Lite data feed. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the NYSE Proprietary Market Data Fees Schedule (''Fee Schedule'') and establish fees for the NYSE Aggregated Lite (''NYSE Agg Lite'') data feed,[4] effective July 11, 2024.[5]

In summary, the NYSE Agg Lite is a NYSE-only frequency-based depth of book market data feed of the NYSE's limit order book for up to ten (10) price levels on both the bid and offer sides of the order book for securities traded on the Exchange and for which the Exchange reports quotes and trades under the Consolidated Tape Association (''CTA'') Plan or the Nasdaq/UTP Plan. The NYSE Agg Lite is a compilation of limit order data that the Exchange provides to vendors and subscribers. The NYSE Agg Lite includes depth of book order data as well as security status messages. The security status message informs subscribers of changes in the status of a specific security, such as trading halts, short sale restriction, etc. In addition, the NYSE Agg Lite includes order imbalance information prior to the opening and closing of trading.

Background

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.''[6]

While Regulation NMS has enhanced competition, it has also fostered a ''fragmented'' market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that ''such competition can lead to the fragmentation of order flow in that stock.''[7] Indeed, cash equity trading is currently dispersed across 16 exchanges,[8] numerous alternative trading systems,[9] and broker-dealer internalizers and wholesalers, all competing for order flow. Based on publicly-available information, no single exchange currently has more than 20% market share (whether including or excluding auction volume).[10]

Proposed NYSE Agg Lite Data Feed Fees

To reflect the value of NYSE's market data, the Exchange proposes to establish the fees listed below for the NYSE Agg Lite data feed. The Exchange proposes

[48] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The proposed rule change establishing the NYSE Agg Lite data feed was immediately effective on February 27, 2024. See Securities Exchange Act Release No. 99689 (March 7, 2024), 89 FR 18466 (March 13, 2024) (SR–NYSE–2024–12) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish the NYSE Aggregated Lite Market Data Feed).

[5] The Exchange originally filed to amend the Fee Schedule on May 13, 2024 (SR–NYSE–2024–29). SR–NYSE–2024–29 was subsequently withdrawn and replaced by this filing.

[6] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (File No. S7–10–04) (Final Rule) (''Regulation NMS'').

[7] *See* Securities Exchange Act Release No. 61358, 75 FR 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

[8] *See* Cboe U.S Equities Market Volume Summary, available at *https://markets.cboe.com/us/equities/market_share. See generally https://www.sec.gov/fastanswers/divisionsmarketregmrexchangesshtml.html.*

[9] *See* FINRA ATS Transparency Data, available at *https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is available at *https://www.sec.gov/foia/docs/atslist.htm.*

[10] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

to charge fees for the same categories of market data use as its affiliated exchanges (namely, NYSE Arca, NYSE American and NYSE National) currently charge. The Exchange believes that adopting the same fee structure as its affiliated exchanges would reduce administrative burdens on market data subscribers that also currently subscribe to market data feeds from the Exchange's affiliates.

1. *Access Fee.* For the receipt of access to the NYSE Agg Lite data feed, the Exchange proposes to charge $3,000 per month. This proposed Access Fee would be charged to any data recipient that receives the NYSE Agg Lite data feed. Data recipients that only use display devices to view NYSE Agg Lite market data and do not separately receive a data feed would not be charged an Access Fee. The proposed Access Fee would be charged only once per firm.

2. *User Fees.* The Exchange proposes to charge a Professional User Fee (Per User) of $35 per month and a Non-Professional User Fee (Per User) of $6 per month. These user fees would apply to each display device that has access to the NYSE Agg Lite data feed.

3. *Redistribution Fee.* For redistribution of the NYSE Agg Lite data feed, the Exchange proposes to establish a fee of $250 per month. The proposed Redistribution Fee would be charged to any Redistributor of the NYSE Agg Lite data feed, which is defined to mean a vendor or any person that provides a real-time NYSE market data product externally to a data recipient that is not its affiliate or wholly-owned subsidiary, or to any system that an external data recipient uses, irrespective of the means of transmission or access. The proposed Redistribution Fee would be charged only once per Redistributor account. As an incentive to potential Redistributors to subscribe to the NYSE Agg Lite data feed, the Exchange proposes to waive the Access Fee and Redistribution Fee for a Redistributor if the Redistributor provides NYSE Agg Lite externally to at least one data feed recipient and reports such data feed recipient or recipients to the Exchange. For example, a Redistributor that subscribes to the NYSE Agg Lite data feed will have the Access Fee and Redistribution Fee waived if such Redistributor provides NYSE Agg Lite externally to at least one data feed recipient and reports such data feed recipient to the Exchange.

By targeting this proposed fee waiver to Redistributors that provide external distribution of NYSE Agg Lite, the Exchange believes that this would provide an incentive for Redistributors to make the NYSE Agg Lite market data product available to its customers. Specifically, if a data recipient is interested in subscribing to NYSE Agg Lite and relies on a Redistributor to obtain market data products from the Exchange, that data recipient would need its Redistributor to subscribe to and redistribute NYSE Agg Lite. The Exchange believes that this proposed fee waiver for Redistributors of NYSE Agg Lite would provide an incentive for Redistributors to make NYSE Agg Lite available to their customers, which will increase the availability of the Exchange's market data products to a larger potential population of data recipients.

Further, the Exchange proposes to adopt a credit that would be applicable to Redistributors that provide external distribution of NYSE Agg Lite to Professional and Non-Professional Users. As proposed, such Redistributors would receive a credit equal to the amount of the monthly Professional User and Non-Professional User Fees for such external distribution, up to a maximum of the combination of the Access Fee and Redistribution Fee for NYSE Agg Lite that the Redistributor would otherwise be required to pay to the Exchange. For example, a Redistributor that reports external Professional Users and Non-Professional Users in a month totaling $3,250 or more would receive a maximum credit of $3,250 for that month, which could effectively reduce its monthly fee for access and redistribution to zero. If that same Redistributor were to report external User quantities in a month totaling $600 of monthly usage, that Redistributor would receive a credit of $600. The Exchange believes the proposed credit would provide Redistributors with an incentive to increase their redistribution of NYSE Agg Lite because the credit they would be eligible to receive would increase if they report additional external User quantities.

4. *Enterprise Fees.* The Exchange proposes to establish an enterprise license that will reduce Exchange fees and administrative costs for subscribers that disseminate NYSE Agg Lite. Subscribers that are broker-dealers will be able to distribute the NYSE Agg Lite data feed for display usage to an unlimited number of non-professional users for a monthly fee of $20,000, with an opportunity to lower that fee to $18,000 per month if they contract for twelve months of service in advance. Alternatively, subscribers that are broker-dealers will be able to distribute the NYSE Agg Lite data feed for display usage to an unlimited number of recipients (professional users and non-professional users) for a monthly fee of $25,000, with an opportunity to lower that fee to $22,500 per month if they contract for twelve months of service in advance.

As proposed, the NYSE Agg Lite data feed may be distributed pursuant to the proposed market data enterprise license only for display usage and in the context of a brokerage relationship with a broker-dealer through such broker-dealer's own devices. Purchase of an enterprise license would eliminate per User subscriber fees for NYSE Agg Lite. Further, the Exchange proposes to waive the Access Fee and the Redistribution Fee for NYSE Agg lite for Redistributors that pay either the Non-Professional Enterprise Fee or the Professional and Non-Professional Enterprise Fee. The Exchange believes the proposed fee waiver would provide an incentive for Redistributors to subscribe to the NYSE Agg Lite market data product at the enterprise level to reduce the fees it would pay to the Exchange and without having to report the number of users that receive the data feed from the Redistributor.

Subscribers that intend to purchase a market data enterprise license for at least twelve months may elect to purchase this product in advance for a monthly fee of $18,000 for distribution of NYSE Agg Lite to an unlimited number of non-professional users, or $22,500 per month for distribution to an unlimited number of professional users and non-professional users. This feature is intended to simplify cost projections and budgeting for both subscribers and the Exchange. Subscribers that elect not to purchase this particular feature will nevertheless be able to obtain all of the market data information offered by NYSE Agg Lite by paying the standard fee of $20,000 per month for distribution of NYSE Agg Lite to an unlimited number of non-professional users, or $25,000 per month for distribution to an unlimited number of professional users and non-professional users. Subscribers that elect to pay the monthly fee will be able to switch to the annual fee at any time, and those that elect to purchase the annual contract would be able to change to the monthly contract, with notice, at the end of the twelve-month period.

The Exchange believes that the proposed market data enterprise license will reduce exchange fees, lower administrative costs for subscribers, and help expand the availability of market information to investors, and thereby increase participation in financial markets.

5. *Non-Display Use Fees.* The Exchange proposes to establish non-

display fees for the NYSE Agg Lite data feed that are based on the non-display use categories charged by NYSE Arca, NYSE American, NYSE National, the CTA, and the UTP Plan for non-display use.[11] Non-display use would mean accessing, processing, or consuming the NYSE Agg Lite data feed delivered directly or through a Redistributor, for a purpose other than in support of a data recipient's display or further internal or external redistribution (''Non-Display Use''). Non-Display Use would include trading uses such as high frequency or algorithmic trading as well as any trading in any asset class, automated order or quote generation and/or order pegging, price referencing for algorithmic trading or smart order routing, operations control programs, investment analysis, order verification, surveillance programs, risk management, compliance, and portfolio management.

Under the proposal, for Non-Display Use of NYSE Agg Lite, there would be three categories of, and fees applicable, to data recipients. One, two, or three categories of Non-Display Use may apply to a data recipient.

- As proposed, the Category 1 Fee would be $4,500 per month and would apply when a data recipient's Non-Display Use of the NYSE Agg Lite data feed is on its own behalf, not on behalf of its clients.
- As proposed, Category 2 Fees would be $4,500 per month and would apply to a data recipient's Non-Display Use of the NYSE Agg Lite data feed on behalf of its clients.
- As proposed, Category 3 Fees would be $4,500 per month and would apply to a data recipient's Non-Display Use of the NYSE Agg Lite data feed for the purpose of internally matching buy and sell orders within an organization, including matching customer orders for a data recipient's own behalf and/or on behalf of its clients. This category would apply to Non-Display Use in trading platforms, such as, but not restricted to, alternative trading systems (''ATSs''), broker crossing networks, broker crossing systems not filed as ATSs, dark pools, multilateral trading facilities, exchanges and systematic internalization systems. A data recipient will be charged $4,500 per month for each platform on which it uses the Non-Display data internally to match buy and sell orders, up to a cap of $13,500 per month; even if the data recipient uses the NYSE Agg Lite data feed for more than three platforms, it will not pay more than $13,500 for such Category 3 use per month.

The description of the three non-display use categories is set forth in the Fee Schedule in endnote 1 and that endnote would be referenced in the NYSE Agg Lite data feed fees on the Fee Schedule. The text in the endnote would remain unchanged.

Data recipients that receive the NYSE Agg Lite data feed for Non-Display Use would be required to complete and submit a Non-Display Use Declaration before they would be authorized to receive the feed. A firm subject to Category 3 Fees would be required to identify each platform that uses the NYSE Agg Lite data feed for a Category 3 Non-Display Use basis, such as ATSs and broker crossing systems not registered as ATSs, as part of the Non-Display Use Declaration.

6. *Non-Display Use Declaration Late Fee.* Data recipients that receive the NYSE Agg Lite data feed for Non-Display Use would be required to complete and submit a Non-Display Use Declaration before they would be authorized to receive the feed. Beginning in 2025, NYSE Agg Lite data feed recipients would be required to submit, by January 31 of each year, the Non-Display Use Declaration. The requirement to submit a Non-Display Use Declaration applies to all real-time NYSE data feed product recipients. The Exchange proposes to charge a Non-Display Use Declaration Late Fee of $1,000 per month to any data recipient that pays an Access Fee for the NYSE Agg Lite data feed that has failed to timely complete and submit a Non-Display Use Declaration. Specifically, with respect to the Non-Display Use Declaration due by January 31 of each year, the Non-Display Use Declaration Late Fee would apply to data recipients that fail to complete and submit the Non-Display Use Declaration by the January 31 due date, and would apply beginning February 1 and for each month thereafter until the data recipient has completed and submitted the annual Non-Display Use Declaration.

The proposed Non-Display Use Declaration Late Fee applicable to NYSE Agg Lite data feed would be set forth in endnote 2 on the Fee Schedule. As proposed, endnote 2 would be amended with the proposed addition of the following new text: ''The Non-Display Declaration Late Fee will apply, beginning in 2025, to NYSE Aggregated Lite data recipients that fail to complete and submit the annual Non-Display Use Declaration by the January 31st due date, and applies beginning February 1st and for each month thereafter until the data recipient has completed and submitted the annual Non-Display use Declaration.''

In addition, if a data recipient's use of the NYSE Agg Lite data feed changes at any time after the data recipient submits a Non-Display Use Declaration, the data recipient must inform the Exchange of the change by completing and submitting at the time of the change an updated declaration reflecting the change of use.

7. *Multiple Data Feed Fee.* The Exchange proposes to establish a monthly fee, the ''Multiple Data Feed Fee,'' that would apply to data recipients that take a data feed for a market data product in more than two locations. Data recipients taking the NYSE Agg Lite data feed in more than two locations would be charged $200 per additional location per month. No new reporting would be required.[12]

8. *Three-Month Fee Waiver.* The Exchange currently provides a one-month free trial to any firm that subscribes to a particular NYSE market data product for the first time. Under the current one-month trial, a first-time subscriber is not charged the Access Fee, Non-Display Fee, any applicable Professional and Non-Professional User Fee and Redistribution Fee for one calendar month.[13] The Exchange now proposes an additional three-month fee waiver for any Redistributor that subscribes to a particular NYSE market data product for the first time for external redistribution. As proposed, a first-time Redistributor would be any firm that has not previously subscribed to and externally redistributed a particular NYSE market data product

[11] *See* Endnote 1 to the NYSE Arca Equites Proprietary Market Data Fees, available here: *https://www.nyse.com/publicdocs/nyse/data/NYSE_Arca_Equities_Proprietary_Data_Fee_Schedule.pdf*; Endnote 1 to the NYSE American LLC Equities Proprietary Market Data Fees, available here: *https://www.nyse.com/publicdocs/nyse/data/NYSE_American_Equities_Market_Data_Fee_Schedule.pdf*; Endnote 1 to the NYSE National Equities Proprietary Market Data Fees, available here: *https://www.nyse.com/publicdocs/nyse/data/NYSE_National_Market_Data_Fee_Schedule.pdf*; Endnote 8 to the Schedule of Market Data Charges for the CTA, available here: *https://www.ctaplan.com/publicdocs/ctaplan/notifications/trader-update/ScheduleOfMarketDataCharges-January1,2015.pdf*; and Non-Display Usage Fees as set forth in the UTP Plan Fee Schedule and Non-Display Policy, available here: *http://utpplan.com/DOC/Datapolicies.pdf. See, e.g.,* Securities Exchange Act Release Nos. 69278 (April 2, 2013), 78 FR 20973 (April 8, 2013) (SR–NYSE–2013–25) and 72923 (Aug. 26, 2014), 79 FR 52079 (Sept. 2, 2014) (SR–NYSE–2014–43).

[12] Data vendors currently report a unique Vendor Account Number for each location at which they provide a data feed to a data recipient. The Exchange considers each Vendor Account Number a location. For example, if a data recipient has five Vendor Account Numbers, representing five locations, for the receipt of the NYSE Agg Lite data feed, that data recipient will pay the Multiple Data Feed fee with respect to three of the five locations.

[13] *See* Fee Schedule.

listed on the Fee Schedule. As proposed, a first-time Redistributor that subscribes to a particular NYSE market data product would not be charged the Access Fee and the Redistribution Fee for that product for three calendar months. Any other fees, including but not limited to, Non-Display Fee, any applicable Professional and Non-Professional User Fee, and Enterprise Fee would be billable after the first calendar month after a first-time Redistributor subscribes to a particular NYSE market data product. For example, a first-time Redistributor that chooses to subscribe to NYSE Agg Lite on July 24, 2024 would not be charged the Access Fee and the Redistribution Fee for the months of August, September, and October 2024. The proposed fee waiver would be for the three calendar months following the date a Redistributor is approved to receive access to the particular NYSE market data product. The Exchange would provide the three-month fee waiver for each particular product to each Redistributor once.

The Exchange believes that providing a three-month fee waiver to NYSE market data products listed on the Fee Schedule would enable potential Redistributors to determine whether a particular NYSE market data product provides value to their business models before fully committing to expend development and implementation costs related to the receipt of that product, and is intended to encourage increased use of the Exchange's market data products by defraying some of the development and implementation costs Redistributors would ordinarily have to expend before using a product. The proposed three-month fee waiver would also provide Redistributors with time to begin onboarding new clients prior to being liable to the Access Fee and the Redistribution Fee, allowing time to choose how to allocate costs and increase revenues to defray costs associated with providing a new feed to its customers.

Application of Proposed Fees

The Exchange is not required to make the NYSE Agg Lite data feed available or to offer any specific pricing alternatives to any customers, nor is any firm required to purchase the NYSE Agg Lite data feed. Firms that choose to purchase the NYSE Agg Lite data feed do so for the primary goals of using it to increase their revenues, reduce their expenses, and in some instances to compete directly with the Exchange (including for order flow). Those firms are able to determine for themselves whether or not the NYSE Agg Lite data feed or any other similar products are attractively priced.

The Exchange believes the proposed rule change would provide an incentive both for data subscribers to subscribe to NYSE Agg Lite and for Redistributors to subscribe to the product for purposes of providing external distribution of NYSE Agg Lite. The Exchange believes that this proposed rule change also has the potential to attract new Redistributors for NYSE Agg Lite.

The proposed fee structure is not novel as it is based on the fee structure currently in place for the NYSE OpenBook feed. The Exchange is proposing fees for the NYSE Agg Lite data feed that are based on the existing fee structure and rates that data recipients already pay for the NYSE OpenBook feed. Specifically, the fees for the NYSE OpenBook feed—which like the NYSE Agg Lite data feed, includes depth of book and security status messages—consist of an Access Fee of $5,000 per month, a Professional User Fee (Per User) of $60 per month, a Non-Professional User Fee (Per User) of $15 per month, Non-Display Fees of $6,000 per month for each of Categories 1, 2 and 3, and a Redistribution Fee of $3,000 per month. The Exchange also charges a Non-Display Use Declaration Late Fee of $1,000 per month and a Multiple Data Feed Fee of $200 per month for NYSE OpenBoook.[14]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[15] in general, and Sections 6(b)(4) and 6(b)(5) of the Act,[16] in particular, in that it provides an equitable allocation of reasonable fees among users and recipients of the data and is not designed to permit unfair discrimination among customers, issuers, and brokers.

The Proposed Rule Change Is Reasonable

In adopting Regulation NMS, the Commission granted SROs and broker-dealers increased authority and flexibility to offer new and unique market data to the public. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues, and also recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [17]

With respect to market data, the decision of the United States Court of Appeals for the District of Columbia Circuit in *NetCoalition* v. *SEC* upheld the Commission's reliance on the existence of competitive market mechanisms to evaluate the reasonableness and fairness of fees for proprietary market data:

> In fact, the legislative history indicates that the Congress intended that the market system ''evolve through the interplay of competitive forces as unnecessary regulatory restrictions are removed'' and that the SEC wield its regulatory power ''in those situations where competition may not be sufficient,'' such as in the creation of a ''consolidated transactional reporting system.'' [18]

The court agreed with the Commission's conclusion that ''Congress intended that 'competitive forces should dictate the services and practices that constitute the U.S. national market system for trading equity securities.' '' [19]

More recently, the Commission confirmed that it applies a ''market-based'' test in its assessment of market data fees, and that under that test:

> the Commission considers whether the exchange was subject to significant competitive forces in setting the terms of its proposal for [market data], including the level of any fees. If an exchange meets this burden, the Commission will find that its fee rule is consistent with the Act unless there is a substantial countervailing basis to find that the terms of the rule violate the Act or the rules thereunder.[20]

As discussed below, the Exchange believes that its proposed fees are constrained by competitive forces.

As the D.C. Circuit recognized in *NetCoalition I,* ''[n]o one disputes that competition for order flow is fierce.'' [21] The court further noted that ''no exchange possesses a monopoly, regulatory or otherwise, in the execution

[14] *See* NYSE Proprietary Market Data Fees at *https://www.nyse.com/publicdocs/nyse/data/NYSE_Market_Data_Fee_Schedule.pdf.*

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(4), (5).

[17] *See* Regulation NMS Adopting Release, 70 FR 37495, at 37499.

[18] *NetCoalition* v. *SEC,* 615 F.3d 525, 535 (D.C. Cir. 2010) (''*NetCoalition I*'') (quoting H.R. Rep. No. 94–229 at 92 (1975), *as reprinted in* 1975 U.S.C.C.A.N. 323).

[19] *Id.* at 535.

[20] *See* Securities Exchange Act Release No. 34–90217 (October 16, 2020), 85 FR 67392 (October 22, 2020) (SR–NYSENAT–2020–05) (''National IF Approval Order'') (internal quotation marks omitted), quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74781 (December 9, 2008).

[21] *NetCoalition I,* 615 F.3d at 544 (internal quotation omitted).

of order flow from broker dealers,'' and that an exchange ''must compete vigorously for order flow to maintain its share of trading volume.'' [22]

As noted above, while Regulation NMS has enhanced competition, it has also fostered a ''fragmented'' market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that ''such competition can lead to the fragmentation of order flow in that stock.'' [23] Indeed, today, equity trading is currently dispersed across 16 exchanges,[24] numerous alternative trading systems,[25] broker-dealer internalizers and wholesalers, all competing for order flow. Based on publicly-available information, no single exchange currently has more than 20% market share.[26]

Further, low barriers to entry mean that new exchanges may rapidly and inexpensively enter the market to compete with the Exchange. For example, since 2020, three new ones have entered the market: Long Term Stock Exchange (LTSE), which began operations as an exchange on August 28, 2020; [27] Members Exchange (MEMX), which began operations as an exchange on September 29, 2020; [28] and Miami International Holdings (MIAX), which began operations of its first equities exchange on September 29, 2020.[29]

These low barriers enable existing exchange customers to disintermediate and start their own exchanges if they think the prices charged for exchange proprietary market data products are too high. This is precisely the rationale behind the creation of MEMX, which was formed by some of the largest and most well capitalized financial firms that are also Exchange customers (including Bank of America, BlackRock, Charles Schwab, Citadel, Citi, E*Trade, Fidelity, Goldman Sachs, J.P. Morgan, Jane Street, Morgan Stanley, TD Ameritrade, and others).[30]

For example, one of MEMX's founding principles is that exchange proprietary market data prices are too high, and that MEMX will benefit its members by offering ''[l]ower pricing on market data.'' [31] Nor is this a new phenomenon: exchange customers formed BATS to compete with incumbent exchanges and once registered as an exchange in 2008, BATS did not initially charge for market data. The BATS venture was a financial success for its founders, first through recouping their investment in its initial public offering and then in the subsequent sale of BATS to Cboe, which now charges for market data from those exchanges. Notably, MEMX has some of the same founding broker-dealer customers, leading some to dub MEMX ''BATS 2.0.'' [32]

The fact that this cycle is viable and repeatable by entities that both trade on and compete with existing exchanges confirms that barriers to entry are low and that these markets are competitive and contestable.[33] And low barriers to entry act as a market check on high prices.[34]

In sum, the fierce competition thus constrains any exchange from pricing its market data at a supracompetitive price and constrains the Exchange in setting its fees at issue here.

More specifically, in setting fees for the NYSE Agg Lite data feed, the Exchange is constrained by the fact that, if its pricing is unattractive to customers, customers have their pick of an increasing number of alternatives to purchase similar data from instead of purchasing it from the Exchange. The existence of alternatives to the Exchange's data product ensures that the Exchange cannot set unreasonable market data fees without suffering the negative effects of that decision in the fiercely competitive market for proprietary market data.

The Exchange notes that the NYSE Agg Lite is entirely optional. The Exchange is not required to make the NYSE Agg Lite available to any customers, nor is any customer required to purchase the NYSE Agg Lite market data feed. Unlike some other data products (*e.g.,* the consolidated quotation and last-sale information feeds) that firms are required to purchase in order to fulfil regulatory obligations,[35] a customer's decision whether to purchase any of the Exchange's proprietary market data feeds, including the NYSE Agg Lite, is entirely discretionary. Most firms that choose to subscribe to the proprietary market data feeds from the Exchange, including NYSE Agg Lite, would do so for the primary goals of using it to increase their revenues, reduce their expenses, and in some instances to compete directly with the Exchange for order flow. Such firms are able to determine for themselves whether the NYSE Agg Lite data feed is necessary for their business needs, and if so, whether

[22] *Id.*

[23] *See* Securities Exchange Act Release No. 61358, 75 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

[24] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[25] *See* FINRA ATS Transparency Data, *available at https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is *available at https://www.sec.gov/foia/docs/atslist.htm.*

[26] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[27] *See* LTSE Market Announcement: MA–2020–020, dated August 14, 2020, announcing LTSE production securities phase-in planned for August 28, available here: *https://assets-global.website-files.com/6462417e8db99f8baa06952c/6462417e8db99f8baa0698e7_MA-2020-020__Production_Securities_Launching_August_28_-_Google_Docs.pdf* and LTSE Market Announcement: MA–2020–025, available here: *https://assets-global.website-files.com/6462417e8db99f8baa06952c/6462417e8db99f8baa069873_MA-2020-025.pdf.*

[28] As of October 29, 2020, MEMX is trading all NMS symbols. *See https://info.memxtrading.com/trader-alert-20-10-memx-trading-symbols-update/.*

[29] *See* MIAX Pearl Press release, dated September 29, 2020, available here: *https://www.miaxoptions.com/sites/default/files/alert-files/MIAX_Press_Release_09292020.pdf.*

[30] MEMX Home Page (''Founded by members and investors, MEMX aims to drive simplicity, efficiency, and competition in equity markets.''), available at *https://memx.com/.*

[31] MEMX home page, available at *https://memx.com/.*

[32] *See* ''MEMX turns up the heat on US stock exchanges,'' Financial Times, January 9, 2019, available at *https://www.ft.com/content/4908c8b0-1418-11e9-a581-4ff78404524e; see also* ''US equities exchanges: If you can't beat them, join them,'' Euromoney, February 13, 2019, available at *https://www.euromoney.com/article/b1d3tfby4p3y4v/us-equities-exchanges-if-you-cant-beat-them-join-them.*

[33] *United States* v. *SunGard Data Sys.,* 172 F. Supp. 2d 172, 186 (D.D.C. 2001) (recognizing that ''[a]s a matter of law, courts have generally recognized that when a customer can replace the services of an external product with an internally-created system, this captive output (*i.e.* the self-production of all or part of the relevant product) should be included in the same market.''). In *SunGard,* the court rejected the Antitrust Division's attempt to block SunGuard's acquisition of the disaster recovery assets of Comdisco on the basis that the acquisition would ''substantially lessen competition in the market for shared hotsite disaster recovery services,'' when the evidence showed that ''internal hotsites'' created by customers competed with the ''external shared hotsite business'' engaged in by the merging parties. *Id.* at 173–74, 187.

[34] *United States* v. *Baker Hughes,* 908 F.2d 981, 987 (1990) (''In the absence of significant barriers [to entry], a company probably cannot maintain supracompetitive pricing for any length of time.''); *see also* David S. Evans and Richard Schmalensee, Markets with Two-Sided Platforms, in 1 Issues In Competition Law And Policy 667, 685 (ABA Section of Antitrust Law 2008) (noting that exchange mergers in 2005 and 2006 were approved by competition authorities in part in reliance on planned and likely entry of other firms).

[35] The Exchange notes that broker-dealers are not required to purchase proprietary market data to comply with their best execution obligations. *See In the Matter of the Application of Securities Industry and Financial Markets Association for Review of Actions Taken by Self-Regulatory Organizations,* Release Nos. 34–72182; AP–3–15350; AP–3–15351 (May 16, 2014). Similarly, there is no requirement in Regulation NMS or any other rule that proprietary data be utilized for order routing decisions, and some broker-dealers and ATSs have chosen not to do so.

or not it is attractively priced. If the NYSE Agg Lite data feed does not provide sufficient value to firms based on the uses those firms may have for it, such firms may simply choose to conduct their business operations in ways that do not use the NYSE Agg Lite data feed.

Further, in the case of products that are also redistributed through market data vendors such as Bloomberg and Refinitiv, the vendors themselves provide additional price discipline for proprietary data products because they control the primary means of access to certain end users. These vendors impose price discipline based upon their business models. For example, vendors that assess a surcharge on data they sell are able to refuse to offer proprietary products that their end users do not or will not purchase in sufficient numbers. Vendors may elect not to make NYSE Agg Lite available to its customers unless their customers request it, and customers will not elect to pay the proposed fees unless NYSE Agg Lite can provide value by sufficiently increasing revenues or reducing costs in the customer's business in a manner that will offset the fees. All of these factors operate as constraints on pricing proprietary data products.

In setting the proposed fees for the NYSE Agg Lite data feed, the Exchange considered the competitiveness of the market for proprietary data and all of the implications of that competition. The Exchange believes that it has considered all relevant factors and has not considered irrelevant factors in order to establish reasonable fees. The proposed fees are therefore reasonable because in setting them, the Exchange is constrained by the availability of numerous substitute market data products. The Commission has been clear that substitute products need not be identical, but only substantially similar to the product at hand.[36]

The NYSE Aggregated Lite market data feed is subject to significant competitive forces that constrain its pricing. Specifically, the NYSE Agg Lite data feed competes head-to-head with similar market data products currently offered by the four U.S. equities exchanges operated by Cboe Exchange, Inc.—Cboe BZX Exchange, Inc. (''BZX''), Cboe BYX Exchange, Inc. (''BYX''), Cboe EDGA Exchange, Inc. (''EDGA''), and Cboe EDGX Exchange, Inc. (''EDGX''), each of which offers a market data product called BZX Summary Depth, BYX Summary Depth, EDGA Summary Depth and EDGX Summary Depth, respectively (collectively, the ''Cboe Summary Depth'').[37] Similar to Cboe Summary Depth, NYSE Agg Lite can be utilized by vendors and subscribers to quickly access and distribute aggregated order book data. As noted above, NYSE Agg Lite, similar to Cboe Summary Depth, would provide aggregated depth per security, including the bid, ask and share quantity for orders received by NYSE, except unlike Cboe Summary Depth, which provides aggregated depth per security for up to five price levels, NYSE Agg Lite would provide aggregated depth per security for up to ten price levels on both the bid and offer sides of the NYSE limit order book as well as auction imbalance data.

The specific fees that the Exchange proposes for the NYSE Agg Lite data feed are reasonable for the following additional reasons.

Overall. The Exchange believes that the proposed fees for the NYSE Agg Lite data feed are reasonable because they represent the value of receiving the data on an aggregated basis. The Exchange believes that providing vendors and subscribers with the option to subscribe to a market data product that integrates a subset of data from existing products and where such aggregated data is published at a pre-defined interval, thus lowering bandwidth, infrastructure and operational requirements, would allow vendors and subscribers to choose the best solution for their specific business needs.

The Exchange believes the proposed fees for the NYSE Agg Lite data feed are also reasonable when compared to fees for comparable products, such as the Cboe Summary Depth.[38] Additionally, the Exchange is proposing fees for the NYSE Agg Lite data feed that are based on the existing fee structure that data recipients already pay for the NYSE's other market data products. The Exchange believes that adopting the same fee structure would reduce administrative burdens on NYSE data subscribers that also currently subscribe to market data feeds from NYSE.

Access Fee. The Exchange believes that the proposed monthly Access Fee of $3,000 for the NYSE Aggregated Lite data feed is reasonable because it is comparable to the fees charged by BZX, BYX, EDGA, and EDGX, each of which charges between $2,500 per month to $5,000 per month for both Internal Distribution and External Distribution of the Cboe Summary Depth market data product.[39]

User Fees. The Exchange believes that having separate Professional and Non-Professional User fees for the NYSE Agg Lite data feed is reasonable because it will make the product more affordable and result in greater availability to Professional and Non-Professional Users. Setting a modest Non-Professional User fee is reasonable because it provides an additional method for Non-Professional Users to access the NYSE Agg Lite data feed by providing the same data that is available to Professional Users. The proposed monthly Professional User Fee (Per User) of $35 and monthly Non-Professional User Fee (Per User) of $6 are reasonable because they are comparable to user fees generally charged by exchanges. For example, NYSE charges a monthly Professional User Fee (Per User) of $60 and a monthly Non-Professional User Fee (Per User) of $15 for the NYSE OpenBook feed.[40] Although the proposed User Fees for Professional and Non-Professional Users are higher than those charged by BZX, BYX, EDGA and EDGX, the Exchange notes that User fees are only a subset of the total fees that vendors and subscribers pay and the lower fees proposed to access and redistribute NYSE Agg Lite would provide such market data recipients with a more affordable alternative to existing substitutes offered by the Exchange and its competitors.

Redistribution Fees. The Exchange believes that it is reasonable to charge redistribution fees because vendors receive value from redistributing the data in their business products for their customers. The Exchange believes that charging a Redistribution Fee is reasonable because the vendors that would be charged such a fee profit by re-transmitting the Exchange's market data to their customers. This fee would be charged only once per month to each

[36] For example, in the National IF Approval Order, the Commission recognized that for some customers, the best bid and offer information from consolidated data feeds may function as a substitute for the NYSE National Integrated Feed product, which contains order by order information. *See* National IF Approval Order, *supra* note 20, at 67397 [release p. 21] (''[I]nformation provided by NYSE National demonstrates that a number of executing broker-dealers do not subscribe to the NYSE National Integrated Feed and executing broker-dealers can otherwise obtain NYSE National best bid and offer information from the consolidated data feeds.'' (internal quotations omitted)).

[37] *See* BZX Rule 11.22(m) BZX Summary Depth; BYX Rule 11.22(k) BYX Summary Depth; EDGA Rule 13.8(f) EDGA Summary Depth; and EDGX Rule 13.8(f) EDGX Summary Depth. The Cboe Summary Depth offered by BZX, BYX, EDGA and EDGX are each a data feed that offers aggregated two-sided quotations for all displayed orders for up to five (5) price levels and contains the individual last sale information, market status, trading status and trade break messages.

[38] *See https://cdn.cboe.com/resources/membership/US_Market_Data_Product_Price_List.pdf.*

[39] *Id.*

[40] *See* Fee Schedule.

vendor account that redistributes the NYSE Agg Lite data feed, regardless of the number of customers to which that vendor redistributes the data. The Exchange believes the proposed monthly Redistribution Fee of $250 for the NYSE Agg Lite data feed is reasonable because it is nominal and lower than the fees charged by BZX, BYX, EDGA and EDGX, each of which charges considerably more for both Internal Distribution and External Distribution of the Cboe Summary Depth market data feed.[41]

Enterprise Fees. The Exchange believes the proposed enterprise license is reasonable because it would reduce exchange fees, lower administrative costs for subscribers that are broker-dealers and help expand the availability of market information to investors, and thereby increase participation in financial markets. Subscribers that are broker-dealers would be able to disseminate the NYSE Agg Lite data feed for display usage to an unlimited number of non-professional users for a monthly fee of $20,000, or $18,000 if they contract for twelve months of service in advance. Alternatively, subscribers that are broker-dealers would be able to disseminate the NYSE Agg Lite data feed for display usage to an unlimited number of professional users and non-professional users for a monthly fee of $25,000, or $22,500 if they contract for twelve months of service in advance. The proposed enterprise license would result in lower fees for subscribers able to reach the largest audience of investors, including retail investors. Discounts for broader dissemination of market data information have routinely been adopted by exchanges and permitted by the Commission as equitable allocations of reasonable dues, fees and charges.[42]

Non-Display Use Fees. The Exchange believes that the proposed Non-Display Use fees reflect the value of the non-display data use to data recipients, which purchase such data on an entirely voluntary basis. Non-display data can be used by data recipients for a wide variety of uses, including proprietary and agency trading and smart order routing, as well as by data recipients that operate order matching and execution platforms. Non-display data also can be used for a variety of non-trading purposes that indirectly support trading, such as risk management and compliance. Although some of these non-trading uses do not directly generate revenues, they can nonetheless substantially reduce a recipient's costs by automating such functions so that they can be carried out in a more efficient and accurate manner and reduce errors and labor costs, thereby benefiting recipients. The Exchange believes that charging for non-trading uses is reasonable because data recipients can derive substantial value from such uses, for example, by automating tasks so that they can be performed more quickly and accurately and less expensively than if they were performed manually.

Previously, the non-display use data pricing policies of many exchanges required customers to count, and the exchanges to audit the count of, the number of non-display devices used by a customer. As non-display use grew more prevalent and varied, however, exchanges received an increasing number of complaints about the impracticality and administrative burden associated with that approach. In response, the Exchange and its affiliated exchanges developed a non-display use pricing structure that does not require non-display devices to be counted or those counts to be audited, and instead looks merely at the three following categories of potential use of non-display data: use of the data on the customer's own behalf (Category 1), use on behalf of clients (Category 2), and use to internally match buy and sell orders within an organization (Category 3).

The Exchange believes that it is reasonable to segment the fee for non-display use into these three categories. As noted above, the uses to which customers can put the NYSE Agg Lite data feed are numerous and varied, and the Exchange believes that charging separate fees for these separate categories of use is reasonable because it reflects the actual value the customer derives from the data, based upon how many categories of use the customer makes of the data. Segmenting the fees for non-display data in this way avoids the unreasonable result of customers that make only limited non-display use of the data paying the same fees as customers that use the data for numerous different purposes.

The Exchange believes that the proposed fees of $4,500 per month for each of Categories 1, 2, and 3 is reasonable. These fees are comparable to non-display use fees generally charged by exchanges. For example, the fees for Non-Display Use of NYSE OpenBook for Categories 1, 2 and 3 is $6,000 per month.[43] The Exchange believes that the proposed fees directly and appropriately reflect the value of using non-display data in a wide range of computer-automated functions relating to both trading and non-trading activities and that the number and range of these functions continue to grow through innovation and technology developments.

The Exchange believes that it is reasonable to cap non-display use fees for Category 3 at $13,500 per month per data recipient, because a higher monthly fee may potentially dissuade competitors from buying the NYSE Agg Lite data feed.

The proposed Non-Display Use fees for the NYSE Agg Lite data feed are also reasonable because they take into account the value of receiving the data for Non-Display Use on an integrated basis. The Exchange believes that the proposed fees directly and appropriately reflect the value of using the NYSE Agg Lite data feed on a non-display basis in a wide range of computer-automated functions relating to both trading and non-trading activities and that the number and range of these functions continue to grow through innovation and technology developments.[44]

Non-Display Use Declaration Late Fee. The Exchange believes that it is reasonable to require annual submissions of the Non-Display Use Declaration so that the Exchange will have current and accurate information about the use of the NYSE Agg Lite data feed and can correctly assess fees for the uses of the NYSE Agg Lite data feed. Requiring annual submissions of such declarations is reasonable because it also allows users to re-assess their own usage each year.

The Exchange believes that it is reasonable to impose a late fee in connection with the submission of the Non-Display Use Declaration. In order to correctly assess fees for the non-display use of the NYSE Agg Lite data feed, the Exchange needs to have current and accurate information about the use of the NYSE Agg Lite data feed. The failure of data recipients to submit the Non-Display Use Declaration on

[41] *See supra,* note 38.

[42] For example, the Commission has permitted pricing discounts for market data under Nasdaq Rules 7023(c) and 7047(b). *See also* Securities Exchange Act Release No. 82182 (November 30, 2017), 82 FR 57627 (December 6, 2017) (SR–NYSE–2017–60) (changing an enterprise fee for NYSE BBO and NYSE Trades).

[43] *See* Fee Schedule.

[44] *See also* Exchange Act Release No. 69157, March 18, 2013, 78 FR 17946, 17949 (March 25, 2013) (SR–CTA/CQ–2013–01) (''[D]ata feeds have become more valuable, as recipients now use them to perform a far larger array of non-display functions. Some firms even base their business models on the incorporation of data feeds into black boxes and application programming interfaces that apply trading algorithms to the data, but that do not require widespread data access by the firm's employees. As a result, these firms pay little for data usage beyond access fees, yet their data access and usage is critical to their businesses.'').

time leads to potentially incorrect billing and administrative burdens, including tracking and obtaining late Non-Display Use Declarations and correcting and following up on payments owed in connection with late Non-Display Use Declarations. The purpose of the late fee is to incent data recipients to submit the Non-Display Use Declaration promptly to avoid the administrative burdens associated with the late submission of Non-Display Use Declarations.

Multiple Data Feed Fee. The Exchange believes that it is reasonable to require data recipients to pay a modest fee for taking a data feed for a market data product in more than two locations, because such data recipients can derive substantial value from being able to consume the product in as many locations as they want. In addition, there are administrative burdens associated with tracking each location at which a data recipient receives the product. The Multiple Data Feed Fee is designed to encourage data recipients to better manage their requests for additional data feeds and to monitor their usage of data feeds. The proposed fee is designed to apply to data feeds received in more than two locations so that each data recipient can have one primary and one backup data location before having to pay a multiple data feed fee.

Three-Month Fee Waiver. The Exchange believes the proposal to waive the Access Fee and the Redistribution Fee for the NYSE Agg Lite data feed to new Redistributors for three calendar months is reasonable because it would enable potential Redistributors to determine whether a particular NYSE market data product provides value to their business models before fully committing to expend development and implementation costs related to the receipt of that product, and is intended to encourage increased use of the Exchange's market data products by defraying some of the development and implementation costs Redistributors would ordinarily have to expend before using a product. The proposed fee waiver would also allow Redistributors to become familiar with the feed and determine whether it suits their needs without incurring fees. Making a new market data product available without charging a fee for three months is consistent with offerings of other exchanges. For example, BZX offers subscribers of BZX Summary Depth a three-month credit for external distribution, which is akin to the three-month fee waiver proposed by the Exchange.[45]

For all of the foregoing reasons, the Exchange believes that the proposed fees for the NYSE Agg Lite data feed are reasonable.

The Proposed Fees Are Equitably Allocated

The Exchange believes the proposed fees for the NYSE Agg Lite data feed are allocated fairly and equitably among the various categories of users of the feed, and any differences among categories of users are justified.

Overall. The Exchange believes that the proposed fees are equitably allocated because they will apply to all data recipients that choose to subscribe to the NYSE Agg Lite data feed. Any subscriber or vendor that chooses to subscribe to the NYSE Agg Lite data feed is subject to the same Fee Schedule, regardless of what type of business they operate or the use they plan to make of the data feed. Subscribers and vendors are not required to purchase the NYSE Agg Lite data feed and may choose to receive the data on the NYSE Agg Lite data feed regardless of what type of business they operate or the use they plan to make of the data feed.

Access Fee. The Exchange believes the proposed monthly Access Fee of $3,000 for the NYSE Agg Lite data feed is equitably allocated because it would be charged on an equal basis to all data recipients that receive a data feed of the NYSE Agg Lite data feed, regardless of what type of business they operate or the use they plan to make of the data feed.

User Fees. The Exchange believes that the fee structure differentiating Professional User fees ($35 per month per user) from Non-Professional User fees ($6 per month per user) for display device access to the NYSE Agg Lite data feed is equitable. This structure has long been used by the Exchange to reduce the price of data to Non-Professional Users and make it more broadly available.[46] Offering the NYSE Agg Lite data feed to Non-Professional Users with the same data as is available to Professional Users results in greater equity among data recipients. These user fees would be charged uniformly to all display devices that have access to the NYSE Agg Lite data feed.

Redistribution Fees. The Exchange believes the proposed monthly fee of $250 for redistributing the NYSE Agg Lite data feed is equitably allocated because it would be charged on an equal basis to those Redistributors that choose to redistribute the feed.

Enterprise Fees. The Exchange believes the proposed enterprise license is equitably allocated because it would be available on an equal basis to all subscribers that are broker-dealers, each of whom would benefit from reduced exchange fees and from lower administrative costs. Moreover, the specific feature of the proposed enterprise license that will allow subscribers to lower fees by subscribing to a twelve-month contract is also an equitable allocation because all subscribers will have the same option of choosing between the stability of a fixed, lower rate, and the more flexible option of maintaining the ability to change market data products after a month of service. Subscribers will be free to move from the monthly to the annual rate at any time, or from annual to a monthly fee, with notice, at the expiration of the twelve-month period.

Non-Display Use Fees. The Exchange believes the proposed Non-Display Use fees are equitably allocated because they would require subscribers to pay fees only for the uses they actually make of the data. As noted above, non-display data can be used by data recipients for a wide variety of purposes (including trading, risk management, and compliance) as well as purposes that reduce the recipient's costs by automating certain functions. The Exchange believes that it is equitable to charge non-display data subscribers a $4,500 fee for each category of use they make of such data—namely, using the data on their own behalf (Category 1), on behalf of their clients (Category 2), and to internally match buy and sell orders within an organization (Category 3)—because this fee structure results in subscribers with greater uses of the data paying higher fees, and subscribers with fewer uses of the data paying lower fees. This segmented fee structure is also equitable because no subscriber of non-display data would be charged a fee for a category of use in which it did not actually engage.

The Exchange believes that it is equitable to cap non-display use fees for Category 3 at $13,500 per month per data recipient, because a higher monthly fee may potentially dissuade

[45] *See e.g.,* Securities Exchange Act Release No. 94432 (March 16, 2022), 87 FR 16277 (March 22, 2022) (SR–CboeBZX–2022–015) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fees Applicable to Various Market Data Products).

[46] *See, e.g.,* Securities Exchange Act Release No. 59544 (March 9, 2009), 74 FR 11162 (March 16, 2009) (SR–NYSE–2008–131) (establishing the $15 Non-Professional User Fee (Per User) for NYSE OpenBook); Securities Exchange Act Release No. 20002, File No. S7–433 (July 22, 1983), 48 FR 34552 (July 29, 1983) (establishing Non-Professional fees for CTA data); NASDAQ BX Equity 7 Pricing Schedule, Section 123.

competitors from buying the NYSE Agg Lite data feed.

Non-Display Use Declaration Late Fee. The Exchange believes that the proposed fee of $1,000 per month for a late Non-Display Use Declaration is equitably allocated because it applies to any data recipient that pays an Access Fee for the NYSE Agg Lite data feed but has failed to complete and submit a Non-Display Use Declaration. In addition, the Exchange believes that it is equitable to charge a late fee to subscribers who fail to timely submit their Non-Display Use Declarations because their failure to do so leads to potentially incorrect billing and administrative burdens on the part of the Exchange. The Exchange believes it is equitable to defray these administrative costs by imposing a late fee only on subscribers' whose declarations were late, as opposed to all subscribers.

Multiple Data Feed Fee. The Exchange believes that the $200 per month per location fee to data recipients taking the NYSE Agg Lite data feed in more than two locations is equitable because it would apply to all such customers, regardless of what type of business they operate or the use they make of the data feed. In addition, the Exchange believes that it is equitable to charge a fee to subscribers for taking a data feed in more than two locations because there are administrative burdens on the part of the Exchange associated with tracking each location at which a data recipient receives the product. The Exchange believes that it is equitable for it to defray these administrative costs by imposing a modest fee only on subscribers who seek to take the feed in more than two locations, as opposed to all subscribers.

Three-Month Fee Waiver. The Exchange believes the proposal to waive the Access Fee and the Redistribution Fee for the NYSE Agg Lite data feed to new Redistributors for three calendar months is equitable because it would apply to any first-time Redistributor, regardless of the use they plan to make of the feed. As proposed, any first-time Redistributor of the NYSE Agg Lite data feed would not be charged the Access Fee and the Redistribution Fee for three calendar months. The Exchange believes it is equitable to restrict the availability of this three-month fee waiver to Redistributors that have not previously subscribed to and redistributed the NYSE Agg Lite data feed, since customers who are current or previous subscribers of the feed are already familiar with it and are able to determine whether it suits their needs.

For all of the foregoing reasons, the Exchange believes that the proposed fees for the NYSE Agg Lite data feed are equitably allocated.

The Proposed Fees Are Not Unfairly Discriminatory

The Exchange believes the proposed fees for the NYSE Agg Lite data feed are not unfairly discriminatory because any differences in the application of the fees are based on meaningful distinctions between customers, and those meaningful distinctions are not unfairly discriminatory between customers.

Overall. The Exchange believes that the proposed fees are not unfairly discriminatory because they would apply to all data recipients that choose to subscribe to the NYSE Agg Lite data feed. Any subscriber, including Redistributor, that chooses to subscribe to the NYSE Agg Lite data feed is subject to the same Fee Schedule, regardless of what type of business they operate or the use they plan to make of the data feed. Subscribers, including Redistributors, may choose to receive the data on the NYSE Agg Lite data feed regardless of what type of business they operate or the use they plan to make of the data feed.

Access Fee. The Exchange believes the proposed monthly Access Fee of $3,000 for the NYSE Agg Lite data feed is not unfairly discriminatory because it would be charged on an equal basis to all data recipients that receive a data feed of the NYSE Agg Lite, regardless of what type of business they operate or the use they plan to make of the data feed.

User Fees. The Exchange believes that the fee structure differentiating Professional User fees ($35 per month per user) from Non-Professional User fees ($6 per month per user) for display device access to the NYSE Agg Lite data feed is not unfairly discriminatory. This structure has long been used by the Exchange to reduce the price of data to Non-Professional Users and make it more broadly available.[47] Offering the NYSE Agg Lite data feed to Non-Professional Users with the same data as is available to Professional Users results in greater equity among data recipients. These user fees would be charged uniformly to all display devices that have access to the NYSE Agg Lite data feed.

Redistribution Fees. The Exchange believes the proposed monthly fee of $250 for redistributing the NYSE Agg Lite data feed is not unfairly discriminatory because it would be charged on an equal basis to those Redistributors that choose to redistribute the feed.

Enterprise Fees. The Exchange believes the proposed enterprise license will not unfairly discriminate between customers, issuers, brokers or dealers. The Act does not prohibit all distinctions among customers, but only discrimination that is unfair, and it is not unfair discrimination to charge those subscribers that are able to reach the largest audiences of investors, including retail investors, a lower fee for incremental investors in order to encourage the widespread distribution of market data. This principle has been repeatedly endorsed by the Commission, as evidenced by the approval of enterprise licenses for other market data products.[48] Moreover, the proposed enterprise license will be subject to significant competition, and that competition will ensure that there is no unfair discrimination. Each subscriber will be able to accept or reject the license depending on whether it will or will not lower costs for that particular subscriber, and, if the license is not sufficiently competitive, the Exchange may lose market share. The proposed enterprise license will compete with other enterprise licenses of the Exchange, underlying fee schedules promulgated by the Exchange, and enterprise licenses and fee structures implemented by other exchanges. As such, it is a voluntary product for which market participants can readily find substitutes. Accordingly, the Exchange is constrained from introducing a fee that would be inequitable or unfairly discriminatory.

Non-Display Use Fees. The Exchange believes the proposed Non-Display Use fees are not unfairly discriminatory because they would require subscribers for non-display use to pay fees only for the categories of use they actually make of the data. As noted above, non-display data can be used by data recipients for a wide variety of purposes (including trading, risk management, and compliance) as well as purposes that reduce the recipient's costs by automating certain functions. The Exchange believes that it is not unfairly discriminatory to charge non-display data subscribers a $4,500 per month fee for each category of use they make of such data—namely, using the data on

[47] *Id.*

[48] *See e.g.,* Securities Exchange Act Release No. 83751 (July 31, 2018), 83 FR 38428 (August 6, 2018) (SR–NASDAQ–2018–058) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Lower Fees and Administrative Costs for Distributors of Nasdaq Basic, Nasdaq Last Sale, NLS Plus and the Nasdaq Depth-of-Book Products Through a Consolidated Enterprise License).

their own behalf (Category 1), on behalf of their clients (Category 2), and to internally match buy and sell orders within an organization (Category 3)—because this fee structure results in subscribers with greater uses for the data paying higher fees, while subscribers with fewer uses of the data pay lower fees. This segmented fee structure is not unfairly discriminatory because no subscriber of non-display data would be charged a fee for a category of use in which it did not actually engage.

The Exchange believes that it is not unreasonably discriminatory to cap non-display use fees for Category 3 at $13,500 per month per data recipient, because a higher monthly fee may potentially dissuade competitors from buying the NYSE Agg Lite data feed.

Non-Display Use Declaration Late Fee. The Exchange believes that the proposed fee of $1,000 per month for a late Non-Display Use Declaration is not unfairly discriminatory because it applies to any data recipient that pays an Access Fee for the NYSE Agg Lite data feed but has failed to complete and submit a Non-Display Use Declaration. In addition, the Exchange believes that it is not unfairly discriminatory to charge a late fee to subscribers who fail to timely submit their Non-Display Use Declarations because their failure to do so leads to potentially incorrect billing and administrative burdens on the part of the Exchange. Nor is it unfairly discriminatory for the Exchange to defray these administrative costs by imposing a late fee only on subscribers' whose declarations were late, as opposed to all subscribers.

Multiple Data Feed Fee. The Exchange believes that the $200 per month per location fee to data recipients taking the NYSE Agg Lite data feed in more than two locations is not unfairly discriminatory because it would apply to all such customers, regardless of what type of business they operate or the use they make of the data feed. In addition, the Exchange believes that it is not unfairly discriminatory to charge a fee to subscribers for taking a data feed in more than two locations because there are administrative burdens on the part of the Exchange associated with tracking each location at which a data recipient receives the product. The Exchange believes that it is not unfairly discriminatory for it to defray these administrative costs by imposing a modest fee only on subscribers who seek to take the feed in more than two locations, as opposed to all subscribers.

Three-Month Fee Waiver. The Exchange believes the proposal to waive the Access Fee and the Redistribution Fee for the NYSE Agg Lite data feed to new Redistributors for three months is not unfairly discriminatory because it would apply to any first-time Redistributor, regardless of the use they plan to make of the feed. As proposed, any first-time Redistributor of the NYSE Agg Lite data feed would not be charged the Access Fee and the Redistribution Fee for three calendar months. The Exchange believes it is not unfairly discriminatory to restrict the availability of this three-month fee waiver to Redistributors that have not previously subscribed to the NYSE Agg Lite data feed, since Redistributors who are current or previous subscribers of the feed are already familiar with it and are able to determine whether it suits their needs.

For all of the foregoing reasons, the Exchange believes that the proposed fees for the NYSE Agg Lite data feed are not unfairly discriminatory.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed fees will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intramarket Competition. The Exchange believes that the proposed fees do not put any market participants at a relative disadvantage compared to other market participants. As noted above, the proposed fees would apply to all subscribers, including Redistributors, of the NYSE Agg Lite data feed, and customers may not only choose whether to subscribe to the feed at all, but also may tailor their subscription to include only the products offered by the Exchange that they deem suitable for their business needs. The Exchange also believes that the proposed fees neither favor nor penalize one or more categories of market participants in a manner that would impose an undue market on competition. As shown above, to the extent that particular proposed fees apply to only a subset of subscribers (*e.g.,* Category 2 fees apply only to those making non-display use on behalf of clients; late fees apply only to customers who fail to timely submit their declarations), those distinctions are not unfairly discriminatory and do not unfairly burden one set of customers over another. To the contrary, by tailoring the proposed fees in this manner, the Exchange believes that it has eliminated the potential burden on competition that might result from unfairly asking subscribers to pay fees for services they did not use, or late fees they did not actually incur.

Intermarket Competition. The Exchange believes that the proposed fees do not impose a burden on competition or on other SROs that is not necessary or appropriate. In setting the proposed fees, the Exchange is constrained by the availability of numerous substitute platforms also offering market data products, and low barriers to entry mean new exchanges are frequently introduced. In setting fees for the NYSE Agg Lite data feed, the Exchange is constrained by the fact that if its pricing for the NYSE Agg Lite data feed is unattractive to customers, customers will have their pick of an increasing number of alternative market data products to purchase instead of purchasing the Exchange's products.

In addition, the Exchange believes that the proposed fees do not impose a burden on competition or on other exchanges that is not necessary or appropriate because of the availability of numerous substitute market data products. Many other exchanges offer proprietary data feeds like the NYSE Agg Lite data feed, supplying depth of book order data, security status updates, stock summary messages, and the exchange's best bid and offer at any given time, on a real-time basis. Because market data users can find suitable substitute feeds, an exchange that overprices its market data products stands a high risk that users may purchase another market's market data product. These competitive pressures ensure that no one exchange's market data fees can impose an unnecessary burden on competition, and the Exchange's proposed fees do not do so here.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective upon filing pursuant to Section 19(b)(3)(A) [49] of the Act and paragraph (f) thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of

[49] 15 U.S.C. 78s(b)(3)(A).

investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSE–2024–38 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSE–2024–38. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSE–2024–38 and should be submitted on or before August 21, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[50]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–16807 Filed 7–30–24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100592; File No. SR–Phlx–2024–37]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish Fees for Its Expanded Co-Location Services

July 25, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 23, 2024, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to establish fees for its expanded co-location services, as described further below.

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on August 15, 2024.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/phlx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose [3]

The Exchange filed a proposal to expand its co-location services by offering new cabinet, power, and power distribution unit options in the Exchange's expanded data center.[4] As described in that filing, the Exchange's current data center (''NY11'') in Carteret, NJ is undergoing an expansion (''NY11–4'') in response to demand for power and cabinets. The purpose of this proposed rule change is to establish fees for the expanded co-location services. Specifically, the Exchange proposes to establish (i) a monthly fee for Ultra High Density Cabinets, (ii) an installation fee for cabinets in NY11–4, (iii) fees for power installation in NY11–4, and (iv) fees for power distribution unit options in NY11–4.

Ultra High Density Cabinet

Currently, co-location customers have the option of obtaining cabinets of various sizes and power densities. Co-location customers may obtain a Half Cabinet,[5] a Low Density Cabinet with power density less than or equal to 2.88 kilowatts (''kW''), a Medium Density Cabinet with power density greater than 2.88 kW and less than or equal to 5 kW, a Medium-High Density Cabinet with power density greater than 5 kW and less than or equal to 7 kW, a High Density Cabinet with power density greater than 7 kW and less than 10 kW, and a Super High Density Cabinet with power density greater than 10 kW and less than or equal to 17.3 kW.

The Exchange filed a proposal to introduce a new cabinet choice in NY11–4, an ''Ultra High Density Cabinet,'' with power density greater than 10 kW and less than or equal to 15 kW.[6] The Ultra High Density Cabinet option will only be offered in NY11–4 because of the power configuration necessary for such cabinets, which is not possible or available in other portions of the data center due to

[50] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange initially filed the proposed pricing change on July 15, 2024 (SR–Phlx–2024–34). The instant filing replaces SR–Phlx–2024–34, which was withdrawn on July 23, 2024.

[4] *See* Securities Exchange Act Release No. 34–100559 (July 18, 2024) (SR–Phlx–2024–32) (not yet published).

[5] Half cabinets are not available to new subscribers. *See* General 8, Section 1(a).

[6] *Supra* note 4.

different power distribution.[7] In addition to the Ultra High Density Cabinet, the Exchange will offer the other, existing cabinet options in NY11–4, with the exception of the Low Density Cabinet and Half Cabinet due to a lack of demand for such cabinets. The ongoing monthly fees for the Super High Density Cabinet, High Density Cabinet, Medium-High Density Cabinet, and Medium Density Cabinet are the same in NY11 and NY11–4 and the Exchange is not proposing to modify such fees.

The Exchange proposes to establish an ongoing monthly fee of $7,230 for the Ultra High Density Cabinets. To effectuate this change, the Exchange proposes to add the $7,230 ongoing monthly fee for Ultra High Density Cabinets to its fee schedule in General 8, Section 1(a). The Exchange notes that the proposed fee amount falls between the $4,748 ongoing monthly fee charged for High Density Cabinets and the $8,440 ongoing monthly fee charged for Super High Density Cabinets. Furthermore, the proposed fee is consistent with the existing ongoing monthly cabinet fees on a per kW basis. The existing monthly cabinet fees range from approximately $475 per kW to $916 per kW, while the proposed ongoing monthly cabinet fee for the Ultra High Density Cabinet ranges from approximately $482 per kW (at the high end of the power density range for Ultra High Density Cabinets) to $723 per kW (at the low end of the power density range for Ultra High Density Cabinets).

Installation Fee for Cabinets in NY11–4

The Exchange proposes to establish a cabinet installation fee of $5,940 for all cabinets in NY11–4. To effectuate this change, the Exchange proposes to add the proposed $5,940 installation fee to its fee schedule in General 8, Section 1(a) for Super High Density Cabinets, Ultra High Density Cabinets, High Density Cabinets, Medium-High Density Cabinets, and Medium Density Cabinets in NY11–4. In the existing data halls, customers may bring their own cabinets or use Exchange-provided cabinets. In NY11–4, because of the cooling system (hot aisle containment),[8] all cabinets must be uniform and therefore, the Exchange will provide all cabinets, the cost of which is included in the $5,940 installation fee.[9] The cabinets in NY11–4 include certain features not included in cabinets provided by the Exchange in the existing data halls. Specifically, the cabinets in NY11–4 include uniform, wider cabinets (32″ W x 48″ D x 91″ H), cable management, and a rear split door and combo lock. In addition, the proposed installation fee of $5,940 is comparable to fees charged for similar products.[10]

Installation Fee for Cabinet Power in NY11–4

The cabinet power options for NY11–4 include: Phase 1 20 amp 240 volt, Phase 1 32 amp 240 volt, Phase 1 40 amp 240 volt, Phase 3 20 amp 415 volt, and Phase 3 32 amp 415 volt. These cabinet power options are specific to NY11–4 and one of these options must be selected for cabinets in NY11–4. The Exchange proposes to establish an installation fee of $3,600 for Phase 1 cabinet power options in NY11–4 and an installation fee of $4,560 for Phase 3 cabinet power options in NY11–4. To effectuate this change, the Exchange proposes to add the proposed fees to its fee schedule in General 8, Section 1(c). The Exchange also proposes not to charge an ongoing monthly fee for the cabinet power options in NY11–4 and update the fee schedule accordingly. For NY11–4, the data center operator is bringing in these higher voltage power options and is likely to experience increased power distribution efficiencies across the data center. The proposed power installation fees are higher in NY11–4 as compared to the existing data halls as the installation of the higher voltage power options costs more to the Exchange and is considered a premium product due to anticipated operational efficiencies.[11] As between the Phase 1 and Phase 3 power options, the Phase 3 options provide a more efficient power source.

Fees for Power Distribution Unit Options

The Exchange will offer power distribution units (''PDUs'')[12] in NY11–4 as a convenience to customers. Rather than sourcing PDUs on a customer-by-customer basis, as the Exchange does for customers in NY11, the Exchange will offer Phase 1 and Phase 3[13] power distribution units in NY11–4. The Exchange proposes to establish a fee of $4,100 for a Phase 1 PDU and $5,260 for a Phase 3 PDU. This service is optional and customers may choose to provide their own PDUs appropriate for their power installation choices. The Exchange notes that, as part of such proposed fees, the Exchange would provide a primary and redundant PDU. As such, the proposed PDU fees covers a pair of PDUs. In addition, customers utilizing a Phase 1 or Phase 3 PDU provided by the Exchange have the ability to upgrade or downgrade between amperage levels without replacing the PDU, by a simple upgrade of the facility cord and a receptacle update.[14] A PDU replacement is required when switching between phases/voltage.

The Exchange will also offer a switch monitored PDU add on in NY11–4, which would allow customers to connect remotely to their PDU and control the power sockets. With the switch monitored PDU option, customers would be able to power cycle or shut off power remotely. The Exchange proposes to establish a $2,000 fee for the switch monitored PDU option. This option is optional as well and customers may choose to provide their own switch monitored PDU, if desired.

Implementation

Although the timing is subject to change,[15] the Exchange anticipates opening NY11–4 Exchange access on October 21, 2024 and providing customers access in advance of this date. The proposed fees are designated to be operative on August 15, 2024. However, customer orders will not be fee liable until customers are provided access to the space.[16]

[7] Because of the addition of the Ultra High Density Cabinet option in NY11–4, the Super High Density Cabinet in NY11–4 will have power density greater than 15 kW and less than or equal to 17.3 kW.

[8] The existing data halls utilize cold aisle containment to manage temperatures. Hot aisle containment is a more effective way to manage heat in the data center.

[9] In contrast, to the extent customers provide their own cabinets in NY11, there is an additional out-of-pocket cost for such cabinets.

[10] For example, NYSE charges an initial $5,000 fee for dedicated cabinets. *See https://www.nyse.com/publicdocs/Wireless_Connectivity_Fees_and_Charges.pdf.*

[11] Benefits include future proofing the data hall to allow for increasing power density in the future, requiring less whips to deliver the same amount of amperage, less circuits need to be installed to reach the same power supply, and safety improvements.

[12] PDUs are devices fitted with multiple outputs designed to distribute electric power. The standardized PDUs would only be offered for NY11–4.

[13] Phase 1 PDUs are compatible with the following power options: Phase 1 20 amp 240 volt, Phase 1 32 amp 240 volt, and Phase 1 40 amp 240 volt. Phase 3 PDUs are compatible with the following power options: Phase 3 20 amp 415 volt and Phase 3 32 amp 415 volt. Phase 1 and Phase 3 are available in NY11 and NY11–4. Phase 3 PDUs provide greater power density than Phase 1 PDUs by delivering power over three wires as opposed to one wire.

[14] This functionality may be available with customer-provided PDUs as well and depends on the PDU provided by the customer.

[15] The Exchange will announce modifications to the proposed timing via the Nasdaq Customer Portal, which is the web portal used for order and inventory management of colocation services, and email communication to all colocation customers.

[16] Charging customers once access is provided is consistent with current practice and allows

Continued

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[17] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[18] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposal to establish a monthly fee for Ultra High Density Cabinets, an installation fee for cabinets in NY11–4, installation fees for power installation in NY11–4, and fees for power distribution unit options in NY11–4 is reasonable. First, the Exchange's proposal to establish a $7,230 ongoing monthly fee for Ultra High Density Cabinets in NY11–4 is reasonable because it is comparable to the Exchange's current ongoing monthly fees for cabinets. The proposed fee amount falls between the $4,748 ongoing monthly fee charged for High Density Cabinets and the $8,440 ongoing monthly fee charged for Super High Density Cabinets. Furthermore, the proposed fee is consistent with the existing ongoing monthly cabinet fees on a per kW basis. The existing monthly cabinet fees range from approximately $475 per kW to $916 per kW, while the proposed ongoing monthly cabinet fee for the Ultra High Density Cabinet ranges from approximately $482 per kW (at the high end of the power density range for Ultra High Density Cabinets) to $723 per kW (at the low end of the power density range for Ultra High Density Cabinets). Second, the Exchange believes that the proposed cabinet installation fee of $5,940 is reasonable as compared to the installation fees in NY11 (of $3,693–$4,748) because the proposed installation fee includes the cabinet itself, which includes certain enhanced features in NY11–4, including uniform, wider cabinets (32″ W x 48″ D x 91″ H), cable management, and a rear split door and combo lock. In contrast, in NY11, customers may choose to provide their own cabinets, incurring an additional cost. Furthermore, the proposed installation fee is comparable to the rate charged by NYSE for a similar product, as described above. Third, the Exchange believes that the power installation fees of $3,600 for Phase 1 power options and $4,560 for Phase 3 power options in NY11–4 are reasonable. As compared to power installation fees in NY11, the proposed rates for NY11–4 are higher because the Exchange will incur increased costs for installation of the higher voltage power options. In addition, the higher voltage power options will provide operational efficiencies for the data hall, as discussed above,[19] warranting a higher fee. Finally, the Exchange believes that the proposed fees for PDUs and the PDU add on are reasonable because such fees are consistent with market rates. Furthermore, the Exchange is providing the PDU options as a convenience to customers. No customer is required to purchase any PDU options from the Exchange. Customers may choose to provide their own PDUs and PDU add ons.

The Exchange believes substitutable products and services are available to market participants, including, among other things, other equities and options exchanges that a market participant may connect to in lieu of the Exchange,[20] connectivity to the Exchange via a third-party reseller of connectivity, and/or trading of equities or options products within markets which do not require connectivity to the Exchange, such as the Over-the-Counter (OTC) markets. Market participants that wish to connect to the Exchange will continue to choose the method of connectivity based on their specific needs. Market participants that wish to connect to the Exchange but want to avoid or mitigate the effect of these proposed fees can choose to connect to the Exchange through a vendor.

In summary, the proposal represents an equitable allocation of reasonable dues, fees and other charges because customers have choices in how they connect to the Exchange, the proposed monthly fee for Ultra High Density Cabinets is comparable to current fees charged by the Exchange for other cabinets, the Exchange will provide uniform cabinets in NY11–4 with special features, the proposed cabinet installation fee is consistent with that of comparable products offered by other providers, the Exchange will incur increased costs for new power installation in NY11–4, higher voltage power options will provide operational efficiencies for the data hall, and PDU options are provided as a convenience to customers and customers may choose to provide their own PDUs.

The Exchange believes that the proposed fee changes are not unfairly discriminatory because the cabinet, power, and PDU fees for NY11–4 are available to and assessed uniformly across all market participants. In addition, all customers have the choice of whether and how to connect to the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal burdens inter-market competition because approval of the proposal does not impose any burden on the ability of other exchanges to compete. The Exchange operates in a highly competitive market in which market participants can determine whether or not to connect to the Exchange based on the value received compared to the cost of doing so. Indeed, market participants have numerous alternative exchanges that they may participate on and direct their order flow, as well as off-exchange venues, where competitive products are available for trading.

Nothing in the proposal burdens intra-market competition because the Ultra High Density Cabinets, cabinet power options, and PDU optionality in NY11–4 are available to any customer under the same fees as any other customer, and any customer that wishes to order cabinets, power and PDUs in NY11–4 can do so on a non-discriminatory basis.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

customers to set up equipment and begin using power.

[17] 15 U.S.C. 78f(b).

[18] 15 U.S.C. 78f(b)(4) and (5).

[19] *Supra* note 11.

[20] There are currently 16 registered equities exchanges that trade equities and 17 exchanges offering options trading services. No single equities exchange has more than 20% of the market share. *See* Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (Last updated July 3, 2024), available at *https://www.cboe.com/us/equities/market_statistics/*. No single options exchange trades more than 15% of the options market by volume and only one of the 17 options exchanges has a market share over 10 percent. *See* Nasdaq, Options Market Statistics (Last updated July 3, 2024), available at *https://www.nasdaqtrader.com/Trader.aspx?id=OptionsVolumeSummary.* This broad dispersion of market share demonstrates that market participants can and do exercise choice in trading venues. Further, low barriers to entry mean that new exchanges may rapidly enter the market and offer additional substitute platforms to further compete with the Exchange and the products it offers.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[21]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–Phlx–2024–37 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–Phlx–2024–37. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–Phlx–2024–37 and should be submitted on or before August 21, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–16799 Filed 7–30–24; 8:45 am]

BILLING CODE 8011–01–P

[21] 15 U.S.C. 78s(b)(3)(A)(ii).

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100596; File No. SR–GEMX–2024–23]

Self-Regulatory Organizations; Nasdaq GEMX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish Fees for Its Expanded Co-Location Services

July 25, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 15, 2024, Nasdaq GEMX, LLC (''GEMX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to establish fees for its expanded co-location services, as described further below.

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on August 15, 2024.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/gemx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange filed a proposal to expand its co-location services by offering new cabinet, power, and power distribution unit options in the Exchange's expanded data center.[3] As described in that filing, the Exchange's current data center (''NY11'') in Carteret, NJ is undergoing an expansion (''NY11–4'') in response to demand for power and cabinets. The purpose of this proposed rule change is to establish fees for the expanded co-location services. Specifically, the Exchange proposes to establish (i) a monthly fee for Ultra High Density Cabinets, (ii) an installation fee for cabinets in NY11–4, (iii) fees for power installation in NY11–4, and (iv) fees for power distribution unit options in NY11–4.

Ultra High Density Cabinet

Currently, co-location customers have the option of obtaining cabinets of various sizes and power densities. Co-location customers may obtain a Half Cabinet,[4] a Low Density Cabinet with power density less than or equal to 2.88 kilowatts (''kW''), a Medium Density Cabinet with power density greater than 2.88 kW and less than or equal to 5 kW, a Medium-High Density Cabinet with power density greater than 5 kW and less than or equal to 7 kW, a High Density Cabinet with power density greater than 7 kW and less than 10 kW, and a Super High Density Cabinet with power density greater than 10 kW and less than or equal to 17.3 kW.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* SR–GEMX–2024–21 (not yet published).

[4] Half cabinets are not available to new subscribers. *See* General 8, Section 1(a).

The Exchange filed a proposal to introduce a new cabinet choice in NY11–4, an ''Ultra High Density Cabinet,'' with power density greater than 10 kW and less than or equal to 15 kW.[5] The Ultra High Density Cabinet option will only be offered in NY11–4 because of the power configuration necessary for such cabinets, which is not possible or available in other portions of the data center due to different power distribution.[6] In addition to the Ultra High Density Cabinet, the Exchange will offer the other, existing cabinet options in NY11–4, with the exception of the Low Density Cabinet and Half Cabinet due to a lack of demand for such cabinets. The ongoing monthly fees for the Super High Density Cabinet, High Density Cabinet, Medium-High Density Cabinet, and Medium Density Cabinet are the same in NY11 and NY11–4 and the Exchange is not proposing to modify such fees.

The Exchange proposes to establish an ongoing monthly fee of $7,230 for the Ultra High Density Cabinets. To effectuate this change, the Exchange proposes to add the $7,230 ongoing monthly fee for Ultra High Density Cabinets to its fee schedule in General 8, Section 1(a). The Exchange notes that the proposed fee amount falls between the $4,748 ongoing monthly fee charged for High Density Cabinets and the $8,440 ongoing monthly fee charged for Super High Density Cabinets. Furthermore, the proposed fee is consistent with the existing ongoing monthly cabinet fees on a per kW basis. The existing monthly cabinet fees range from approximately $475 per kW to $916 per kW, while the proposed ongoing monthly cabinet fee for the Ultra High Density Cabinet ranges from approximately $482 per kW (at the high end of the power density range for Ultra High Density Cabinets) to $723 per kW (at the low end of the power density range for Ultra High Density Cabinets).

Installation Fee for Cabinets in NY11–4

The Exchange proposes to establish a cabinet installation fee of $5,940 for all cabinets in NY11–4. To effectuate this change, the Exchange proposes to add the proposed $5,940 installation fee to its fee schedule in General 8, Section 1(a) for Super High Density Cabinets, Ultra High Density Cabinets, High Density Cabinets, Medium-High Density Cabinets, and Medium Density Cabinets in NY11–4. In the existing data halls, customers may bring their own cabinets or use Exchange-provided cabinets. In NY11–4, because of the cooling system (hot aisle containment),[7] all cabinets must be uniform and therefore, the Exchange will provide all cabinets, the cost of which is included in the $5,940 installation fee.[8] The cabinets in NY11–4 include certain features not included in cabinets provided by the Exchange in the existing data halls. Specifically, the cabinets in NY11–4 include uniform, wider cabinets (32″ W x 48″ D x 91″ H), cable management, and a rear split door and combo lock. In addition, the proposed installation fee of $5,940 is comparable to fees charged for similar products.[9]

Installation Fee for Cabinet Power in NY11–4

The cabinet power options for NY11–4 include: Phase 1 20 amp 240 volt, Phase 1 32 amp 240 volt, Phase 1 40 amp 240 volt, Phase 3 20 amp 415 volt, and Phase 3 32 amp 415 volt. These cabinet power options are specific to NY11–4 and one of these options must be selected for cabinets in NY11–4. The Exchange proposes to establish an installation fee of $3,600 for Phase 1 cabinet power options in NY11–4 and an installation fee of $4,560 for Phase 3 cabinet power options in NY11–4. To effectuate this change, the Exchange proposes to add the proposed fees to its fee schedule in General 8, Section 1(c). The Exchange also proposes not to charge an ongoing monthly fee for the cabinet power options in NY11–4 and update the fee schedule accordingly. For NY11–4, the data center operator is bringing in these higher voltage power options and is likely to experience increased power distribution efficiencies across the data center. The proposed power installation fees are higher in NY11–4 as compared to the existing data halls as the installation of the higher voltage power options costs more to the Exchange and is considered a premium product due to anticipated operational efficiencies.[10] As between the Phase 1 and Phase 3 power options, the Phase 3 options provide a more efficient power source.

Fees for Power Distribution Unit Options

The Exchange will offer power distribution units (''PDUs'')[11] in NY11–4 as a convenience to customers. Rather than sourcing PDUs on a customer-by-customer basis, as the Exchange does for customers in NY11, the Exchange will offer Phase 1 and Phase 3[12] power distribution units in NY11–4. The Exchange proposes to establish a fee of $4,100 for a Phase 1 PDU and $5,260 for a Phase 3 PDU. This service is optional and customers may choose to provide their own PDUs appropriate for their power installation choices. The Exchange notes that, as part of such proposed fees, the Exchange would provide a primary and redundant PDU. As such, the proposed PDU fees covers a pair of PDUs. In addition, customers utilizing a Phase 1 or Phase 3 PDU provided by the Exchange have the ability to upgrade or downgrade between amperage levels without replacing the PDU, by a simple upgrade of the facility cord and a receptacle update.[13] A PDU replacement is required when switching between phases/voltage.

The Exchange will also offer a switch monitored PDU add on in NY11–4, which would allow customers to connect remotely to their PDU and control the power sockets. With the switch monitored PDU option, customers would be able to power cycle or shut off power remotely. The Exchange proposes to establish a $2,000 fee for the switch monitored PDU option. This option is optional as well and customers may choose to provide their own switch monitored PDU, if desired.

Implementation

Although the timing is subject to change,[14] the Exchange anticipates

[5] *Supra* note 3.

[6] Because of the addition of the Ultra High Density Cabinet option in NY11–4, the Super High Density Cabinet in NY11–4 will have power density greater than 15 kW and less than or equal to 17.3 kW.

[7] The existing data halls utilize cold aisle containment to manage temperatures. Hot aisle containment is a more effective way to manage heat in the data center.

[8] In contrast, to the extent customers provide their own cabinets in NY11, there is an additional out-of-pocket cost for such cabinets.

[9] For example, NYSE charges an initial $5,000 fee for dedicated cabinets. *See https://www.nyse.com/publicdocs/Wireless_Connectivity_Fees_and_Charges.pdf.*

[10] Benefits include future proofing the data hall to allow for increasing power density in the future, requiring less whips to deliver the same amount of amperage, less circuits need to be installed to reach the same power supply, and safety improvements.

[11] PDUs are devices fitted with multiple outputs designed to distribute electric power. The standardized PDUs would only be offered for NY11–4.

[12] Phase 1 PDUs are compatible with the following power options: Phase 1 20 amp 240 volt, Phase 1 32 amp 240 volt, and Phase 1 40 amp 240 volt. Phase 3 PDUs are compatible with the following power options: Phase 3 20 amp 415 volt and Phase 3 32 amp 415 volt. Phase 1 and Phase 3 are available in NY11 and NY11–4. Phase 3 PDUs provide greater power density than Phase 1 PDUs by delivering power over three wires as opposed to one wire.

[13] This functionality may be available with customer-provided PDUs as well and depends on the PDU provided by the customer.

[14] The Exchange will announce modifications to the proposed timing via the Nasdaq Customer Portal, which is the web portal used for order and

opening NY11–4 Exchange access on October 21, 2024 and providing customers access in advance of this date. The proposed fees are designated to be operative on August 15, 2024. However, customer orders will not be fee liable until customers are provided access to the space.[15]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[16] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[17] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposal to establish a monthly fee for Ultra High Density Cabinets, an installation fee for cabinets in NY11–4, installation fees for power installation in NY11–4, and fees for power distribution unit options in NY11–4 is reasonable. First, the Exchange's proposal to establish a $7,230 ongoing monthly fee for Ultra High Density Cabinets in NY11–4 is reasonable because it is comparable to the Exchange's current ongoing monthly fees for cabinets. The proposed fee amount falls between the $4,748 ongoing monthly fee charged for High Density Cabinets and the $8,440 ongoing monthly fee charged for Super High Density Cabinets. Furthermore, the proposed fee is consistent with the existing ongoing monthly cabinet fees on a per kW basis. The existing monthly cabinet fees range from approximately $475 per kW to $916 per kW, while the proposed ongoing monthly cabinet fee for the Ultra High Density Cabinet ranges from approximately $482 per kW (at the high end of the power density range for Ultra High Density Cabinets) to $723 per kW (at the low end of the power density range for Ultra High Density Cabinets). Second, the Exchange believes that the proposed cabinet installation fee of $5,940 is reasonable as compared to the installation fees in NY11 (of $3,693–$4,748) because the proposed installation fee includes the cabinet itself, which includes certain enhanced features in NY11–4, including uniform, wider cabinets (32″ W x 48″ D x 91″ H), cable management, and a rear split door and combo lock. In contrast, in NY11, customers may choose to provide their own cabinets, incurring an additional cost. Furthermore, the proposed installation fee is comparable to the rate charged by NYSE for a similar product, as described above. Third, the Exchange believes that the power installation fees of $3,600 for Phase 1 power options and $4,560 for Phase 3 power options in NY11–4 are reasonable. As compared to power installation fees in NY11, the proposed rates for NY11–4 are higher because the Exchange will incur increased costs for installation of the higher voltage power options. In addition, the higher voltage power options will provide operational efficiencies for the data hall, as discussed above,[18] warranting a higher fee. Finally, the Exchange believes that the proposed fees for PDUs and the PDU add on are reasonable because such fees are consistent with market rates. Furthermore, the Exchange is providing the PDU options as a convenience to customers. No customer is required to purchase any PDU options from the Exchange. Customers may choose to provide their own PDUs and PDU add ons.

The Exchange believes substitutable products and services are available to market participants, including, among other things, other options exchanges that a market participant may connect to in lieu of the Exchange,[19] connectivity to the Exchange via a third-party reseller of connectivity, and/or trading of options products within markets which do not require connectivity to the Exchange, such as the Over-the-Counter (OTC) markets. Market participants that wish to connect to the Exchange will continue to choose the method of connectivity based on their specific needs. Market participants that wish to connect to the Exchange but want to avoid or mitigate the effect of these proposed fees can choose to connect to the Exchange through a vendor.

In summary, the proposal represents an equitable allocation of reasonable dues, fees and other charges because customers have choices in how they connect to the Exchange, the proposed monthly fee for Ultra High Density Cabinets is comparable to current fees charged by the Exchange for other cabinets, the Exchange will provide uniform cabinets in NY11–4 with special features, the proposed cabinet installation fee is consistent with that of comparable products offered by other providers, the Exchange will incur increased costs for new power installation in NY11–4, higher voltage power options will provide operational efficiencies for the data hall, and PDU options are provided as a convenience to customers and customers may choose to provide their own PDUs.

The Exchange believes that the proposed fee changes are not unfairly discriminatory because the cabinet, power, and PDU fees for NY11–4 are available to and assessed uniformly across all market participants. In addition, all customers have the choice of whether and how to connect to the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal burdens inter-market competition because approval of the proposal does not impose any burden on the ability of other exchanges to compete. The Exchange operates in a highly competitive market in which market participants can determine whether or not to connect to the Exchange based on the value received compared to the cost of doing so. Indeed, market participants have numerous alternative exchanges that they may participate on and direct their order flow, as well as off-exchange venues, where competitive products are available for trading.

Nothing in the proposal burdens intra-market competition because the Ultra High Density Cabinets, cabinet power options, and PDU optionality in NY11–4 are available to any customer under the same fees as any other customer, and any customer that wishes to order cabinets, power and PDUs in NY11–4 can do so on a non-discriminatory basis.

inventory management of colocation services, and email communication to all colocation customers.

[15] Charging customers once access is provided is consistent with current practice and allows customers to set up equipment and begin using power.

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(4) and (5).

[18] *Supra* note 10.

[19] There are currently 17 exchanges offering options trading services. No single options exchange trades more than 15% of the options market by volume and only one of the 17 options exchanges has a market share over 10 percent. *See* Nasdaq, Options Market Statistics (Last updated July 3, 2024), available at *https://www.nasdaqtrader.com/Trader.aspx?id=OptionsVolumeSummary.* This broad dispersion of market share demonstrates that market participants can and do exercise choice in trading venues. Further, low barriers to entry mean that new exchanges may rapidly enter the market and offer additional substitute platforms to further compete with the Exchange and the products it offers.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[20] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–GEMX–2024–23 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–GEMX–2024–23. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–GEMX–2024–23 and should be submitted on or before August 21, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–16803 Filed 7–30–24; 8:45 am]

BILLING CODE 8011–01–P

[20] 15 U.S.C. 78s(b)(3)(A)(ii).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100599; File No. SR–Phlx–2024–26]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Options 2, Sections 5 and 10 and Options 3, Section 15

July 25, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 16, 2024, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Options 2, Sections 5 and 10 and Options 3, Section 15.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/phlx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Phlx proposes to amend: (1) Directed Market Maker quoting obligations in Options 2, Section 5, Electronic Market Maker Obligations and Quoting Requirements; (2) a reference to ''Exchange's best price'' in Options 2, Section 10, Directed Orders; and (3) rule text related to the Acceptable Trade Range in Options 3, Section 15, Simple Order Risk Protections. Each change will be discussed below.

Options 2, Section 5

The Exchange proposes to amend the rule text within Options 2, Section 5(c)(2)(C) related to the quoting obligations applicable to a Directed Market Maker.

The current rule text states that Directed SQTs and Directed RSQTs, associated with the same member organization, are collectively required to provide two-sided quotations in 90% of the cumulative number of seconds, or such higher percentage as Phlx may announce in advance, for which that member organization's assigned options series are open for trading. With respect to a Directed Market Maker, Phlx currently requires that the Directed Market Maker provide two-sided quotations in 90% of the cumulative number of seconds, or such higher percentage as Phlx may announce in advance, in any options series in which the Directed Market Maker has executed a Directed Order on a daily basis. Phlx requires the Market Maker to fulfill this requirement in addition to its

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

requirement to quote as a Market Maker or a Lead Market Maker.

Below the Exchange presents examples of how the new rule text would operate.

Example 1

- Assume a Market Maker was assigned in options overlying AAPL, SPY, NFLX, ORCL and ADBE.
- Assume this Market Maker had previously executed a Directed Order and executes a Directed Order in NFLX and ADBE on February 27, 2024.
- The Directed Market Maker obligation is a daily obligation once triggered and continues until the Directed Market Maker notifies the Exchange that it no longer desires to be a part of the Directed Order program.
- Moreover, on February 28, 2024 and each day thereafter the Directed Market Maker is required to provide two-sided quotations in 90% of the cumulative number of seconds among all options series in which the Directed Market Maker has executed a Directed Order on a daily basis until a Directed Market Maker notifies the Exchange that it is no longer directed. Therefore, the Directed Market Maker would be required to quote at 90% of the cumulative number of seconds among all options series in which the Directed Market Maker has executed a Directed Order each day, regardless of whether the Directed Market Maker executed a Directed Order that day.

Obligations

This Market Maker is required to provide two-sided quotations in 60% of the cumulative number of seconds, or such higher percentage as Phlx may announce in advance, for which that member's assigned options series are open for trading among AAPL, SPY, and ORCL to fulfill its Market Maker obligation.

Separately, this Market Maker would be obligated, separate and apart from its Market Maker obligations described in this example, to provide two-sided quotations in 90% of the cumulative number of seconds, or such higher percentage as Phlx may announce in advance, among NFLX and ADBE to fulfill its Directed Market Maker Obligation.

This Market Maker would not be required to make two-sided markets in any Quarterly Option Series, any Adjusted Option Series, and any option series with an expiration of nine months or greater for options on equities and ETFs or with an expiration of twelve months or greater for index options in AAPL, SPY, NFLX, ORCL and ADBE when meeting its Market Maker or Directed Market Maker requirements.

Example 2

- Assume a Lead Market Maker was assigned in options overlying AAPL, SPY, NFLX, ORCL and ADBE.
- Assume this Lead Market Maker had previously executed a Directed Order and executes a Directed Order in NFLX and ADBE on February 27, 2024. The Directed Market Maker obligation is a daily obligation once triggered and continues until the Directed Market Maker notifies the Exchange that it no longer desires to be a part of the Directed Order program.
- The Directed Market Maker obligation is a daily obligation once triggered and continues until the Directed Market Maker notifies the Exchange that it no longer desires to be a part of the Directed Order program.
- Moreover, on February 28, 2024 and each day thereafter the Directed Market Maker is required to provide two-sided quotations in 90% of the cumulative number of seconds among all options series in which the Directed Market Maker has executed a Directed Order on a daily basis until a Directed Market Maker notifies the Exchange that it is no longer directed. Therefore, the Directed Market Maker would be required to quote at 90% of the cumulative number of seconds among all options series in which the Directed Market Maker has executed a Directed Order each day, regardless of whether the Directed Market Maker executed a Directed Order that day.

Obligations

This Lead Market Maker, associated with the same member, is collectively required to provide two-sided quotations in 90% of the cumulative number of seconds, or such higher percentage as Phlx may announce in advance, among AAPL, SPY, and ORCL to fulfill its Lead Market Maker obligation.[3]

Separately, this Lead Market Maker would be obligated, separate and apart from its Lead Market Maker obligations described in this example, to provide two-sided quotations in 90% of the cumulative number of seconds, or such higher percentage as Phlx may announce in advance, among NFLX and ADBE to fulfill its Directed Market Maker obligation.

This Market Maker would not be required to make two-sided markets in any Quarterly Option Series, any Adjusted Option Series, and any option series with an expiration of nine months or greater for options on equities and ETFs or with an expiration of twelve months or greater for index options in AAPL, SPY, NFLX, ORCL and ADBE when meeting its Lead Market Maker or Directed Market Maker requirements.

The Exchange proposes to amend the rule text in Options 2, Section 5(c)(2)(C) to require Directed Lead Market Makers, Directed SQTs and Directed RSQTs (collectively ''Directed Market Makers''),[4] associated with the same member organization, collectively, to provide two-sided quotations in 90% of the cumulative number of seconds, or such higher percentage as Phlx may announce in advance, among all option series in which the Directed Market Maker has executed a Directed Order on a daily basis, except that a Directed Market Maker shall not be required to make two-sided markets in any Quarterly Option Series, any Adjusted Option Series, and any option series with an expiration of nine months or greater for options on equities and exchange-traded funds (''ETFs'') or with an expiration of twelve months or greater for index options. The Exchange notes that the proposed requirements are similar to requirements imposed by other options exchanges. NYSE Arca, Inc. (''NYSE Arca'') and NYSE American LLC (''NYSE American'') require that their lead market makers and market makers provide continuous two-sided quotations throughout the trading day in issues for which it receives Directed Orders for 90% of the time the Exchange is open for trading in each issue.[5]

The Exchange also proposes to relocate certain rule text within Options 2, Section 5(c)(2)(C) to make clear the requirements applicable to a Directed Market Maker and make other amendments as well. The Exchange

[3] *See* Options 2, Section 4(j)(1).

[4] The Exchange will utilize the term ''Directed Market Makers'' throughout to refer to Directed Lead Market Makers, Directed SQTs and Directed RSQTs. The Exchange will also utilize the term ''Market Maker'' in this 19b4 to refer to a Lead Market Maker, SQT and an RSQT. *See* Options 7, Section 1(b)(28), ''A 'Market Maker' means a Streaming Quote Trader or a Remote Streaming Quote Trader who enters quotations for his own account electronically into the System.'' Further, *see* Options 7, Section 1(b)(27), ''A 'Lead Market Maker' means a member who is registered as an options Lead Market Maker pursuant to Options 2, Section 12(a). A Lead Market Maker includes a Remote Lead Market Maker which is defined as a Lead Market Maker in one or more classes that does not have a physical presence on the Exchange's Trading Floor and is approved by the Exchange pursuant to Options 2, Section 11.''

[5] *See* NYSE Arca Rule 6.88–O and NYSE American Rule 964.1NY. NYSE Arca Rule 6.88–O(iv) states that these obligations will apply collectively to all series in all of the issues for which the Directed Order Market Maker receives Directed Orders, rather than on an issue-by-issue basis.

proposes to amend the timeframe in which a Directed Market Maker is obligated to commence complying with the quoting obligations of Options 2, Section 5(c)(2)(C).[6] Today, a Directed Market Maker must commence complying with the quoting obligations specified in Options 2, Section 5(c)(2)(C) when a Directed Market Maker receives a Directed Order in any option in which they are assigned until such time as the Directed Market Maker notifies the Exchange that they are no longer directed. Pursuant to Options 2, Section 10(a)(ii), ''[w]hen the Exchange's disseminated price is the NBBO at the time of receipt of the Directed Order, and the Directed Lead Market Maker, SQT or RSQT is quoting at the Exchange's best price, the Directed Order shall be automatically executed and allocated in accordance with Options 3, Section 10(a)(1).'' The Exchange proposes to amend Options 2, Section 5(c)(2)(C) to instead begin requiring a Directed Market Maker to comply with the Directed Market Maker quoting obligations in Options 2, Section 5(c)(2)(C) when the Directed Market Maker executes its first Directed Order in any option in which they are assigned. A Directed Market Maker has the ongoing quoting obligation from the time a Directed Market Maker executes its first Directed Order in the options in which the Directed Market Maker is assigned until a Directed Market Maker notifies the Exchange that the Directed Market Maker is no longer directed. Because Directed Market Makers are unaware if an order is directed to them until such time as they execute the Directed Order and receive an allocation pursuant to Options 3, Section 10, the Exchange believes that starting the quoting obligation once a Directed Order is executed is a practical approach to ensuring that Directed Market Makers comply with their quoting obligations.

The proposed rule text would provide,

Directed Lead Market Makers, Directed SQTs and Directed RSQTs (''Directed Market Makers''), associated with the same member organization, are collectively required to provide two-sided quotations in 90% of the cumulative number of seconds, or such higher percentage as Phlx may announce in advance, among all options series in which the Directed Market Maker has executed a Directed Order on a daily basis, except that a Directed Market Maker shall not be required to make two-sided markets in any Quarterly Options Series, any Adjusted Options Series, and any options series with an expiration of nine months or greater for options on equities and ETFs or with an expiration of twelve months or greater for index options. A Directed Market Maker has the ongoing quoting obligation from the time a Directed Market Maker executes its first Directed Order in the options in which the Directed Market Maker is assigned until a Directed Market Maker notifies the Exchange that the Directed Market Maker is no longer directed.

A Directed Market Maker shall not be required to make two-sided markets in any Quarterly Options Series, any Adjusted Options Series, and any options series with an expiration of nine months or greater for options on equities and ETFs or with an expiration of twelve months or greater for index options and would receive a participation entitlement in the Quarterly Options Series, the Adjusted Options Series, and an options series with an expiration of nine months or greater for options on equities and ETFs or with an expiration of twelve months or greater for index options for the Directed Order, only if it complies with the heightened 90% quoting requirement.

As is the case today, a Directed Market Maker must be quoting at the Exchange's best price[7] at the time of receipt of the Directed Order to be entitled to the allocation in accordance with Options 3, Section 10. The Exchange notes that the amendment adds clarity to the Exchange's current practice[8] and harmonizes the rules of Phlx with those of other Nasdaq affiliated markets.

Options 2, Section 10

The Exchange proposes to amend Options 2, Section 10, Directed Orders. Specifically, Options 2, Section 10(a)(ii) provides, ''When the Exchange's disseminated price is the NBBO at the time of receipt of the Directed Order, and the Directed Lead Market Maker, SQT or RSQT is quoting at the Exchange's best price, the Directed Order shall be automatically executed and allocated in accordance with Options 3, Section 10(a)(1).'' The Exchange proposes to amend this sentence to replace the words ''Exchange's best price'' with ''better of the internal PBBO or the NBBO.'' The Exchange proposes this amendment to conform the rule text with language throughout the Options 3 trading rules that describe the Exchange's best price with references to the internal PBBO and NBBO. Pursuant to Options 3, Section 5, the System automatically executes eligible orders using the Exchange's displayed best bid and offer (''PBBO'') or the Exchange's non-displayed order book (''internal PBBO'') if there are non-displayed orders on the order book or the best bid and/or offer on the Exchange has been repriced pursuant to Options 3, Section 5(d) or Options 3, Section 4(b)(6) which describes trade-through compliance and locked and crossed markets. The Exchange also proposes to amend the citation to ''Options 3, Section 10(a)(1)'' to the more precise citation ''Options 3, Section 10(a)(1)(C)'' which describes the Directed Market Maker Priority allocation. The Exchange's amendment will bring additional clarity to current rule text and harmonize the rule text with Options 3 language.

Options 3, Section 15

Today, Options 3, Section 15(b)(1)(A) provides that, ''Upon receipt of a new order/quote, the Reference Price is the better of the National Best Bid (''NBB'') or internal best bid for sell orders/quotes and the National Best Offer (''NBO'') or internal best offer for buy orders/quotes, excluding All-or-None Orders which cannot be satisfied, or the last price at which the order/quote is posted whichever is higher for a buy order/quote or lower for a sell order/quote.'' The Exchange proposes to remove the phrase ''excluding All-or-None Orders which cannot be satisfied'' from the rule text. The Exchange previously filed a rule change[9] to amend All-or-None Orders so that they may only be submitted by a Public Customer as an Immediate-or-Cancel Order. As a result of this rule change, All-or-None Orders no longer rest on the order book. Upon entry, an All-or-None Order is executed in its entirety or cancelled if it cannot execute. The Exchange inadvertently did not remove the aforementioned rule text which would require an All-or-None Order to

[6] Options 2, Section 5(c)(2)(C) provides that a member organization shall be considered directed in all assigned options once the member organization receives a Directed Order in any option in which they are assigned and shall be considered a Directed SQT or Directed RSQT until such time as the member organization notifies the Exchange that they are no longer directed.

[7] As part of this proposed rule change the Exchange is amending Options 2, Section 10(a)(ii) to replace the words ''Exchange's best price'' with ''better of the internal PBBO or the NBBO.'' The ''internal PBBO'' is comprised of non-displayed and displayed orders on the Exchange's order book.

[8] Phlx noted in a 2018 rule change that if a member desired to become a Directed SQT that the quoting obligations specified in Rule 1081(c)(ii)(C) (now Options 2, Section 5) would commence when that Directed SQT executed an order directed to the Directed SQT. *See* Securities Exchange Act Release No. 82975 (March 30, 2018), 83 FR 14690, 14694 (April 5, 2018) (SR–Phlx–2018–22) (Notice of Filing of Proposed Rule Change To Create a New Rule 1081, To Amend Electronic Market Maker Obligations and Quoting Requirements for Electronic ROTs, Which Will Be Defined To Include SQTs, RSQTs, Directed SQTs, Directed RSQTs, Specialists, and Remote Specialists).

[9] *See* Securities Exchange Act Release No. 98142 (August 16, 2023), 88 FR 57140 (August 22, 2023) (SR–Phlx–2023–34) (Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Phlx's All-or-None Order) (''SR–Phlx–2023–34'').

rest to be applicable. At this time, the Exchange proposes to also remove this rule text reference to All-or-None Orders in Options 3, Section 15(b)(1)(A), similar to the other rule text rule references that were removed in SR–Phlx–2023–34.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Section 6(b)(5) of the Act,[11] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

Options 2, Section 5

The Exchange's proposal to amend the Directed Market Maker quoting obligations in Options 2, Section 5(c)(2)(C) is consistent with the Act. Other options exchanges today require Directed Market Makers, collectively, to provide two-sided quotations in 90% of the cumulative number of seconds among all options series in which the Directed Market Maker has received a Directed Order on a daily basis. The proposed Directed Market Maker quoting obligations would require Directed Market Makers, collectively, to provide two-sided quotations in 90% of the cumulative number of seconds or such higher percentage as Phlx may announce in advance, among all options series in which the Directed Market Maker has executed a Directed Order on a daily basis in addition to their quoting requirements as Market Makers and Lead Market Makers.

The Exchange believes that these quoting requirements create a direct nexus between the allocation that would be received by a Directed Market Maker pursuant to Options 3, Section 10 and the liquidity that the Directed Market Maker would be required to provide to the market in that particular options series. The Exchange notes that any Directed Market Maker quoting at the NBBO would need to provide two-sided quotations in 90% of the cumulative number of seconds among all options series in which the Directed Market Maker has executed a Directed Order for the entire day in which the Directed Market Maker received the Directed Order and each day thereafter, on a daily basis, until a Directed Market Maker notifies the Exchange that it is no longer directed. The Exchange believes that this quoting obligation is designed to promote just and equitable principles of trade by ensuring that Directed Market Makers quote competitively in as many series as possible to attract Directed Orders so that they may receive an enhanced allocation as a Directed Market Maker.

The proposed rule text would harmonize the Directed Market Maker's quoting obligations with other options exchanges, such as NYSE Arca and NYSE American which require that their lead market makers and market makers provide continuous two-sided quotations throughout the trading day in issues for which it receives Directed Orders for 90% of the time the Exchange is open for trading in each issue.[12]

The Exchange's proposal to amend Options 2, Section 5(c)(2)(C) to require a Directed Market Maker to commence complying with the Options 2, Section 5(c)(2)(C) quoting obligations when the Directed Market Maker executes its first Directed Order in any option in which they are assigned is a practical approach to ensuring that Directed Market Makers comply with their quoting obligations. Directed Market Makers are unaware if an order is directed to them until such time as they execute the Directed Order and receive an allocation pursuant to Options 3, Section 10. Further, the Exchange notes that a Directed Market Maker must be quoting at the Exchange's best price[13] at the time of receipt of the Directed Order to be entitled to the allocation in accordance with Options 3, Section 10.

Options 2, Section 10

The Exchange's proposal to amend Options 2, Section 10, Directed Orders, to replace the words ''Exchange's best price'' with ''better of the internal PBBO or the NBBO'' is consistent with the Act. The proposed amendment will conform the rule text with language throughout the Options 3 trading rules that describe the Exchange's best price with references to the internal PBBO and NBBO. Additionally, the Exchange's amendment will protect investors and the general public by adding clarity to current rule text as well as harmonizing the rule text with Options 3 language.

Options 3, Section 15

The Exchange's proposal to remove rule text within Options 3, Section 15(b)(1)(A), related to the Acceptable Trade Range, is consistent with the Act as SR–Phlx–2023–34 amended All-or-None Orders such that they may only be submitted by a Public Customer as an Immediate-or-Cancel Order. An All-Or-None Order will either execute immediately or be cancelled back to the member or member organization. The Exchange inadvertently did not remove the aforementioned rule text which would require an All-or-None Order to rest to be applicable. This change will remove the incorrect rule text and bring greater clarity to the rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Options 2, Section 5

The Exchange's proposal to amend the Directed Market Maker quoting obligations in Options 2, Section 5(c)(2)(C) does not impose an undue burden on competition as every Directed Market Maker would be required, collectively, to provide two-sided quotations in 90% of the cumulative number of seconds or such higher percentage as Phlx may announce in advance, among all options series in which the Directed Market Maker has executed a Directed Order for the entire day in which the Directed Market Maker received the Directed Order, on a daily basis, until a Directed Market Maker notifies the Exchange that it is no longer directed. The proposal does not impose a burden on inter-market competition as other options markets today impose similar quoting obligations.

The Exchange's proposal to amend Options 2, Section 5(c)(2)(C) to require a Directed Market Maker to commence complying with the Options 2, Section 5(c)(2)(C) quoting obligations when the Directed Market Maker executes its first Directed Order in any option in which they are assigned does not impose an undue burden on competition because all Directed Market Makers will be required to commence complying with Options 2, Section 5(c)(2)(C) when the Directed Market Maker executes its first Directed Order in any option in which they are assigned. The proposal does not impose a burden on inter-market competition as other options markets today impose similar quoting obligations and may amend their rules to mirror those of Phlx.

Options 2, Section 10

The Exchange's proposal to amend Options 2, Section 10, Directed Orders, to replace the words ''Exchange's best price'' with ''better of the internal PBBO or the NBBO'' does not impose an

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] *See supra* note 5.

[13] *See supra* note 7.

undue burden on competition because the amendment more specifically describes the Exchange's best price with references to the internal PBBO and NBBO. The Exchange's amendment will add clarity to current rule text.

Options 3, Section 15

The Exchange's proposal to remove rule text within Options 3, Section 15(b)(1)(A), related to the Acceptable Trade Range, does not impose an undue burden on competition as All-or-None Orders may only be submitted by a Public Customer as an Immediate-or-Cancel Order. An All-Or-None Order will either execute immediately or be cancelled back to the member or member organization. Removing the incorrect rule text will bring greater clarity to the rules.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[14] and subparagraph (f)(6) of Rule 19b–4 thereunder.[15]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–Phlx–2024–26 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–Phlx–2024–26. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–Phlx–2024–26 and should be submitted on or before August 21, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–16805 Filed 7–30–24; 8:45 am]

BILLING CODE 8011–01–P

[14] 15 U.S.C. 78s(b)(3)(A)(iii).

[15] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100588; File No. SR–SAPPHIRE–2024–01]

Self-Regulatory Organizations; MIAX Sapphire, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Establish Proprietary Market Data Products

July 25, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 19, 2024, MIAX Sapphire, LLC (''MIAX Sapphire'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to establish proprietary market data products. The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/miax-sapphire/rule-filings,* at the Exchange's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to establish the MIAX Sapphire Top of Market (''ToM'') data feed, MIAX Sapphire Complex Top of Market (''cToM'') data

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

feed, and MIAX Sapphire Liquidity Feed (''SLF'').

The proposed ToM data feed will provide market participants with a direct data feed that includes the Exchange's best bid [3] and offer,[4] with aggregate size, and last sale information, based on displayable order and quoting interest on the Exchange. The proposed ToM data feed will include data that is identical to the data sent to the processor for the Options Price Reporting Authority (''OPRA''). The ToM and OPRA data will leave the MIAX Sapphire System [5] at the same time, as required under Section 5.2(c)(iii)(B) of the Limited Liability Company Agreement of the Options Price Reporting Authority LLC (the ''OPRA Plan''), which prohibits the dissemination of proprietary information on any more timely basis than the same information is furnished to the OPRA system for inclusion in OPRA's consolidated dissemination of options information. ToM will also contain a feature that provides the number of Priority Customer [6] contracts that are included in the size associated with the Exchange's best bid and offer.

The proposed cToM data feed will provide subscribers with the same information as the ToM data product as it relates to complex orders [7] on the Strategy Book,[8] *i.e.,* the Exchange's best bid and offer for a complex strategy, with aggregate size, based on displayable order and quoting interest in the complex strategy on the Exchange. The proposed cToM data feed will also provide subscribers with the identification of the complex strategies currently trading on MIAX Sapphire; complex strategy last sale information; and the status of securities underlying the complex strategy (*e.g.,* halted, open, or resumed). cToM will be distinct from ToM, and any firm that would like to receive cToM data must subscribe to cToM regardless of whether they are a current ToM subscriber. ToM subscribers will not be required to subscribe to cToM, and cToM subscribers will not be required to subscribe to ToM.

The proposed SLF data product will provide market participants with a direct data feed that allows subscribers to receive real-time updates of options orders, products traded on MIAX Sapphire, MIAX Sapphire System status, and MIAX Sapphire underlying trading status. When an order is received or an order state changes, published order information will be transmitted over the SLF, including time stamp, action, product ID, order ID, order side, order type, order price, original order size, open order size, time in force, origin, open or close, and route instruction. For complex orders, complex strategy definition notification and complex order notice are also included. Subscribers to the SLF data feed will get a list of all options symbols and strategies that will be traded and sourced on that feed at the start of every session.

The proposed data products provide valuable information that can help subscribers make informed investment decisions, and operate in the same manner as similar data products offered by the Exchange's affiliate, including Miami International Securities Exchange, LLC (''MIAX''), namely the MIAX Top of Market data feed (''MIAX ToM''),[9] MIAX Complex Top of Market data feed (''MIAX cToM''),[10] and the MIAX Order Feed (''MIAX MOR'').[11] The proposed data products also operate in the same manner as similar data products offered by the Exchange's affiliate, MIAX Emerald, LLC (''MIAX Emerald''), namely the MIAX Emerald Top of Market data feed (''Emerald ToM''), MIAX Emerald Complex Top of Market data feed (''Emerald cToM''), and the MIAX Emerald Order Feed (''Emerald MOR'').[12]

The Exchange represents that it will make ToM, cToM, and SLF equally available to any market participant that wishes to subscribe to any of those products. The Exchange will submit a separate proposed rule change for immediate effectiveness pursuant to Section 19(b)(3)(A) of the Act [13] and Rule 19b–4(f)(2) [14] thereunder to establish fees for the ToM, cToM and SLF data feeds. The Exchange notes that its affiliate, MIAX Emerald, filed a substantively similar proposal to adopt its own market data products—Emerald ToM, Emerald cToM and Emerald MOR—prior to offering such products to market participants prior to launching operations as a national securities exchange.[15]

2. Statutory Basis

The Exchange believes that its proposed rule change is consistent with Section 6(b) [16] of the Act in general, and furthers the objectives of Section 6(b)(5) [17] of the Act in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in facilitating transactions in securities, remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest.

The ToM market data product is designed to promote just and equitable principles of trade by providing all subscribers with top of market data that includes the Exchange's best bid and offer, with aggregate size, and last sale information, based on order and quoting interest on the Exchange that should enable them to make informed decisions on trading on MIAX Sapphire by using the ToM data to assess current market conditions that directly affect such decisions.

The cToM market data product is designed to promote just and equitable principles of trade by providing all subscribers with top of market data that includes similar information provided via ToM but for the Exchange's complex

[3] The term ''bid'' means a limit order to buy one or more options contracts. *See* Exchange Rule 100.

[4] The term ''offer'' means a limit order to sell one or more options contracts. *See id.*

[5] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See id.*

[6] The term ''Priority Customer'' means a person or entity that (i) is not a broker or dealer in securities, and (ii) does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). The number of orders shall be counted in accordance with Interpretation and Policy .01. *See id.*

[7] A ''complex order'' is ''any order involving the concurrent purchase and/or sale of two or more different options in the same underlying security (the 'legs' or 'components' of the complex order), for the same account, in a conforming or non-conforming ratio. . . .'' *See* Exchange Rule 518(a).

[8] The term ''complex strategy'' means a particular combination of components and their ratios to one another. New complex strategies can be created as the result of the receipt of a complex order or by the Exchange for a complex strategy that is not currently in the System. The Exchange may limit the number of new complex strategies that may be in the System at a particular time and will communicate this limitation to Members via Regulatory Circular. *See* Exchange Rule 518(a). The ''Strategy Book'' is the Exchange's electronic book of complex orders. *See* Exchange Rule 100. The Strategy Book is organized by complex strategy in that individual orders for a defined complex strategy are organized together in a book that is separate from the orders for a different complex strategy.

[9] *See* Securities Exchange Act Release Nos. 69007 (February 28, 2013), 78 FR 14617 (March 6, 2013) (SR–MIAX–2013–05); 69518 (May 6, 2013), 78 FR 27462 (May 10, 2013) (SR–MIAX–2013–18); 73395 (October 21, 2014), 79 FR 63979 (October 27, 2014) (SR–MIAX–2014–53).

[10] *See* Securities Exchange Act Release No. 79146 (October 24, 2016), 81 FR 75171 (October 28, 2016) (SR–MIAX–2016–36).

[11] *See* Securities Exchange Act Release No. 74759 (April 17, 2015), 80 FR 22749 (April 23, 2015) (SR–MIAX–2015–28).

[12] *See* Securities Exchange Act Release No. 85207 (February 27, 2019), 84 FR 7963 (March 5, 2019) (SR–EMERALD–2019–09).

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(2).

[15] *See supra* note 12.

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

orders on the Strategy Book, including the Exchange's best bid and offer for a complex strategy, with aggregate size, based on displayable order and quoting interest in the complex strategy on the Exchange that should enable subscribers to make informed decisions on trading on MIAX Sapphire by using the cToM data to assess current market conditions that directly affect such decisions.

The SLF market data product is designed to promote just and equitable principles of trade by providing all subscribers with limit order book data that should enable subscribers to make informed decisions on trading in MIAX Sapphire options by using the SLF data to assess current market conditions that directly affect such decisions. The proposed market data product facilitates transactions in securities, removes impediments to and perfect the mechanisms of a free and open market and a national market system by enhancing the subscribers' ability to make decisions on trading strategy, and by providing data that should help bring about such decisions in a timely manner to the protection of investors and the public interest. The market data provided by SLF removes impediments to, and is designed to further perfect, the mechanisms of a free and open market and a national market system by making the MIAX Sapphire market more transparent and accessible to market participants making routing decisions concerning their options orders. The SLF market data product is also designed to protect investors and the public interest by providing data to subscribers that is already currently available on other exchanges and will enable MIAX Sapphire to compete with such other exchanges, thereby offering market participants with additional data in order to seek the market center with the best price and the most liquidity on which to execute their transactions, all to the benefit of investors and the public interest, and to the marketplace as a whole.

The proposed ToM, cToM, and SLF market data products facilitate transactions in securities, remove impediments to and perfect the mechanisms of a free and open market and a national market system by enhancing the subscriber's ability to make decisions on trading strategies and by providing data which should help bring about such decisions in a timely manner to benefit the protection of investors and the public interest. The market data provided by ToM, cToM, and SLF removes impediments to, and is designed to further perfect, the mechanisms of a free and open market and a national market system by making the MIAX Sapphire market more transparent and accessible to market participants making routing decisions concerning their options orders. The Exchange notes that these data products are similar to, and provide data that is equivalent to, the ToM, cToM, and MOR data products for MIAX and MIAX Emerald with respect to options traded on those exchanges.[18] The Exchange believes that it is in the public interest to make similar information available with respect to options traded on MIAX Sapphire.

The proposed ToM, cToM, and SLF market data products are also designed to protect investors and the public interest by providing data to subscribers that is already currently available on at least one other competing options exchange [19] and will enable MIAX Sapphire to compete with such other exchanges, thereby offering market participants with additional data in order to seek the market center with the best price and the most liquidity on which to execute their transactions, all to the benefit of investors and the public interest, and to the marketplace as a whole.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. On the contrary, the Exchange believes that the new market data products will enhance competition in the U.S. options markets by providing users of MIAX Sapphire market data products that are similar to that which are currently provided on other competing options exchanges.[20]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [21] and Rule 19b–4(f)(6) thereunder.[22]

A proposed rule change filed under Rule 19b–4(f)(6) [23] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[24] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that waiver of the operative delay will enable the Exchange to make the ToM, cToM, and SLF market data products available to subscribers at the time of the launch of trading on the Exchange, which is scheduled for August 12, 2024.[25] The Exchange further states that the proposed rule change does not present any new or novel issues because the proposed market data products are substantially similar to market data products offered by the Exchange's affiliates, MIAX and MIAX Emerald, and by at least one other competing options exchange.[26] For these reasons, and because the proposal does not raise any new or novel issues, the Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative

[18] *See supra* notes 9, 10, 11, and 12.

[19] For example, Nasdaq GEMX, LLC (''GEMX'') has similar data products to ToM and MOR available for purchase by GEMX users, including the Nasdaq GEMX Top Feed and Nasdaq GEMX Order Feed. *See* Nasdaq GEMX Options 7, Pricing Schedule, Section 7, Market Data.

[20] *Id.*

[21] 15 U.S.C. 78s(b)(3)(A)(iii).

[22] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[23] 17 CFR 240.19b–4(f)(6).

[24] 17 CFR 240.19b–4(f)(6)(iii).

[25] *See* MIAX Sapphire Options Exchange Trading Alert, Regulatory Alert, Technical Alert, dated July 15, 2024, *available at https://www.miaxglobal.com/alert/2024/07/15/miax-sapphire-options-exchange-july-20th-mock-trading-test-plan-preparation; see also* Securities Exchange Act Release No. 100539 (July 15, 2024) (File No. 10–240) (In the Matter of the Application of MIAX Sapphire, LLC for Registration as a National Securities Exchange; Findings, Opinion, and Order of the Commission) (order approving MIAX Sapphire, LLC for registration as a national securities exchange).

[26] *See supra* notes 9, 10, 11, 12 and 19.

delay and designates the proposal operative upon filing.[27]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[28] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–SAPPHIRE–2024–01 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–SAPPHIRE–2024–01. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–SAPPHIRE–2024–01 and should be submitted on or before August 21, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[29]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–16795 Filed 7–30–24; 8:45 am]

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[27] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[28] 15 U.S.C. 78s(b)(2)(B).

[29] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100597; File No. SR–NYSEARCA–2024–61]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 1.1 and Rule 5.2–E(j)(6)

July 25, 2024.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 15, 2024, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to (1) amend Rule 1.1 to include Exchange-Traded Fund Shares in the definition of ''UTP Derivative Securities Product,'' and (2) amend Rule 5.2–E(j)(6) to exclude Exchange-Traded Fund Shares when applying the quantitative generic listing criteria applicable to Equity Index-Linked Securities. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Rule 1.1

The Exchange proposes to amend Rule 1.1, which sets forth definitions of terms used in Exchange rules, including the meanings of ''Derivative Securities Product'' and ''UTP Derivative Securities Product.''

Specifically, the Exchange proposes to amend the definition of ''UTP Derivative Securities Product'' to include Exchange-Traded Fund Shares listed pursuant to NYSE Arca, Inc. (''NYSE Arca'') Rule 5.2–E(j)(8), Exchange-Traded Fund Shares listed pursuant to New York Stock Exchange LLC (''NYSE'') Rule 5.2(j)(8), Exchange-Traded Fund Shares listed pursuant to Cboe BZX Exchange, Inc. (''BZX'') Rule 14.11(l), and Exchange Traded Fund Shares listed pursuant to Nasdaq Stock Market LLC (''Nasdaq'') Rule 5704 as additional types of Exchange Traded Product (''ETPs'') that may trade on the Exchange pursuant to unlisted trading privileges (''UTP'').[4]

[4] Exchange-Traded Fund Shares and Exchange Traded Fund Shares are substantially similar products that generally refer to shares of exchange-traded funds eligible to operate in reliance on Rule 6c–11 under the Investment Company Act of 1940. *See* Securities Exchange Act Release Nos. 88625 (April 13, 2020), 85 FR 21479 (April 17, 2020) (SR–NYSEArca–2019–81) (order approving NYSE Arca Rule 5.2–E(j)(8) governing the listing and trading of Exchange-Traded Fund Shares); 91029 (February 1, 2021), 86 FR 8420 (February 5, 2021) (SR–NYSE–2020–86) (order approving NYSE Rule 5.2(j)(8) governing the listing and trading of Exchange-Traded Fund Shares); 88566 (April 6, 2020), 85 FR 20312 (April 10, 2020) (SR–CboeBZX–2019–097)

Continued

To effect this change, the Exchange proposes to add a bullet point listing ''Exchange-Traded Fund Shares listed pursuant to NYSE Arca, Inc. Rule 5.2–E(j)(8), New York Stock Exchange LLC Rule 5.2(j)(8), or Cboe BZX Exchange, Inc. Rule 14.11(l) and Exchange Traded Fund Shares listed pursuant to Nasdaq Stock Market LLC Rule 5704'' in Rule 1.1 to include them in the enumerated list of Derivative Securities Products that may trade on the Exchange on a UTP basis. The Exchange also proposes non-substantive changes to accommodate the addition of this bullet point as the final item in the bulleted list in Rule 1.1.

The Exchange believes that the proposed change would ensure that the definition of ''UTP Derivative Securities Product'' in Rule 1.1 reflects a complete list of Derivative Securities Products that may trade on the Exchange pursuant to UTP, thereby improving the clarity and transparency of Exchange Rules.

Rule 5.2–E(j)(6)

Rule 5.2–E(j)(6) sets forth criteria applicable to Exchange listing of equity index-linked securities (''Equity Index-Linked Securities''), commodity-linked securities, currency-linked securities, fixed income index-linked securities, futures-linked securities, and multifactor index-linked securities.

As defined in Rule 5.2–E(j)(6)(B)(I)(1), Equity Index-Linked Securities are securities that provide for the payment at maturity (or earlier redemption) based on the performance of an underlying index or indexes of equity securities, securities of closed-end management investment companies registered under the Investment Company Act of 1940,[5] and/or Investment Company Units. In addition to certain other generic listing criteria, Equity Index-Linked Securities must satisfy the generic quantitative initial and continued listing criteria under Rule 5.2–E(j)(6)(B)(I) in order to become, and continue to be, listed and traded on the Exchange. Certain of the applicable quantitative criteria specify minimum or maximum thresholds that must be satisfied with respect to, for example, market value, trading volume, and dollar weight of an index represented by a single component or groups of components.

Currently, Rule 5.2–E(j)(6)(B)(I)(1)(a) provides that each underlying index of an Equity Index-Linked Security is required to have at least ten component securities, provided, however, that there shall be no minimum number of component securities if one or more issues of Derivative Securities Products (*i.e.,* Investment Company Units (as described in Rule 5.2–E(j)(3)) and securities described in Section 2 of Rule 8) or Index-Linked Securities (as described in Rule 5.2–E(j)(6)), constitute, at least in part, component securities underlying an issue of Equity Index-Linked Securities. The Exchange proposes to amend Rule 5.2–E(j)(6)(B)(I)(1)(a) to include Exchange-Traded Fund Shares, as described in Rule 5.2–E(j)(8), in the group of Derivative Securities Products to which the ten component security minimum would not apply. The Exchange also proposes to exclude Derivative Securities Products, consistent with this proposed change to the description of Derivative Securities Products in Rule 5.2–E(j)(6)(B)(I)(1)(a), from consideration when determining whether the applicable quantitative generic thresholds have been satisfied under the initial listing standards specified in Rules 5.2–E(j)(6)(B)(I)(1)(b)(i) through (iv) and the continued listing standards specified in Rules 5.2–E(j)(6)(B)(I)(2)(a)(i) and (ii). Thus, for example, when determining compliance with Rule 5.2–E(j)(6)(B)(I)(1)(b)(ii), component stocks, excluding Derivative Securities Products (which would, as proposed, include Exchange-Traded Fund Shares) or Index-Linked Securities, that in the aggregate account for at least 90% of the remaining index weight, excluding any Derivative Securities Products (including, as proposed, Exchange-Traded Fund Shares) or Index-Linked Securities, would be required to have a minimum global monthly trading volume of 1,000,000 shares, or minimum global notional volume traded per month of $25,000,000, averaged over the last six months.

In addition, Rule 5.2–E(j)(6)(B)(I)(1)(a) currently provides that the securities described in Rule 5.2–E(j)(3), Section 2 of Rule 8, and Rule 5.2–E(j)(6), as referenced in Rule 5.2–E(j)(6)(B)(I)(1)(b)(2) and Rule 5.2–E(j)(6)(B)(I)(2)(a), shall include securities listed on another national securities exchange pursuant to substantially equivalent listing rules. The Exchange proposes to update this list to include a reference to Rule 5.2–E(j)(8), consistent with the proposed change described above. The Exchange also proposes non-substantive changes in two places in Rule 5.2–E(j)(6)(B)(I)(1)(a) to refer to ''Section 2 of Rule 8–E'' (instead of ''Section 2 of Rule 8'') to reflect the current NYSE Arca rule numbering convention. Finally, the Exchange proposes non-substantive changes to delete the extra spaces that appear in the term ''Index-Linked Securities'' in Rules 5.2–E(j)(6)(B)(I)(1)(b)(ii), 5.2–E(j)(6)(B)(I)(2)(a)(i), and 5.2–E(j)(6)(B)(I)(2)(a)(ii).

The Exchange notes that the inclusion of Exchange-Traded Fund Shares in the group of Derivative Securities Products that are excepted from the generic listing and continued listing criteria specified above for Equity Index-Linked Securities would align the Exchange's rules with the listing criteria for Equity Index-Linked Securities on at least one other equity exchange.[6]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Section 6(b)(5) of the Act,[8] in particular, because it is designed to remove impediments to and perfect the mechanism of a free and open market, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest.

The proposed rule change with respect to the definition of ''UTP Derivative Securities Products'' in Rule 1.1 is designed to remove impediments to and perfect the mechanism of a free and open market, promote just and equitable principles of trade, and, in general, to protect investors and the public interest because it modifies Rule

(order approving BZX Rule 14.11(l) governing the listing and trading of Exchange-Traded Fund Shares); 88561 (April 3, 2020), 85 FR 19984 (April 9, 2020) (SR–NASDAQ–2019–090) (order approving Nasdaq Rule 5704 governing the listing and trading of Exchange Traded Fund Shares).

[5] 15 U.S.C. 80–1.

[6] *See, e.g.,* BZX Rule 14.11(d)(2)(K)(i)(a) (describing listing criteria for Equity Index-Linked Securities, including that ''each underlying index is required to have at least ten (10) component securities; provided, however, that there shall be no minimum number of component securities if one or more issues of Derivative Securities Products (which are defined in Rule 14.11(c)(3)(A)(i)(a)). . .constitute, at least in part, component securities underlying an issue of Equity Index-Linked Securities''); BZX Rule 14.11(c)(3)(A)(i)(a) (defining ''Derivative Securities Products'' to include Index Fund Shares, Portfolio Depositary Receipts, Trust Issued Receipts, ETF Shares, and Managed Fund Shares); and BZX 14.11(l) (defining Exchange-Traded Fund Shares or ETF Shares). *Cf.* Nasdaq Rule 5705(b)(3)(A)(i)(a) (describing listing criteria for Index Fund Shares, including that ''Component stocks (excluding ''Derivative Securities Products'' as defined in this subsection a.) that in the aggregate account for at least 90% of the weight of the U.S. Component Stocks portion of the index or portfolio (excluding Derivative Securities Products) each shall have a minimum market value of at least $75 million'' and defining ''Derivative Securities Products'' as including Exchange Traded Fund Shares listed under Nasdaq Rule 5704).

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(4) & (5).

1.1 to state the complete list of Derivative Securities Products that may trade on a UTP basis on the Exchange, providing specificity, clarity, and transparency in the Exchange's rules. Moreover, the proposed rule change would facilitate the trading of additional types of Derivative Securities Products on the Exchange pursuant to UTP, thereby enhancing competition among market participants for the benefit of investors and the marketplace.

The Exchange believes that the proposed change with respect to Rule 5.2–E(j)(6) is designed to remove impediments to and perfect the mechanism of a free and open market, promote just and equitable principles of trade, and, in general, to protect investors and the public interest because including Exchange-Traded Fund Shares as Derivative Securities Products excepted from certain generic listing and continued listing criteria for Equity Index-Linked Securities would facilitate the listing and trading of additional types of Equity Index-Linked Securities. The Exchange further believes the proposed change would remove impediments to and perfect the mechanism of a free and open market and promote competition, to the benefit of investors and the marketplace, because the proposed change would amend the Exchange's rules to be consistent with the listing criteria for Equity Index-Linked Securities on at least one other equity exchange.[9]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change would provide the public and investors with up-to-date information about the types of Derivative Securities Products that can trade on the Exchange on a UTP basis and would promote competition by providing for additional types of Derivative Securities Products that may trade on the Exchange pursuant to UTP. The Exchange also believes that the proposed change would encourage competition by enabling additional types of Equity Index-Linked Securities to be listed on the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Pursuant to Section 19(b)(3)(A) of the Act[10] and Rule 19b–4(f)(6)[11] thereunder, the Exchange has designated this proposal as one that effects a change that: (i) does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) by its terms, does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest.[12]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[13] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The proposed rule change, which adds Exchange-Traded Fund Shares (or Exchange Traded Fund Shares, as the case may be) to the definition of ''UTP Derivative Securities Product'' in NYSE Arca Rule 1.1 and modifies certain listing standards applicable to Equity Index-Linked Securities, conforms to substantially similar rules of other exchanges[14] and raises no unique or novel legal or regulatory issues. Therefore, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.[15]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–NYSEARCA–2024–61 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSEARCA–2024–61. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the

[9] *See* note 6, *supra.*

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6).

[12] In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] *See, e.g.,* BZX Rule 1.5(ee) (incorporating ''Exchange-Traded Fund Shares'' in the definition of UTP Derivative Securities); and BZX Rule 14.11(d)(2)(K)(i)(a) and (b) (setting forth the initial and continued listing standards for Equity Index-Linked Securities).

[15] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSEARCA–2024–61 and should be submitted on or before August 21, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–16804 Filed 7–30–24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100590; File No. SR–NASDAQ–2024–039]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish Fees for Its Expanded Co-Location Services

July 25, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 15, 2024, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to establish fees for its expanded co-location services, as described further below.

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on August 15, 2024.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange filed a proposal to expand its co-location services by offering new cabinet, power, and power distribution unit options in the Exchange's expanded data center.[3] As described in that filing, the Exchange's current data center (''NY11'') in Carteret, NJ is undergoing an expansion (''NY11–4'') in response to demand for power and cabinets. The purpose of this proposed rule change is to establish fees for the expanded co-location services. Specifically, the Exchange proposes to establish (i) a monthly fee for Ultra High Density Cabinets, (ii) an installation fee for cabinets in NY11–4, (iii) fees for power installation in NY11–4, and (iv) fees for power distribution unit options in NY11–4.

Ultra High Density Cabinet

Currently, co-location customers have the option of obtaining cabinets of various sizes and power densities. Co-location customers may obtain a Half Cabinet,[4] a Low Density Cabinet with power density less than or equal to 2.88 kilowatts (''kW''), a Medium Density Cabinet with power density greater than 2.88 kW and less than or equal to 5 kW, a Medium-High Density Cabinet with power density greater than 5 kW and less than or equal to 7 kW, a High Density Cabinet with power density greater than 7 kW and less than 10 kW, and a Super High Density Cabinet with power density greater than 10 kW and less than or equal to 17.3 kW.

The Exchange filed a proposal to introduce a new cabinet choice in NY11–4, an ''Ultra High Density Cabinet,'' with power density greater than 10 kW and less than or equal to 15 kW.[5] The Ultra High Density Cabinet option will only be offered in NY11–4 because of the power configuration necessary for such cabinets, which is not possible or available in other portions of the data center due to different power distribution.[6] In addition to the Ultra High Density Cabinet, the Exchange will offer the other, existing cabinet options in NY11–4, with the exception of the Low Density Cabinet and Half Cabinet due to a lack of demand for such cabinets. The ongoing monthly fees for the Super High Density Cabinet, High Density Cabinet, Medium-High Density Cabinet, and Medium Density Cabinet are the same in NY11 and NY11–4 and the Exchange is not proposing to modify such fees.

The Exchange proposes to establish an ongoing monthly fee of $7,230 for the Ultra High Density Cabinets. To effectuate this change, the Exchange proposes to add the $7,230 ongoing monthly fee for Ultra High Density Cabinets to its fee schedule in General 8, Section 1(a). The Exchange notes that the proposed fee amount falls between the $4,748 ongoing monthly fee charged for High Density Cabinets and the $8,440 ongoing monthly fee charged for Super High Density Cabinets. Furthermore, the proposed fee is consistent with the existing ongoing monthly cabinet fees on a per kW basis. The existing monthly cabinet fees range from approximately $475 per kW to $916 per kW, while the proposed ongoing monthly cabinet fee for the Ultra High Density Cabinet ranges from approximately $482 per kW (at the high end of the power density range for Ultra High Density Cabinets) to $723 per kW (at the low end of the power density range for Ultra High Density Cabinets).

Installation Fee for Cabinets in NY11–4

The Exchange proposes to establish a cabinet installation fee of $5,940 for all cabinets in NY11–4. To effectuate this change, the Exchange proposes to add the proposed $5,940 installation fee to its fee schedule in General 8, Section 1(a) for Super High Density Cabinets, Ultra High Density Cabinets, High Density Cabinets, Medium-High Density Cabinets, and Medium Density Cabinets in NY11–4. In the existing data halls, customers may bring their own cabinets or use Exchange-provided cabinets. In NY11–4, because of the cooling system

[16] 17 CFR 200.30–3(a)(12), (59).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 34–100440 (June 27, 2024), 89 FR 55294 (July 3, 2024) (SR–NASDAQ–2024–026).

[4] Half cabinets are not available to new subscribers. *See* General 8, Section 1(a).

[5] *Supra* note 3.

[6] Because of the addition of the Ultra High Density Cabinet option in NY11–4, the Super High Density Cabinet in NY11–4 will have power density greater than 15 kW and less than or equal to 17.3 kW.

(hot aisle containment),[7] all cabinets must be uniform and therefore, the Exchange will provide all cabinets, the cost of which is included in the $5,940 installation fee.[8] The cabinets in NY11–4 include certain features not included in cabinets provided by the Exchange in the existing data halls. Specifically, the cabinets in NY11–4 include uniform, wider cabinets (32″ W x 48″ D x 91″ H), cable management, and a rear split door and combo lock. In addition, the proposed installation fee of $5,940 is comparable to fees charged for similar products.[9]

Installation Fee for Cabinet Power in NY11–4

The cabinet power options for NY11–4 include: Phase 1 20 amp 240 volt, Phase 1 32 amp 240 volt, Phase 1 40 amp 240 volt, Phase 3 20 amp 415 volt, and Phase 3 32 amp 415 volt. These cabinet power options are specific to NY11–4 and one of these options must be selected for cabinets in NY11–4. The Exchange proposes to establish an installation fee of $3,600 for Phase 1 cabinet power options in NY11–4 and an installation fee of $4,560 for Phase 3 cabinet power options in NY11–4. To effectuate this change, the Exchange proposes to add the proposed fees to its fee schedule in General 8, Section 1(c). The Exchange also proposes not to charge an ongoing monthly fee for the cabinet power options in NY11–4 and update the fee schedule accordingly. For NY11–4, the data center operator is bringing in these higher voltage power options and is likely to experience increased power distribution efficiencies across the data center. The proposed power installation fees are higher in NY11–4 as compared to the existing data halls as the installation of the higher voltage power options costs more to the Exchange and is considered a premium product due to anticipated operational efficiencies.[10] As between the Phase 1 and Phase 3 power options, the Phase 3 options provide a more efficient power source.

Fees for Power Distribution Unit Options

The Exchange will offer power distribution units (''PDUs'')[11] in NY11–4 as a convenience to customers. Rather than sourcing PDUs on a customer-by-customer basis, as the Exchange does for customers in NY11, the Exchange will offer Phase 1 and Phase 3[12] power distribution units in NY11–4. The Exchange proposes to establish a fee of $4,100 for a Phase 1 PDU and $5,260 for a Phase 3 PDU. This service is optional and customers may choose to provide their own PDUs appropriate for their power installation choices. The Exchange notes that, as part of such proposed fees, the Exchange would provide a primary and redundant PDU. As such, the proposed PDU fees covers a pair of PDUs. In addition, customers utilizing a Phase 1 or Phase 3 PDU provided by the Exchange have the ability to upgrade or downgrade between amperage levels without replacing the PDU, by a simple upgrade of the facility cord and a receptacle update.[13] A PDU replacement is required when switching between phases/voltage.

The Exchange will also offer a switch monitored PDU add on in NY11–4, which would allow customers to connect remotely to their PDU and control the power sockets. With the switch monitored PDU option, customers would be able to power cycle or shut off power remotely. The Exchange proposes to establish a $2,000 fee for the switch monitored PDU option. This option is optional as well and customers may choose to provide their own switch monitored PDU, if desired.

Implementation

Although the timing is subject to change,[14] the Exchange anticipates opening NY11–4 Exchange access on October 21, 2024 and providing customers access in advance of this date. The proposed fees are designated to be operative on August 15, 2024. However, customer orders will not be fee liable until customers are provided access to the space.[15]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[16] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[17] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposal to establish a monthly fee for Ultra High Density Cabinets, an installation fee for cabinets in NY11–4, installation fees for power installation in NY11–4, and fees for power distribution unit options in NY11–4 is reasonable. First, the Exchange's proposal to establish a $7,230 ongoing monthly fee for Ultra High Density Cabinets in NY11–4 is reasonable because it is comparable to the Exchange's current ongoing monthly fees for cabinets. The proposed fee amount falls between the $4,748 ongoing monthly fee charged for High Density Cabinets and the $8,440 ongoing monthly fee charged for Super High Density Cabinets. Furthermore, the proposed fee is consistent with the existing ongoing monthly cabinet fees on a per kW basis. The existing monthly cabinet fees range from approximately $475 per kW to $916 per kW, while the proposed ongoing monthly cabinet fee for the Ultra High Density Cabinet ranges from approximately $482 per kW (at the high end of the power density range for Ultra High Density Cabinets) to $723 per kW (at the low end of the power density range for Ultra High Density Cabinets). Second, the Exchange believes that the proposed cabinet installation fee of $5,940 is reasonable as compared to the installation fees in NY11 (of $3,693–$4,748) because the proposed installation fee includes the cabinet itself, which includes certain enhanced features in NY11–4, including uniform, wider cabinets (32′ W x 48′ D x 91′ H), cable management, and a rear split door and combo lock. In contrast,

[7] The existing data halls utilize cold aisle containment to manage temperatures. Hot aisle containment is a more effective way to manage heat in the data center.

[8] In contrast, to the extent customers provide their own cabinets in NY11, there is an additional out-of-pocket cost for such cabinets.

[9] For example, NYSE charges an initial $5,000 fee for dedicated cabinets. *See https://www.nyse.com/publicdocs/Wireless_Connectivity_Fees_and_Charges.pdf.*

[10] Benefits include future proofing the data hall to allow for increasing power density in the future, requiring less whips to deliver the same amount of amperage, less circuits need to be installed to reach the same power supply, and safety improvements.

[11] PDUs are devices fitted with multiple outputs designed to distribute electric power. The standardized PDUs would only be offered for NY11–4.

[12] Phase 1 PDUs are compatible with the following power options: Phase 1 20 amp 240 volt, Phase 1 32 amp 240 volt, and Phase 1 40 amp 240 volt. Phase 3 PDUs are compatible with the following power options: Phase 3 20 amp 415 volt and Phase 3 32 amp 415 volt. Phase 1 and Phase 3 are available in NY11 and NY11–4. Phase 3 PDUs provide greater power density than Phase 1 PDUs by delivering power over three wires as opposed to one wire.

[13] This functionality may be available with customer-provided PDUs as well and depends on the PDU provided by the customer.

[14] The Exchange will announce modifications to the proposed timing via the Nasdaq Customer Portal, which is the web portal used for order and inventory management of colocation services, and email communication to all colocation customers.

[15] Charging customers once access is provided is consistent with current practice and allows customers to set up equipment and begin using power.

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(4) and (5).

in NY11, customers may choose to provide their own cabinets, incurring an additional cost. Furthermore, the proposed installation fee is comparable to the rate charged by NYSE for a similar product, as described above. Third, the Exchange believes that the power installation fees of $3,600 for Phase 1 power options and $4,560 for Phase 3 power options in NY11–4 are reasonable. As compared to power installation fees in NY11, the proposed rates for NY11–4 are higher because the Exchange will incur increased costs for installation of the higher voltage power options. In addition, the higher voltage power options will provide operational efficiencies for the data hall, as discussed above,[18] warranting a higher fee. Finally, the Exchange believes that the proposed fees for PDUs and the PDU add on are reasonable because such fees are consistent with market rates. Furthermore, the Exchange is providing the PDU options as a convenience to customers. No customer is required to purchase any PDU options from the Exchange. Customers may choose to provide their own PDUs and PDU add ons.

The Exchange believes substitutable products and services are available to market participants, including, among other things, other equities and options exchanges that a market participant may connect to in lieu of the Exchange,[19] connectivity to the Exchange via a third-party reseller of connectivity, and/or trading of equities or options products within markets which do not require connectivity to the Exchange, such as the Over-the-Counter (OTC) markets. Market participants that wish to connect to the Exchange will continue to choose the method of connectivity based on their specific needs. Market participants that wish to connect to the Exchange but want to avoid or mitigate the effect of these proposed fees can choose to connect to the Exchange through a vendor.

In summary, the proposal represents an equitable allocation of reasonable dues, fees and other charges because customers have choices in how they connect to the Exchange, the proposed monthly fee for Ultra High Density Cabinets is comparable to current fees charged by the Exchange for other cabinets, the Exchange will provide uniform cabinets in NY11–4 with special features, the proposed cabinet installation fee is consistent with that of comparable products offered by other providers, the Exchange will incur increased costs for new power installation in NY11–4, higher voltage power options will provide operational efficiencies for the data hall, and PDU options are provided as a convenience to customers and customers may choose to provide their own PDUs.

The Exchange believes that the proposed fee changes are not unfairly discriminatory because the cabinet, power, and PDU fees for NY11–4 are available to and assessed uniformly across all market participants. In addition, all customers have the choice of whether and how to connect to the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal burdens inter-market competition because approval of the proposal does not impose any burden on the ability of other exchanges to compete. The Exchange operates in a highly competitive market in which market participants can determine whether or not to connect to the Exchange based on the value received compared to the cost of doing so. Indeed, market participants have numerous alternative exchanges that they may participate on and direct their order flow, as well as off-exchange venues, where competitive products are available for trading.

Nothing in the proposal burdens intra-market competition because the Ultra High Density Cabinets, cabinet power options, and PDU optionality in NY11–4 are available to any customer under the same fees as any other customer, and any customer that wishes to order cabinets, power and PDUs in NY11–4 can do so on a non-discriminatory basis.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[20]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–NASDAQ–2024–039 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NASDAQ–2024–039. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than

[18] *Supra* note 10.

[19] There are currently 16 registered equities exchanges that trade equities and 17 exchanges offering options trading services. No single equities exchange has more than 20% of the market share. *See* Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (Last updated July 3, 2024), available at *https://www.cboe.com/us/equities/market_statistics/*. No single options exchange trades more than 15% of the options market by volume and only one of the 17 options exchanges has a market share over 10 percent. *See* Nasdaq, Options Market Statistics (Last updated July 3, 2024), available at *https://www.nasdaqtrader.com/Trader.aspx?id=OptionsVolumeSummary*. This broad dispersion of market share demonstrates that market participants can and do exercise choice in trading venues. Further, low barriers to entry mean that new exchanges may rapidly enter the market and offer additional substitute platforms to further compete with the Exchange and the products it offers.

[20] 15 U.S.C. 78s(b)(3)(A)(ii).

those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NASDAQ–2024–039 and should be submitted on or before August 21, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–16797 Filed 7–30–24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100593; File No. SR–MRX–2024–24]

Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish Fees for Its Expanded Co-Location Services

July 25, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 15, 2024, Nasdaq MRX, LLC (''MRX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to establish fees for its expanded co-location services, as described further below.

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on August 15, 2024.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/mrx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange filed a proposal to expand its co-location services by offering new cabinet, power, and power distribution unit options in the Exchange's expanded data center.[3] As described in that filing, the Exchange's current data center (''NY11'') in Carteret, NJ is undergoing an expansion (''NY11–4'') in response to demand for power and cabinets. The purpose of this proposed rule change is to establish fees for the expanded co-location services. Specifically, the Exchange proposes to establish (i) a monthly fee for Ultra High Density Cabinets, (ii) an installation fee for cabinets in NY11–4, (iii) fees for power installation in NY11–4, and (iv) fees for power distribution unit options in NY11–4.

Ultra High Density Cabinet

Currently, co-location customers have the option of obtaining cabinets of various sizes and power densities. Co-location customers may obtain a Half Cabinet,[4] a Low Density Cabinet with power density less than or equal to 2.88 kilowatts (''kW''), a Medium Density Cabinet with power density greater than 2.88 kW and less than or equal to 5 kW, a Medium-High Density Cabinet with power density greater than 5 kW and less than or equal to 7 kW, a High Density Cabinet with power density greater than 7 kW and less than 10 kW, and a Super High Density Cabinet with power density greater than 10 kW and less than or equal to 17.3 kW.

The Exchange filed a proposal to introduce a new cabinet choice in NY11–4, an ''Ultra High Density Cabinet,'' with power density greater than 10 kW and less than or equal to 15 kW.[5] The Ultra High Density Cabinet option will only be offered in NY11–4 because of the power configuration necessary for such cabinets, which is not possible or available in other portions of the data center due to different power distribution.[6] In addition to the Ultra High Density Cabinet, the Exchange will offer the other, existing cabinet options in NY11–4, with the exception of the Low Density Cabinet and Half Cabinet due to a lack of demand for such cabinets. The ongoing monthly fees for the Super High Density Cabinet, High Density Cabinet, Medium-High Density Cabinet, and Medium Density Cabinet are the same in NY11 and NY11–4 and the Exchange is not proposing to modify such fees.

The Exchange proposes to establish an ongoing monthly fee of $7,230 for the Ultra High Density Cabinets. To effectuate this change, the Exchange proposes to add the $7,230 ongoing monthly fee for Ultra High Density Cabinets to its fee schedule in General 8, Section 1(a). The Exchange notes that the proposed fee amount falls between the $4,748 ongoing monthly fee charged for High Density Cabinets and the $8,440 ongoing monthly fee charged for Super High Density Cabinets. Furthermore, the proposed fee is consistent with the existing ongoing monthly cabinet fees on a per kW basis. The existing monthly cabinet fees range from approximately $475 per kW to $916 per kW, while the proposed ongoing monthly cabinet fee for the Ultra High Density Cabinet ranges from approximately $482 per kW (at the high end of the power density range for Ultra High Density Cabinets) to $723 per kW (at the low end of the power density range for Ultra High Density Cabinets).

Installation Fee for Cabinets in NY11–4

The Exchange proposes to establish a cabinet installation fee of $5,940 for all cabinets in NY11–4. To effectuate this change, the Exchange proposes to add the proposed $5,940 installation fee to

[21] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* SR–MRX–2024–23 (not yet published).

[4] Half cabinets are not available to new subscribers. *See* General 8, Section 1(a).

[5] *Supra* note 3.

[6] Because of the addition of the Ultra High Density Cabinet option in NY11–4, the Super High Density Cabinet in NY11–4 will have power density greater than 15 kW and less than or equal to 17.3 kW.

its fee schedule in General 8, Section 1(a) for Super High Density Cabinets, Ultra High Density Cabinets, High Density Cabinets, Medium-High Density Cabinets, and Medium Density Cabinets in NY11–4. In the existing data halls, customers may bring their own cabinets or use Exchange-provided cabinets. In NY11–4, because of the cooling system (hot aisle containment),[7] all cabinets must be uniform and therefore, the Exchange will provide all cabinets, the cost of which is included in the $5,940 installation fee.[8] The cabinets in NY11–4 include certain features not included in cabinets provided by the Exchange in the existing data halls. Specifically, the cabinets in NY11–4 include uniform, wider cabinets (32″ W x 48″ D x 91″ H), cable management, and a rear split door and combo lock. In addition, the proposed installation fee of $5,940 is comparable to fees charged for similar products.[9]

Installation Fee for Cabinet Power in NY11–4

The cabinet power options for NY11–4 include: Phase 1 20 amp 240 volt, Phase 1 32 amp 240 volt, Phase 1 40 amp 240 volt, Phase 3 20 amp 415 volt, and Phase 3 32 amp 415 volt. These cabinet power options are specific to NY11–4 and one of these options must be selected for cabinets in NY11–4. The Exchange proposes to establish an installation fee of $3,600 for Phase 1 cabinet power options in NY11–4 and an installation fee of $4,560 for Phase 3 cabinet power options in NY11–4. To effectuate this change, the Exchange proposes to add the proposed fees to its fee schedule in General 8, Section 1(c). The Exchange also proposes not to charge an ongoing monthly fee for the cabinet power options in NY11–4 and update the fee schedule accordingly. For NY11–4, the data center operator is bringing in these higher voltage power options and is likely to experience increased power distribution efficiencies across the data center. The proposed power installation fees are higher in NY11–4 as compared to the existing data halls as the installation of the higher voltage power options costs more to the Exchange and is considered a premium product due to anticipated operational efficiencies.[10] As between the Phase 1 and Phase 3 power options, the Phase 3 options provide a more efficient power source.

Fees for Power Distribution Unit Options

The Exchange will offer power distribution units (''PDUs'')[11] in NY11–4 as a convenience to customers. Rather than sourcing PDUs on a customer-by-customer basis, as the Exchange does for customers in NY11, the Exchange will offer Phase 1 and Phase 3[12] power distribution units in NY11–4. The Exchange proposes to establish a fee of $4,100 for a Phase 1 PDU and $5,260 for a Phase 3 PDU. This service is optional and customers may choose to provide their own PDUs appropriate for their power installation choices. The Exchange notes that, as part of such proposed fees, the Exchange would provide a primary and redundant PDU. As such, the proposed PDU fees covers a pair of PDUs. In addition, customers utilizing a Phase 1 or Phase 3 PDU provided by the Exchange have the ability to upgrade or downgrade between amperage levels without replacing the PDU, by a simple upgrade of the facility cord and a receptacle update.[13] A PDU replacement is required when switching between phases/voltage.

The Exchange will also offer a switch monitored PDU add on in NY11–4, which would allow customers to connect remotely to their PDU and control the power sockets. With the switch monitored PDU option, customers would be able to power cycle or shut off power remotely. The Exchange proposes to establish a $2,000 fee for the switch monitored PDU option. This option is optional as well and customers may choose to provide their own switch monitored PDU, if desired.

Implementation

Although the timing is subject to change,[14] the Exchange anticipates opening NY11–4 Exchange access on October 21, 2024 and providing customers access in advance of this date. The proposed fees are designated to be operative on August 15, 2024. However, customer orders will not be fee liable until customers are provided access to the space.[15]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[16] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[17] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposal to establish a monthly fee for Ultra High Density Cabinets, an installation fee for cabinets in NY11–4, installation fees for power installation in NY11–4, and fees for power distribution unit options in NY11–4 is reasonable. First, the Exchange's proposal to establish a $7,230 ongoing monthly fee for Ultra High Density Cabinets in NY11–4 is reasonable because it is comparable to the Exchange's current ongoing monthly fees for cabinets. The proposed fee amount falls between the $4,748 ongoing monthly fee charged for High Density Cabinets and the $8,440 ongoing monthly fee charged for Super High Density Cabinets. Furthermore, the proposed fee is consistent with the existing ongoing monthly cabinet fees on a per kW basis. The existing monthly cabinet fees range from approximately $475 per kW to $916 per kW, while the proposed ongoing monthly cabinet fee for the Ultra High Density Cabinet ranges from approximately $482 per kW (at the high end of the power density range for Ultra High Density Cabinets) to $723 per kW (at the low end of the power density range for Ultra High Density Cabinets). Second, the Exchange believes that the proposed cabinet

[7] The existing data halls utilize cold aisle containment to manage temperatures. Hot aisle containment is a more effective way to manage heat in the data center.

[8] In contrast, to the extent customers provide their own cabinets in NY11, there is an additional out-of-pocket cost for such cabinets.

[9] For example, NYSE charges an initial $5,000 fee for dedicated cabinets. *See https://www.nyse.com/publicdocs/Wireless_Connectivity_Fees_and_Charges.pdf.*

[10] Benefits include future proofing the data hall to allow for increasing power density in the future, requiring less whips to deliver the same amount of amperage, less circuits need to be installed to reach the same power supply, and safety improvements.

[11] PDUs are devices fitted with multiple outputs designed to distribute electric power. The standardized PDUs would only be offered for NY11–4.

[12] Phase 1 PDUs are compatible with the following power options: Phase 1 20 amp 240 volt, Phase 1 32 amp 240 volt, and Phase 1 40 amp 240 volt. Phase 3 PDUs are compatible with the following power options: Phase 3 20 amp 415 volt and Phase 3 32 amp 415 volt. Phase 1 and Phase 3 are available in NY11 and NY11–4. Phase 3 PDUs provide greater power density than Phase 1 PDUs by delivering power over three wires as opposed to one wire.

[13] This functionality may be available with customer-provided PDUs as well and depends on the PDU provided by the customer.

[14] The Exchange will announce modifications to the proposed timing via the Nasdaq Customer Portal, which is the web portal used for order and inventory management of colocation services, and email communication to all colocation customers.

[15] Charging customers once access is provided is consistent with current practice and allows customers to set up equipment and begin using power.

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(4) and (5).

installation fee of $5,940 is reasonable as compared to the installation fees in NY11 (of $3,693–$4,748) because the proposed installation fee includes the cabinet itself, which includes certain enhanced features in NY11–4, including uniform, wider cabinets (32″ W x 48″ D x 91″ H), cable management, and a rear split door and combo lock. In contrast, in NY11, customers may choose to provide their own cabinets, incurring an additional cost. Furthermore, the proposed installation fee is comparable to the rate charged by NYSE for a similar product, as described above. Third, the Exchange believes that the power installation fees of $3,600 for Phase 1 power options and $4,560 for Phase 3 power options in NY11–4 are reasonable. As compared to power installation fees in NY11, the proposed rates for NY11–4 are higher because the Exchange will incur increased costs for installation of the higher voltage power options. In addition, the higher voltage power options will provide operational efficiencies for the data hall, as discussed above,[18] warranting a higher fee. Finally, the Exchange believes that the proposed fees for PDUs and the PDU add on are reasonable because such fees are consistent with market rates. Furthermore, the Exchange is providing the PDU options as a convenience to customers. No customer is required to purchase any PDU options from the Exchange. Customers may choose to provide their own PDUs and PDU add ons.

The Exchange believes substitutable products and services are available to market participants, including, among other things, other options exchanges that a market participant may connect to in lieu of the Exchange,[19] connectivity to the Exchange via a third-party reseller of connectivity, and/or trading of options products within markets which do not require connectivity to the Exchange, such as the Over-the-Counter (OTC) markets. Market participants that wish to connect to the Exchange will continue to choose the method of connectivity based on their specific needs. Market participants that wish to connect to the Exchange but want to avoid or mitigate the effect of these proposed fees can choose to connect to the Exchange through a vendor.

In summary, the proposal represents an equitable allocation of reasonable dues, fees and other charges because customers have choices in how they connect to the Exchange, the proposed monthly fee for Ultra High Density Cabinets is comparable to current fees charged by the Exchange for other cabinets, the Exchange will provide uniform cabinets in NY11–4 with special features, the proposed cabinet installation fee is consistent with that of comparable products offered by other providers, the Exchange will incur increased costs for new power installation in NY11–4, higher voltage power options will provide operational efficiencies for the data hall, and PDU options are provided as a convenience to customers and customers may choose to provide their own PDUs.

The Exchange believes that the proposed fee changes are not unfairly discriminatory because the cabinet, power, and PDU fees for NY11–4 are available to and assessed uniformly across all market participants. In addition, all customers have the choice of whether and how to connect to the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal burdens inter-market competition because approval of the proposal does not impose any burden on the ability of other exchanges to compete. The Exchange operates in a highly competitive market in which market participants can determine whether or not to connect to the Exchange based on the value received compared to the cost of doing so. Indeed, market participants have numerous alternative exchanges that they may participate on and direct their order flow, as well as off-exchange venues, where competitive products are available for trading.

Nothing in the proposal burdens intra-market competition because the Ultra High Density Cabinets, cabinet power options, and PDU optionality in NY11–4 are available to any customer under the same fees as any other customer, and any customer that wishes to order cabinets, power and PDUs in NY11–4 can do so on a non-discriminatory basis.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[20] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–MRX–2024–24 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–MRX–2024–24. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than

[18] *Supra* note 10.

[19] There are currently 17 exchanges offering options trading services. No single options exchange trades more than 15% of the options market by volume and only one of the 17 options exchanges has a market share over 10 percent. *See* Nasdaq, Options Market Statistics (Last updated July 3, 2024), available at *https://www.nasdaqtrader.com/Trader.aspx?id=OptionsVolumeSummary*. This broad dispersion of market share demonstrates that market participants can and do exercise choice in trading venues. Further, low barriers to entry mean that new exchanges may rapidly enter the market and offer additional substitute platforms to further compete with the Exchange and the products it offers.

[20] 15 U.S.C. 78s(b)(3)(A)(ii).

those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–MRX–2024–24 and should be submitted on or before August 21, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–16800 Filed 7–30–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100591; File No. SR–BX–2024–027]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish Fees for Its Expanded Co-Location Services

July 25, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 23, 2024, Nasdaq BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to establish fees for its expanded co-location services, as described further below.

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on August 15, 2024.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/bx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose [3]

The Exchange filed a proposal to expand its co-location services by offering new cabinet, power, and power distribution unit options in the Exchange's expanded data center.[4] As described in that filing, the Exchange's current data center (''NY11'') in Carteret, NJ is undergoing an expansion (''NY11–4'') in response to demand for power and cabinets. The purpose of this proposed rule change is to establish fees for the expanded co-location services. Specifically, the Exchange proposes to establish (i) a monthly fee for Ultra High Density Cabinets, (ii) an installation fee for cabinets in NY11–4, (iii) fees for power installation in NY11–4, and (iv) fees for power distribution unit options in NY11–4.

Ultra High Density Cabinet

Currently, co-location customers have the option of obtaining cabinets of various sizes and power densities. Co-location customers may obtain a Half Cabinet,[5] a Low Density Cabinet with power density less than or equal to 2.88 kilowatts (''kW''), a Medium Density Cabinet with power density greater than 2.88 kW and less than or equal to 5 kW, a Medium-High Density Cabinet with power density greater than 5 kW and less than or equal to 7 kW, a High Density Cabinet with power density greater than 7 kW and less than 10 kW, and a Super High Density Cabinet with power density greater than 10 kW and less than or equal to 17.3 kW.

The Exchange filed a proposal to introduce a new cabinet choice in NY11–4, an ''Ultra High Density Cabinet,'' with power density greater than 10 kW and less than or equal to 15 kW.[6] The Ultra High Density Cabinet option will only be offered in NY11–4 because of the power configuration necessary for such cabinets, which is not possible or available in other portions of the data center due to different power distribution.[7] In addition to the Ultra High Density Cabinet, the Exchange will offer the other, existing cabinet options in NY11–4, with the exception of the Low Density Cabinet and Half Cabinet due to a lack of demand for such cabinets. The ongoing monthly fees for the Super High Density Cabinet, High Density Cabinet, Medium-High Density Cabinet, and Medium Density Cabinet are the same in NY11 and NY11–4 and the Exchange is not proposing to modify such fees.

The Exchange proposes to establish an ongoing monthly fee of $7,230 for the Ultra High Density Cabinets. To effectuate this change, the Exchange proposes to add the $7,230 ongoing monthly fee for Ultra High Density Cabinets to its fee schedule in General 8, Section 1(a). The Exchange notes that the proposed fee amount falls between the $4,748 ongoing monthly fee charged for High Density Cabinets and the $8,440 ongoing monthly fee charged for Super High Density Cabinets. Furthermore, the proposed fee is consistent with the existing ongoing monthly cabinet fees on a per kW basis. The existing monthly cabinet fees range from approximately $475 per kW to $916 per kW, while the proposed ongoing monthly cabinet fee for the Ultra High Density Cabinet ranges from approximately $482 per kW (at the high end of the power density range for Ultra High Density Cabinets) to $723 per kW (at the low end of the power density range for Ultra High Density Cabinets).

[21] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange initially filed the proposed pricing change on July 15, 2024 (SR–BX–2024–025). The instant filing replaces SR–BX–2024–025, which was withdrawn on July 23, 2024.

[4] *See* Securities Exchange Act Release No. 34–100558 (July 18, 2024) (SR–BX–2024–024) (not yet published).

[5] Half cabinets are not available to new subscribers. *See* General 8, Section 1(a).

[6] *Supra* note 4.

[7] Because of the addition of the Ultra High Density Cabinet option in NY11–4, the Super High Density Cabinet in NY11–4 will have power density greater than 15 kW and less than or equal to 17.3 kW.

Installation Fee for Cabinets in NY11–4

The Exchange proposes to establish a cabinet installation fee of $5,940 for all cabinets in NY11–4. To effectuate this change, the Exchange proposes to add the proposed $5,940 installation fee to its fee schedule in General 8, Section 1(a) for Super High Density Cabinets, Ultra High Density Cabinets, High Density Cabinets, Medium-High Density Cabinets, and Medium Density Cabinets in NY11–4. In the existing data halls, customers may bring their own cabinets or use Exchange-provided cabinets. In NY11–4, because of the cooling system (hot aisle containment),[8] all cabinets must be uniform and therefore, the Exchange will provide all cabinets, the cost of which is included in the $5,940 installation fee.[9] The cabinets in NY11–4 include certain features not included in cabinets provided by the Exchange in the existing data halls. Specifically, the cabinets in NY11–4 include uniform, wider cabinets (32″ W x 48″ D x 91″ H), cable management, and a rear split door and combo lock. In addition, the proposed installation fee of $5,940 is comparable to fees charged for similar products.[10]

Installation Fee for Cabinet Power in NY11–4

The cabinet power options for NY11–4 include: Phase 1 20 amp 240 volt, Phase 1 32 amp 240 volt, Phase 1 40 amp 240 volt, Phase 3 20 amp 415 volt, and Phase 3 32 amp 415 volt. These cabinet power options are specific to NY11–4 and one of these options must be selected for cabinets in NY11–4. The Exchange proposes to establish an installation fee of $3,600 for Phase 1 cabinet power options in NY11–4 and an installation fee of $4,560 for Phase 3 cabinet power options in NY11–4. To effectuate this change, the Exchange proposes to add the proposed fees to its fee schedule in General 8, Section 1(c). The Exchange also proposes not to charge an ongoing monthly fee for the cabinet power options in NY11–4 and update the fee schedule accordingly. For NY11–4, the data center operator is bringing in these higher voltage power options and is likely to experience increased power distribution efficiencies across the data center. The proposed power installation fees are higher in NY11–4 as compared to the existing data halls as the installation of the higher voltage power options costs more to the Exchange and is considered a premium product due to anticipated operational efficiencies.[11] As between the Phase 1 and Phase 3 power options, the Phase 3 options provide a more efficient power source.

Fees for Power Distribution Unit Options

The Exchange will offer power distribution units (''PDUs'')[12] in NY11–4 as a convenience to customers. Rather than sourcing PDUs on a customer-by-customer basis, as the Exchange does for customers in NY11, the Exchange will offer Phase 1 and Phase 3[13] power distribution units in NY11–4. The Exchange proposes to establish a fee of $4,100 for a Phase 1 PDU and $5,260 for a Phase 3 PDU. This service is optional and customers may choose to provide their own PDUs appropriate for their power installation choices. The Exchange notes that, as part of such proposed fees, the Exchange would provide a primary and redundant PDU. As such, the proposed PDU fees covers a pair of PDUs. In addition, customers utilizing a Phase 1 or Phase 3 PDU provided by the Exchange have the ability to upgrade or downgrade between amperage levels without replacing the PDU, by a simple upgrade of the facility cord and a receptacle update.[14] A PDU replacement is required when switching between phases/voltage.

The Exchange will also offer a switch monitored PDU add on in NY11–4, which would allow customers to connect remotely to their PDU and control the power sockets. With the switch monitored PDU option, customers would be able to power cycle or shut off power remotely. The Exchange proposes to establish a $2,000 fee for the switch monitored PDU option. This option is optional as well and customers may choose to provide their own switch monitored PDU, if desired.

Implementation

Although the timing is subject to change,[15] the Exchange anticipates opening NY11–4 Exchange access on October 21, 2024 and providing customers access in advance of this date. The proposed fees are designated to be operative on August 15, 2024. However, customer orders will not be fee liable until customers are provided access to the space.[16]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[17] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[18] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposal to establish a monthly fee for Ultra High Density Cabinets, an installation fee for cabinets in NY11–4, installation fees for power installation in NY11–4, and fees for power distribution unit options in NY11–4 is reasonable. First, the Exchange's proposal to establish a $7,230 ongoing monthly fee for Ultra High Density Cabinets in NY11–4 is reasonable because it is comparable to the Exchange's current ongoing monthly fees for cabinets. The proposed fee amount falls between the $4,748 ongoing monthly fee charged for High Density Cabinets and the $8,440 ongoing monthly fee charged for Super High Density Cabinets. Furthermore, the proposed fee is consistent with the existing ongoing monthly cabinet fees on a per kW basis. The existing monthly cabinet fees range from approximately $475 per kW to $916 per kW, while the proposed ongoing monthly cabinet fee for the Ultra High Density Cabinet ranges from approximately $482 per kW (at the high end of the power density

[8] The existing data halls utilize cold aisle containment to manage temperatures. Hot aisle containment is a more effective way to manage heat in the data center.

[9] In contrast, to the extent customers provide their own cabinets in NY11, there is an additional out-of-pocket cost for such cabinets.

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range for Ultra High Density Cabinets) to $723 per kW (at the low end of the power density range for Ultra High Density Cabinets). Second, the Exchange believes that the proposed cabinet installation fee of $5,940 is reasonable as compared to the installation fees in NY11 (of $3,693–$4,748) because the proposed installation fee includes the cabinet itself, which includes certain enhanced features in NY11–4, including uniform, wider cabinets (32″ W x 48″ D x 91″ H), cable management, and a rear split door and combo lock. In contrast, in NY11, customers may choose to provide their own cabinets, incurring an additional cost. Furthermore, the proposed installation fee is comparable to the rate charged by NYSE for a similar product, as described above. Third, the Exchange believes that the power installation fees of $3,600 for Phase 1 power options and $4,560 for Phase 3 power options in NY11–4 are reasonable. As compared to power installation fees in NY11, the proposed rates for NY11–4 are higher because the Exchange will incur increased costs for installation of the higher voltage power options. In addition, the higher voltage power options will provide operational efficiencies for the data hall, as discussed above,[19] warranting a higher fee. Finally, the Exchange believes that the proposed fees for PDUs and the PDU add on are reasonable because such fees are consistent with market rates. Furthermore, the Exchange is providing the PDU options as a convenience to customers. No customer is required to purchase any PDU options from the Exchange. Customers may choose to provide their own PDUs and PDU add ons.

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In summary, the proposal represents an equitable allocation of reasonable dues, fees and other charges because customers have choices in how they connect to the Exchange, the proposed monthly fee for Ultra High Density Cabinets is comparable to current fees charged by the Exchange for other cabinets, the Exchange will provide uniform cabinets in NY11–4 with special features, the proposed cabinet installation fee is consistent with that of comparable products offered by other providers, the Exchange will incur increased costs for new power installation in NY11–4, higher voltage power options will provide operational efficiencies for the data hall, and PDU options are provided as a convenience to customers and customers may choose to provide their own PDUs.

The Exchange believes that the proposed fee changes are not unfairly discriminatory because the cabinet, power, and PDU fees for NY11–4 are available to and assessed uniformly across all market participants. In addition, all customers have the choice of whether and how to connect to the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal burdens inter-market competition because approval of the proposal does not impose any burden on the ability of other exchanges to compete. The Exchange operates in a highly competitive market in which market participants can determine whether or not to connect to the Exchange based on the value received compared to the cost of doing so. Indeed, market participants have numerous alternative exchanges that they may participate on and direct their order flow, as well as off-exchange venues, where competitive products are available for trading.

Nothing in the proposal burdens intra-market competition because the Ultra High Density Cabinets, cabinet power options, and PDU optionality in NY11–4 are available to any customer under the same fees as any other customer, and any customer that wishes to order cabinets, power and PDUs in NY11–4 can do so on a non-discriminatory basis.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[21]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–BX–2024–027 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–BX–2024–027. This file number should be included on the subject line if email is used. To help the

[19] *Supra* note 11.

[20] There are currently 16 registered equities exchanges that trade equities and 17 exchanges offering options trading services. No single equities exchange has more than 20% of the market share. *See* Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (Last updated July 3, 2024), available at *https://www.cboe.com/us/equities/market_statistics/*. No single options exchange trades more than 15% of the options market by volume and only one of the 17 options exchanges has a market share over 10 percent. *See* Nasdaq, Options Market Statistics (Last updated July 3, 2024), available at *https://www.nasdaqtrader.com/Trader.aspx?id=OptionsVolumeSummary*. This broad dispersion of market share demonstrates that market participants can and do exercise choice in trading venues. Further, low barriers to entry mean that new exchanges may rapidly enter the market and offer additional substitute platforms to further compete with the Exchange and the products it offers.

[21] 15 U.S.C. 78s(b)(3)(A)(ii).

Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–BX–2024–027 and should be submitted on or before August 21, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–16798 Filed 7–30–24; 8:45 am]

BILLING CODE 8011–01–P

[22] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20415 and #20416; IOWA Disaster Number IA–20005]

Presidential Declaration Amendment of a Major Disaster for the State of Iowa

AGENCY: Small Business Administration.

ACTION: Amendment 4.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Iowa (FEMA—4796–DR), dated 06/24/2024.

Incident: Severe Storms, Flooding, Straight-line Winds, and Tornadoes.

Incident Period: 06/16/2024 and continuing.

DATES: Issued on 07/23/2024.

Physical Loan Application Deadline Date: 08/23/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 03/24/2025.

ADDRESSES: Visit the MySBA Loan Portal at *https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of Iowa, dated 06/24/2024, is hereby amended to include the following areas as adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans): Osceola, Pottawattamie.

Contiguous Counties (Economic Injury Loans Only):

Iowa: Cass, Harrison, Mills, Montgomery, Shelby

Nebraska: Douglas, Sarpy, Washington

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Francisco Sánchez, Jr.,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–16784 Filed 7–30–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20496 and #20497; IOWA Disaster Number IA–20009]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Iowa

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Iowa (FEMA–4796–DR), dated 07/24/2024.

Incident: Severe Storms, Flooding, Straight-line Winds, and Tornadoes.

Incident Period: 06/16/2024 and continuing.

DATES: Issued on 07/24/2024.

Physical Loan Application Deadline Date: 09/23/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 04/24/2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 07/24/2024, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications online using the MySBA Loan Portal *https://lending.sba.gov* or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Buena Vista, Cherokee, Clay, Dickinson, Humboldt, O'Brien, Palo Alto, Plymouth, Scott, Sioux, Winnebago, Woodbury, Worth.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere	3.250
Non-Profit Organizations without Credit Available Elsewhere	3.250
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	3.250

The number assigned to this disaster for physical damage is 204966 and for economic injury is 204970.

(Catalog of Federal Domestic Assistance Number 59008)

Francisco Sánchez, Jr.,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–16879 Filed 7–30–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20486 and #20487; KENTUCKY Disaster Number KY–20005]

Presidential Declaration of a Major Disaster for Public Assistance Only for the Commonwealth of Kentucky

AGENCY: Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major

disaster for Public Assistance Only for the Commonwealth of Kentucky (FEMA–4804–DR), dated 07/23/2024.

Incident: Severe Storms, Straight-line Winds, Tornadoes, Landslides, and Mudslides.

Incident Period: 05/21/2024 through 05/27/2024.

DATES: Issued on 07/23/2024.

Physical Loan Application Deadline Date: 09/23/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 04/23/2025.

ADDRESSES: Visit the MySBA Loan Portal at *https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Vanessa Morgan, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 07/23/2024, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications online using the MySBA Loan Portal *https://lending.sba.gov* or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Adair, Allen, Ballard, Barren, Breckinridge, Butler, Caldwell, Calloway, Carlisle, Christian, Clay, Clinton, Crittenden, Cumberland, Edmonson, Estill, Fulton, Garrard, Graves, Grayson, Green, Hart, Hickman, Hopkins, Jackson, Knox, Larue, Laurel, Lee, Leslie, Livingston, Logan, Lyon, Marshall, McCracken, McCreary, McLean, Meade, Menifee, Metcalfe, Monroe, Muhlenberg, Ohio, Owsley, Pulaski, Rockcastle, Russell, Simpson, Todd, Trigg, Warren, Washington, Wayne, Whitley, Woodford.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere	3.250
Non-Profit Organizations without Credit Available Elsewhere	3.250
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	3.250

The number assigned to this disaster for physical damage is 20486C and for economic injury is 204870.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–16776 Filed 7–30–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20448 and #20449; NEW HAMPSHIRE Disaster Number NH–20005]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of New Hampshire

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of New Hampshire (FEMA–4799–DR), dated 07/10/2024.

Incident: Severe Winter Storm and Flooding.

Incident Period: 04/03/2024 through 04/05/2024.

DATES: Issued on 07/22/2024.

Physical Loan Application Deadline Date: 09/09/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 04/10/2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of New Hampshire, dated 07/10/2024, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Grafton.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Francisco Sánchez, Jr.,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–16888 Filed 7–30–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20482 and #20483; PUERTO RICO Disaster Number PR–20002]

Presidential Declaration of a Major Disaster for Public Assistance Only for the Commonwealth of Puerto Rico

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the Commonwealth of Puerto Rico (FEMA–4805–DR), dated 07/23/2024.

Incident: Severe Storms, Flooding, Landslides, and Mudslides.

Incident Period: 04/29/2024 through 05/10/2024.

DATES: Issued on 07/23/2024.

Physical Loan Application Deadline Date: 09/23/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 04/23/2025.

ADDRESSES: Visit the MySBA Loan Portal at *https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 07/23/2024, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications online using the MySBA Loan Portal *https://lending.sba.gov* or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Municipalities: Adjuntas, Guánica, Lajas, Las Marìas, Luquillo, Maricao, Naranjito, Orocovis, Sàbana Grande, San Sebastìan, Toa Alta, Utuado, Yauco.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere ...	3.250
Non-Profit Organizations without Credit Available Elsewhere	3.250
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	3.250

The number assigned to this disaster for physical damage is 204826 and for economic injury is 204830.

(Catalog of Federal Domestic Assistance Number 59008)

Francisco Sánchez, Jr.,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–16881 Filed 7–30–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20480 and #20481; MISSOURI Disaster Number MO–20003]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Missouri

AGENCY: Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Missouri (FEMA–4803–DR), dated 07/23/2024.

Incident: Severe Storms, Straight-line Winds, Tornadoes, and Flooding.

Incident Period: 05/19/2024 through 05/27/2024.

DATES: Issued on 07/23/2024.

Physical Loan Application Deadline Date: 09/23/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 04/23/2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 07/23/2024, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications online using the MySBA Loan Portal *https://lending.sba.gov* or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Barry, Bollinger, Butler, Carter, Howell, Madison, McDonald, New Madrid, Oregon, Reynolds, Ripley, Scott, Shannon, Stoddard, Texas.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere	3.250
Non-Profit Organizations without Credit Available Elsewhere	3.250
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	3.250

The number assigned to this disaster for physical damage is 204806 and for economic injury is 204810.

(Catalog of Federal Domestic Assistance Number 59008)

Francisco Sánchez, Jr.,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–16774 Filed 7–30–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20364 and #20365; OKLAHOMA Disaster Number OK–20004]

Presidential Declaration Amendment of a Major Disaster for the State of Oklahoma

AGENCY: Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Oklahoma (FEMA–4791–DR), dated 06/14/2024.

Incident: Severe Storms, Straight-line Winds, Tornadoes, and Flooding.

Incident Period: 05/19/2024 through 05/28/2024.

DATES: Issued on 07/24/2024.

Physical Loan Application Deadline Date: 08/14/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 03/14/2025.

ADDRESSES: Visit the MySBA Loan Portal at *https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of Oklahoma, dated 06/14/2024, is hereby amended to extend the deadline for filing applications for physical damages as a result of this disaster to 08/14/2024.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Francisco Sánchez, Jr.,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–16785 Filed 7–30–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20445 and #20446; TEXAS Disaster Number TX–20016]

Presidential Declaration Amendment of a Major Disaster for the State of Texas

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Texas (FEMA–4798–DR), dated 07/12/2024.

Incident: Hurricane Beryl.

Incident Period: 07/05/2024 through 07/09/2024.

DATES: Issued on 07/13/2024.

Physical Loan Application Deadline Date: 09/10/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 04/14/2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of Texas, dated 07/12/2024, is hereby amended to include the following areas as adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans): Fort Bend, Nacogdoches.

Contiguous Counties (Economic Injury Loans Only):

Texas: Cherokee, Rusk, Shelby.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Francisco Sánchez, Jr.,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–16887 Filed 7–30–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20494 and #20495; CHICKASAW NATION Disaster Number OK–20009]

Presidential Declaration of a Major Disaster for Public Assistance Only for the Chickasaw Nation

AGENCY: Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the Chickasaw Nation (FEMA—4802–DR), dated 07/23/2024.

Incident: Severe Storms.

Incident Period: 03/14/2024 through 03/15/2024.

DATES: Issued on 07/23/2024.

Physical Loan Application Deadline Date: 09/23/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 04/23/2025.

ADDRESSES: Visit the MySBA Loan Portal at *https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 07/24/2024, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications online using the MySBA Loan Portal *https://lending.sba.gov* or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Area: Chickasaw Nation.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere	3.250
Non-Profit Organizations without Credit Available Elsewhere	3.250
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	3.250

The number assigned to this disaster for physical damage is 20494B and for economic injury is 204950.

(Catalog of Federal Domestic Assistance Number 59008)

Francisco Sánchez, Jr.,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–16778 Filed 7–30–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day notice.

SUMMARY: The Small Business Administration (SBA) is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act and OMB procedures, SBA is publishing this notice to allow all interested member of the public an additional 30 days to provide comments on the proposed collection of information.

DATES: Submit comments on or before August 30, 2024.

ADDRESSES: Written comments and recommendations for this information collection request should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/*PRAMain. Find this particular information collection request by selecting ''Small Business Administration''; ''Currently Under Review,'' then select the ''Only Show ICR for Public Comment'' checkbox. This information collection can be identified by title and/or OMB Control Number.

FOR FURTHER INFORMATION CONTACT: You may obtain a copy of the information collection and supporting documents from the Agency Clearance Office at *Curtis.Rich@sba.gov;* (202) 205–7030, or from *www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: SBA is required by statute to administer the 8(a) Business Development (15 U.S.C. 637(a); 13 CFR 124); Historically Underutilized Business Zone (HUBZone) (15 U.S.C. 657a; 13 CFR 126); Veteran-Owned/Service-Disabled Veteran-Owned (VOSB/SDVOSB) (15 U.S.C. 657f and 657f–1; 13 CFR 128); and Women-Owned/Economically Disadvantaged Women-Owned (WOSB/EDWOSB) (15 U.S.C. 636(m); 13 CFR 127) certification programs. The Small Business Act requires small businesses to apply to SBA for 8(a), HUBZone, VOSB/SDVOSB, and WOSB/EDWOSB certifications. SBA's regulations require the applications for certification to be submitted electronically. All of the collections are overseen by Government Contracting and Business Development staff. The HUBZone program requires small businesses to recertify their eligibility annually, while WOSB/EDWOSB and VOSB/SDVOSB require recertification every three years. All recertifications are done electronically. This information collection will allow for application, certification, recertification, and administration of the 8(a), HUBZone, WOSB/EDWOSB, and VOSB/SDVOSB programs in one system. By having one system, the process is streamlined and easier for small businesses applying to SBA for certification.

Failing to collect the information described above would impede SBA's ability to fulfill its statutory mandates to certify 8(a), HUBZone, VOSB/SDVOSB, and WOSB/EDWOSB certification programs, and maintain and update the list of certified small business concerns.

This PRA submission will amend SBA forms from the current HUBZone (OMB Control No. 3245–0320), 8(a) (OMB Control No. 3245–0331), VOSB/SDVOSB (OMB Control No. 3245–0426), and WOSB/EDWOSB (OMB Control No. 3245–0374) information collections into one unified information collection.

Solicitation of Public Comments

Comments may be submitted on (a) whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

OMB Control Number 3245–0374.

Title: SBA Unified Certification System.

Description of Respondents: Small Business concerns applying for SBA certification in the 8(a), HUBZone,

WOSB/EDWOSB, and VOSB/SDVOSB programs.

SBA Form Number: SBA Form 2413.

Estimated Number of Respondents: 29,329.

Estimated Annual Responses: 29,329.

Estimated Annual Hour Burden: 39,330.

Curtis Rich,

Agency Clearance Officer.

[FR Doc. 2024–16853 Filed 7–30–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20374 and #20375; MISSOURI Disaster Number MO–20002]

Presidential Declaration of a Major Disaster for the State of Missouri

AGENCY: Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for the State of Missouri (FEMA—4803–DR), dated 07/23/2024.

Incident: Severe Storms, Straight-line Winds, Tornadoes, and Flooding.

Incident Period: 05/19/2024 through 05/27/2024.

DATES: Issued on 07/23/2024.

Physical Loan Application Deadline Date: 09/23/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 04/23/2025.

ADDRESSES: Visit the MySBA Loan Portal at *https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 07/23/2024, applications for disaster loans may be submitted online using the MySBA Loan Portal *https://lending.sba.gov* or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans): Barry, Butler, Carter, Howell, New Madrid, Ripley, Scott, Shannon, Stoddard, Texas.

Contiguous Counties (Economic Injury Loans Only):

Missouri: Bollinger, Cape Girardeau, Dent, Douglas, Dunklin, Laclede, Lawrence, McDonald, Mississippi, Newton, Oregon, Ozark, Pemiscot, Phelps, Pulaski, Reynolds, Stone, Wayne, Wright

Arkansas: Benton, Clay, Carroll, Fulton, Randolph

Illinois: Alexander

Kentucky: Fulton

Tennessee: Lake

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	5.375
Homeowners without Credit Available Elsewhere	2.688
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere	3.250
Non-Profit Organizations without Credit Available Elsewhere	3.250
For Economic Injury:	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	3.250

The number assigned to this disaster for physical damage is 203746 and for economic injury is 203750.

(Catalog of Federal Domestic Assistance Number 59008)

Francisco Sánchez, Jr.,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–16775 Filed 7–30–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20466 and #20467; KANSAS Disaster Number KS–20012]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Kansas

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Kansas (FEMA—4800–DR), dated 07/15/2024.

Incident: Severe Storms, Straight-line Winds, Tornadoes, and Flooding.

Incident Period: 04/25/2024 through 04/30/2024.

DATES: Issued on 07/15/2024.

Physical Loan Application Deadline Date: 09/13/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 04/15/2025.

ADDRESSES: Visit the MySBA Loan Portal at *https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 07/15/2024, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications online using the MySBA Loan Portal *https://lending.sba.gov* or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Allen, Anderson, Bourbon, Chautauqua, Cherokee, Elk, Greenwood, Linn, Morris, Neosho, Pottawatomie, Wilson.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere	3.250
Non-Profit Organizations without Credit Available Elsewhere	3.250
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	3.250

The number assigned to this disaster for physical damage is 20466B and for economic injury is 204670.

(Catalog of Federal Domestic Assistance Number 59008)

Francisco Sánchez, Jr.,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–16882 Filed 7–30–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20484 and #20485; KENTUCKY Disaster Number KY–20004]

Presidential Declaration of a Major Disaster for the Commonwealth of Kentucky

AGENCY: Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for the Commonwealth of Kentucky (FEMA–4804–DR), dated 07/23/2024.

Incident: Severe Storms, Straight-line Winds, Tornadoes, Landslides, and Mudslides.

Incident Period: 05/21/2024 through 05/27/2024.

DATES: Issued on 07/23/2024.

Physical Loan Application Deadline Date: 09/23/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 04/23/2025.

ADDRESSES: Visit the MySBA Loan Portal at *https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Vanessa Morgan, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 07/23/2024, applications for disaster loans may be submitted online using the MySBA Loan Portal *https://lending.sba.gov* or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans): Butler, Caldwell, Calloway, Christian, Clay, Greenup, Hopkins, Knox, Logan, Muhlenberg, Simpson, Todd, Trigg, Warren, Whitley.

Contiguous Counties (Economic Injury Loans Only):

Kentucky: Allen, Barren, Bell, Boyd, Carter, Crittenden, Edmonson, Graves, Grayson, Jackson, Laurel, Leslie, Lewis, Lyon, Marshall, McCreary, McLean, Ohio, Owsley, Perry, Webster

Ohio: Lawrence, Scioto

Tennessee: Campbell, Claiborne, Henry, Montgomery, Robertson, Sumner, Stewart

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	5.375
Homeowners without Credit Available Elsewhere	2.688
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere	3.250
Non-Profit Organizations without Credit Available Elsewhere	3.250
For Economic Injury:	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	3.250

The number assigned to this disaster for physical damage is 20484C and for economic injury is 204850.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–16777 Filed 7–30–24; 8:45 am]

BILLING CODE 8026–09–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 55 (Sub-No. 816X)]

CSX Transportation, Inc.—Abandonment Exemption—in Pike County, KY

CSX Transportation, Inc. (CSXT), has filed a verified notice of exemption under 49 CFR part 1152 subpart F—*Exempt Abandonments* to abandon an approximately 5.1-mile rail line that runs between milepost CML 9.0 and milepost CML 14.1, Louisville Division, Winns Branch-Big Sandy Subdivision, in Pike County, Ky. (the Line). The Line traverses U.S. Postal Service Zip Codes 41557 and 41501.

CSXT has certified that: (1) no local freight traffic has moved over the Line during the past two years; (2) any overhead traffic on the Line can be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government on behalf of such user) regarding cessation of service over the Line is pending with either the Surface Transportation Board (Board) or any U.S. District Court or has been decided in favor of a complainant within the two-year period; and (4) the requirements at 49 CFR 1105.7(b) and 1105.8(c) (notice of environmental and historic reports), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to government agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received,[1] this exemption will be effective on August 30, 2024, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues[2] must be filed by August 9, 2024. Formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2) and interim trail use/rail banking requests under 49 CFR 1152.29 must be filed by August 12, 2024.[3] Petitions to reopen and requests for public use conditions under 49 CFR 1152.28 must be filed by August 20, 2024.

All pleadings, referring to Docket No. AB 55 (Sub-No. 816X), must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on CSXT's representative, Louis E. Gitomer, Law Offices of Louis E. Gitomer, LLC, 600 Baltimore Avenue, Suite 301, Towson, MD 21204.

If the verified notice contains false or misleading information, the exemption is void ab initio.

CSXT has filed a combined environmental and historic report that addresses the potential effects, if any, of

[1] Persons interested in submitting an OFA must first file a formal expression of intent to file an offer, indicating the type of financial assistance they wish to provide (*i.e.,* subsidy or purchase) and demonstrating that they are preliminarily financially responsible. *See* 49 CFR 1152.27(c)(2)(i).

[2] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Serv. Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[3] Filing fees for OFAs and trail use requests can be found at 49 CFR 1002.2(f)(25) and (27), respectively.

the abandonment on the environment and historic resources. OEA will issue a Draft Environmental Assessment (Draft EA) by August 5, 2024. The Draft EA will be available to interested persons on the Board's website, by writing to OEA, or by calling OEA at (202) 245–0294. If you require an accommodation under the Americans with Disabilities Act, please call (202) 245–0245. Comments on environmental or historic preservation matters must be filed within 15 days after the Draft EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), CSXT shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the Line. If consummation has not been effected by CSXT's filing of a notice of consummation by July 31, 2025, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available at *www.stb.gov.*

Decided: July 24, 2024.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Stefan Rice,

Clearance Clerk.

[FR Doc. 2024–16823 Filed 7–30–24; 8:45 am]

BILLING CODE 4915–01–P

TENNESSEE VALLEY AUTHORITY

Meeting of the Regional Resource Stewardship Council

AGENCY: Tennessee Valley Authority (TVA).

ACTION: Notice of meeting.

SUMMARY: The TVA Regional Resource Stewardship Council (RRSC) will hold a virtual meeting on August 13, 2024, to kick off the 13th term of the RRSC. The Council will receive updates about TVA's work in Natural Resources, River Management, and Cultural Compliance. RRSC members will also hear an update on the development of TVA's Integrated Resource Plan (IRP).

DATES: The meeting will be held virtually via webinar, on Tuesday, August 13, 2024, from 1 p.m. to 5 p.m. EST. The public must register to attend the webinar. You may register by going to *www.tva.com/rrsc.* A 30-minute public listening session for the public to present comments during the webinar will be held August 13, 2024, at 2 p.m. ET. Persons who wish to speak during the public listening session must pre-register by 5 p.m. ET Friday, August 9, 2024, by emailing *bhaliti@tva.gov.*

ADDRESSES: The meeting will be fully virtual, and the meeting link is provided at *www.tva.com/rrsc.* Anyone needing special accommodations should let the contact below know at least one week in advance.

FOR FURTHER INFORMATION CONTACT: Bekim Haliti, *bhaliti@tva.gov* or 931–349–1894.

SUPPLEMENTARY INFORMATION: The RRSC is a discretionary advisory committee established under the authority of the Tennessee Valley Authority (TVA) in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. app. 2.

The meeting agenda includes the following:

August 13

1. Welcome and Introductions
2. Public Listening Session
3. River Management Update
4. Natural Resources Update
5. Cultural Compliance Update
6. IRP Development Update

The RRSC will hear views of citizens by providing a 30-minute public comment session starting August 13 at 2 p.m. ET. Persons registered will be called on during the public listening session to share their views for up to five minutes, depending on the number of registrants. Persons wishing to speak virtually must register by sending an email to *bhaliti@tva.gov* or by calling 931–349–1894 by 5 p.m. ET, on Friday, August 9, 2024. Written comments are invited and may be emailed to *bhaliti@tva.gov.*

The DFO of the Tennessee Valley Authority and Vice President of External Strategy and Regulatory Oversight, Melanie Farrell, having reviewed and approved this document, is delegating the authority to sign this document to Bekim Haliti, Specialist of Valley Alliances for publication in the **Federal Register**.

Dated: July 26, 2024.

Bekim Haliti,

Specialist, Valley Alliances, Tennessee Valley Authority.

[FR Doc. 2024–16826 Filed 7–30–24; 8:45 am]

BILLING CODE 8120–08–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2024–1988]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Small Unmanned Aircraft Systems (sUAS) Safety Event Reporting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection involves information that must be reported to the FAA about small unmanned aircraft system (sUAS) safety events if they result in serious injury or damage exceeding certain thresholds.

DATES: Written comments should be submitted by September 30, 2024.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (Enter docket number into search field).

By mail: Benjamin Walsh, FAA Flight Standards Service, Emerging Technologies Division, AFS–700, 800 Independence Ave. SW, Washington, DC 20591.

By fax: 202–267–8233.

FOR FURTHER INFORMATION CONTACT: Benjamin Walsh by email at: *ben.walsh@faa.gov;* phone: 202–267–8233.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0767.

Title: Small Unmanned Aircraft Systems (sUAS) Safety Event Reporting.

Form Numbers: N/A (web portal: *https://faadronezone.faa.gov*).

Type of Review: Renewal of an information collection.

Background: The title of this information collection is being changed from ''Small Unmanned Aircraft Systems (sUAS) Accident Reporting'' to ''Small Unmanned Aircraft Systems (sUAS) Safety Event Reporting'' to reflect the change made to the title of the applicable regulation (14 CFR, 107.9) in 2022. 14 CFR part 107.9 requires that a small unmanned aircraft system safety event be reported if it causes: (1) serious injury to any person or any loss of consciousness; or (2) damage to any property, other than the small unmanned aircraft, unless the cost of repair or fair market value in the event of total loss does not exceed $500. The information collected by the FAA through its DroneZone web portal, Flight Standards District Offices, one of the Regional Operations Centers, or the Washington Operations Center for each small UAS safety event will be used to investigate and determine regulatory compliance. In addition, the safety event information will go into the FAA aircraft accident database for safety analysis purposes by the FAA Office of Accident Investigation and Analysis, pursuant to its statutory safety mission.

As is currently the case for manned aircraft accidents, small UAS safety event data will be made available to the public and the National Transportation Safety Board (NTSB).

Respondents: Small Unmanned Aircraft System operators that experience a safety event that must be reported to the FAA per 14 CFR, 107.9. Approximately 41 per year.

Frequency: On occasion.

Estimated Average Burden per Response: 15 minutes.

Estimated Total Annual Burden: 10.25 hours.

Issued in Washington, DC, on July 26, 2024.

Joseph Morra,

Manager, Emerging Technologies Division, AFS–700.

[FR Doc. 2024–16892 Filed 7–30–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2010–0054]

Alaska Railroad's Request To Amend Its Positive Train Control Safety Plan and Positive Train Control System

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of availability and request for comments.

SUMMARY: This document provides the public with notice that, on July 18, 2024, Alaska Railroad (ARR) submitted a request for amendment (RFA) to its FRA-approved Positive Train Control Safety Plan (PTCSP). As this RFA involves a request for FRA's approval of proposed material modifications to an FRA-certified positive train control (PTC) system, FRA is publishing this notice and inviting public comment on the railroad's RFA to its PTCSP.

DATES: FRA will consider comments received by August 20, 2024. FRA may consider comments received after that date to the extent practicable and without delaying implementation of valuable or necessary modifications to a PTC system.

ADDRESSES:

Comments: Comments may be submitted by going to *https://www.regulations.gov* and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and the applicable docket number. The relevant PTC docket number for this host railroad is Docket No. FRA–2010–0054. For convenience, all active PTC dockets are hyperlinked on FRA's website at *https://railroads.dot.gov/research-development/program-areas/train-control/ptc/railroads-ptc-dockets.* All comments received will be posted without change to *https://www.regulations.gov;* this includes any personal information.

FOR FURTHER INFORMATION CONTACT: Gabe Neal, Staff Director, Signal, Train Control, and Crossings Division, telephone: 816–516–7168, email: *Gabe.Neal@dot.gov.*

SUPPLEMENTARY INFORMATION: In general, Title 49 United States Code (U.S.C.) section 20157(h) requires FRA to certify that a host railroad's PTC system complies with Title 49 Code of Federal Regulations (CFR) part 236, subpart I, before the technology may be operated in revenue service. Before making certain changes to an FRA-certified PTC system or the associated FRA-approved PTCSP, a host railroad must submit, and obtain FRA's approval of, an RFA to its PTCSP under 49 CFR 236.1021.

Under 49 CFR 236.1021(e), FRA's regulations provide that FRA will publish a notice in the **Federal Register** and invite public comment in accordance with 49 CFR part 211, if an RFA includes a request for approval of a material modification of a signal or train control system. Accordingly, this notice informs the public that, on July 18, 2024, ARR submitted an RFA to its PTCSP for its Interoperable Electronic Train Management System (I–ETMS), which seeks FRA's approval of ARR's proposed I–ETMS onboard software upgrade. The upgrade includes changes and enhancements to software functionality to improve operational efficiencies in managing high volumes of passenger traffic during Alaska's tourist season. That RFA is available in Docket No. FRA–2010–0054.

Interested parties are invited to comment on ARR's RFA to its PTCSP by submitting written comments or data. During FRA's review of this railroad's RFA, FRA will consider any comments or data submitted within the timeline specified in this notice and to the extent practicable, without delaying implementation of valuable or necessary modifications to a PTC system. *See* 49 CFR 236.1021; *see also* 49 CFR 236.1011(e). Under 49 CFR 236.1021, FRA maintains the authority to approve, approve with conditions, or deny a railroad's RFA to its PTCSP at FRA's sole discretion.

Privacy Act Notice

In accordance with 49 CFR 211.3, FRA solicits comments from the public to better inform its decisions. DOT posts these comments, without edit, including any personal information the commenter provides, to *https://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See *https://www.regulations.gov/privacy-notice* for the privacy notice of *regulations.gov.* To facilitate comment tracking, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. If you wish to provide comments containing proprietary or confidential information, please contact FRA for alternate submission instructions.

Issued in Washington, DC.

Carolyn R. Hayward-Williams,

Director, Office of Railroad Systems and Technology.

[FR Doc. 2024–16811 Filed 7–30–24; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

[Docket No. OCC–2024–0014]

FEDERAL RESERVE SYSTEM

[Docket No. OP–1836]

FEDERAL DEPOSIT INSURANCE CORPORATION

RIN 3064–ZA43

Request for Information on Bank-Fintech Arrangements Involving Banking Products and Services Distributed to Consumers and Businesses

AGENCY: Office of the Comptroller of the Currency, Treasury; Board of Governors of the Federal Reserve System; and Federal Deposit Insurance Corporation.

ACTION: Request for information and comment.

SUMMARY: Over the past several years, the Office of the Comptroller of the Currency (OCC), Treasury; the Board of Governors of the Federal Reserve System (Board); and the Federal Deposit Insurance Corporation (FDIC) (collectively, ''the agencies'' or ''agency'' when referencing the singular) have observed and reviewed arrangements between banks and financial technology (fintech) companies. The agencies support responsible innovation and banks pursuing bank-fintech arrangements in a manner consistent with safe and sound banking practices, and with applicable laws and regulations, including consumer protection requirements and those addressing financial crimes. Bank-fintech arrangements can provide benefits; however, supervisory experience has highlighted a range of potential risks with these bank-fintech arrangements. This request solicits input on the nature of bank-fintech arrangements, effective risk management practices regarding bank-fintech arrangements, and the implications of such arrangements, including whether enhancements to existing supervisory guidance may be helpful in addressing risks associated with these arrangements.

DATES: Comments must be received on or before September 30, 2024.

ADDRESSES: Comments should be directed to:

OCC: Commenters are encouraged to submit comments through the Federal eRulemaking Portal, if possible. Please use the title ''Request for Information on Bank-Fintech Arrangements Involving Banking Products and Services Distributed to Consumers and Businesses'' to facilitate the organization and distribution of the comments. You may submit comments by any of the following methods:

- *Federal eRulemaking Portal—Regulations.gov:* Go to *https://www.regulations.gov.* Enter ''Docket ID OCC–2024–0014'' in the Search Box and click ''Search.'' Public comments can be submitted via the ''Comment'' box below the displayed document information or by clicking on the document title and then clicking the ''Comment'' box on the top-left side of the screen. For help with submitting effective comments, please click on ''Commenter's Checklist.'' For assistance with the *Regulations.gov* site, please call 1–866–498–2945 (toll free) Monday–Friday, 8:00 a.m. to 7:00 p.m. ET, or email *regulationshelpdesk@gsa.gov.*
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.

Instructions: You must include ''OCC'' as the agency name and ''Docket ID OCC–2024–0014'' in your comment. In general, the OCC will enter all comments received into the docket and publish the comments on the *Regulations.gov* website without change, including any business or personal information provided such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this action by the following method:

- *Viewing Comments Electronically—Regulations.gov:* Go to *https://regulations.gov/.* Enter ''Docket ID OCC–2024–0014'' in the Search Box and click ''Search.'' Click on the ''Dockets'' tab and then the document's title. After clicking the document's title, click the ''Browse All Comments'' tab. Comments can be viewed and filtered by clicking on the ''Sort By'' drop-down on the right side of the screen or the ''Refine Comments Results'' options on the left side of the screen. Supporting materials can be viewed by clicking on the ''Browse Documents'' tab. Click on the ''Sort By'' drop-down on the right side of the screen or the ''Refine Results'' options on the left side of the screen checking the ''Supporting & Related Materials'' checkbox. For assistance with the *Regulations.gov* site, please call 1–866–498–2945 (toll free) Monday–Friday, 8:00 a.m. to 7:00 p.m. ET, or email *regulationshelpdesk@gsa.gov.*

The docket may be viewed after the close of the comment period in the same manner as during the comment period.

Board: You may submit comments, identified by Docket No. OP–1836, by any of the following methods:

- *Agency Website: https://www.federalreserve.gov/.* Follow the instructions for submitting comments at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx.*
- *Email: regs.comments@federalreserve.gov.* Include the OMB number or FR number in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Federal Reserve Board of Governors, Attn: Ann E. Misback, Secretary of the Board, Mailstop M–4775, 2001 C St. NW, Washington, DC 20551.

All public comments are available from the Board's website at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any confidential business information, identifying information, or contact information. Public comments may also be viewed electronically or in paper in Room M–4365A, 2001 C St. NW, Washington, DC 20551, between 9:00 a.m. and 5:00 p.m. on weekdays, except for Federal holidays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452–3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

FDIC: You may submit comments, identified by RIN 3064–ZA43, by any of the following methods:

- *Agency Website: https://www.fdic.gov/resources/regulations/federal-register-publications/.* Follow instructions for submitting comments on the FDIC's website.
- *Email: Comments@fdic.gov.* Include ''Request for Information on Bank-Fintech Arrangements Involving Banking Products and Services Distributed to Consumers and

Businesses/RIN 3064–ZA43'' in the subject line of the message.

• *Mail:* James P. Sheesley, Assistant Executive Secretary, Attention: Request for Information on Bank-Fintech Arrangements Involving Banking Products and Services Distributed to Consumers and Businesses—RIN 3064–ZA43, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

• *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 550 17th Street NW, building (located on F Street NW) on business days between 7:00 a.m. and 5:00 p.m. ET.

• *Public Inspection:* Comments received, including any personal information provided, may be posted without change to *https://www.fdic.gov/resources/regulations/federal-register-publications/.* Commenters should submit only information that the commenter wishes to make available publicly. The FDIC may review, redact, or refrain from posting all or any portion of any comment that it may deem to be inappropriate for publication, such as irrelevant or obscene material. The FDIC may post only a single representative example of identical or substantially identical comments, and in such cases will generally identify the number of identical or substantially identical comments represented by the posted example. All comments that have been redacted, as well as those that have not been posted, that contain comments on the merits of this notice will be retained in the public comment file and will be considered as required under all applicable laws. All comments may be accessible under the Freedom of Information Act.

FOR FURTHER INFORMATION CONTACT:

OCC: Miriam Bazan, Financial Technology Policy Specialist, or Tracy Chin, Director for Payment Systems Policy, Bank Supervision Policy (202) 649–5200; or Beth Knickerbocker, Special Counsel, Micah Cogen, Counsel, or Graham Bannon, Counsel, Chief Counsel's Office (202) 649–5490. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

Board: Kavita Jain, Associate Director, Novel Activities and Innovation Policy, (202) 452–2062, Jeff Ernst, Manager, Innovation Policy, (202) 452–2814, or Roman Goldstein, Lead Financial Institution Policy Analyst, (202) 452–3802, Division of Supervision and Regulation; Drew Kohan, Associate Director, Program Direction, Division of Consumer and Community Affairs, (202) 452–3040; Asad Kudiya, Deputy Associate General Counsel, (202) 475–6358 or Isabel Echarte, Attorney, (202) 452–2514, Legal Division, Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551. For the hearing impaired only, Telecommunication Device for the Deaf (TDD), (202) 263–4869.

FDIC: Rae-Ann Miller, Senior Deputy Director, (202) 898–3898, or Tom Lyons, Associate Director, (202) 898–6850, Division of Risk Management Supervision; Luke Brown, Associate Director, (202) 898–3842, or Meron Wondwosen, Chief, (571) 438–7127, Division of Depositor and Consumer Protection; Annmarie Boyd, Senior Counsel, (202) 898–3714, or Vivek Khare, Senior Counsel, (202) 898–6847; FDIC, 550 17th Street NW, Washington, DC 20429; FDIC, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION:

Background Information

The agencies are responsible for supervising certain Federally-chartered and State-chartered banks (herein referred to as ''banks'').[1] Over the past several years, the agencies have observed and reviewed arrangements between banks and fintech companies [2] that provide consumers and businesses (herein referred to as ''end users''), access to banking products and services. Although these arrangements may provide benefits, supervisory experience has highlighted a range of risks with these bank-fintech arrangements. The agencies support responsible innovation and support banks in pursuing bank-fintech arrangements in a manner consistent with safe and sound practices and applicable laws and regulations, including but not limited to, consumer protection requirements (such as fair lending laws and prohibitions against unfair, deceptive, or abusive acts or practices) and those addressing financial crimes (such as fraud and money laundering).[3] This request solicits input on the nature of bank-fintech arrangements, including their benefits and risks, effective risk management practices regarding bank-fintech arrangements, and the implications of such arrangements, including whether enhancements to existing supervisory guidance may be helpful in addressing risks associated with these arrangements.

For many years, non-banks have provided access to financial products and services, such as consumer credit products, commercial loans, payment products, and deposit accounts. Rapid technological advances and evolving customer preferences are accelerating these trends. Over the past decade, fintech companies have significantly expanded their ability to distribute financial products and services directly to end users. These companies include small- and medium-sized firms specifically focused on the financial services sector as well as larger firms with established, multi-use technology platforms (sometimes referred to as ''Big Tech''). For purposes of this Request for Information (RFI), we refer to all of these types of non-bank firms as ''fintech companies.'' [4]

To facilitate providing end users with access to banking products and services, fintech companies may enter into arrangements with banks. In these arrangements, a bank typically makes products or services available through an arrangement with one or more fintech companies in which the fintech company, rather than the bank, markets, distributes, or otherwise provides access

[1] For a description of the banks supervised by each agency and relevant to this request for information, refer to the definition of ''appropriate Federal banking agency'' in the Federal Deposit Insurance Act (12 U.S.C. 1813(q)(1), (2), and (3)(A)–(E)).

[2] In some cases, the fintech company may be an affiliate of the bank, such as, for example, where a bank holding company owns a fintech, and that fintech relies on the holding company's subsidiary bank to provide end users access to banking products or services.

[3] Examples of relevant issuances may include the following: Interagency Guidance on Third-Party Relationships: Risk Management, 88 FR 37920 (Jun. 9, 2023); Interagency Guidelines Establishing Information Security Standards, 70 FR 15736 (Mar. 29, 2005); Interagency Guidelines Establishing Standards for Safety and Soundness, 61 FR 43948 (Oct. 1, 1996); FDIC FIL–15–2024, Collecting Identifying Information Required Under the Customer Identification Program (CIP) Rule (Mar. 28, 2024); Third-Party Risk Management: A Guide for Community Banks (May 2024); Conducting Due Diligence on Financial Technology Companies: A Guide for Community Banks (Oct. 2023); FDIC FIL–35–2022, Advisory to FDIC-Insured Institutions Regarding Deposit Insurance and Dealings with Crypto Companies (July 20, 2022); Joint Statement on the Risk-Based Approach to Assessing Customer Relationships and Conducting Customer Due Diligence (July 6, 2022); Interagency Guidance to Issuing Banks on Applying Customer Identification Program Requirements to Holders of Prepaid Cards (Mar. 21, 2016); Interagency Policy Statement on Funding and Liquidity Risk Management, 75 FR 13656 (Mar. 22, 2010); Interagency Interpretive Guidance on Customer Identification Program Requirements, (Apr. 28, 2005); Unfair or Deceptive Acts or Practices by State-Chartered Banks (Mar. 11, 2004).

[4] This term includes, among many others, intermediate platform providers (as defined below), as well as certain processors and payments platforms. It also includes certain non-financial retail businesses seeking to expand into markets for financial products and services through arrangements that could allow them to leverage their existing infrastructure and customer relationships to offer a one-stop-shop to access financial and non-financial products and services.

to or facilitates the provision of the product or service directly to the end user.[5] These arrangements enable fintech companies to provide end users with access to a range of banking products, including deposit products (*e.g.,* checking or savings accounts); payment services (*e.g.,* peer-to-peer, debit card, contactless payments, Automated Clearing House (ACH) transactions, or wire transfer capabilities); or lending products (*e.g.,* unsecured consumer or small business loans) through online and mobile applications, platforms, or digital wallets. In some of these cases, fintech companies (sometimes referred to as a ''middleware provider'' or ''intermediate platform provider'') act as intermediaries by engaging in a variety of functions, as described in detail below. For purposes of this RFI, we refer to all of these types of arrangements as ''bank-fintech arrangements.''

Bank-fintech arrangements may enable banks to leverage newer technology and offer innovative products or services to further their digitalization efforts and to meet evolving customer demands and expectations. These arrangements may also provide banks with the ability to quickly and more cost effectively deploy products or services into the market through the fintech company. In addition, these arrangements may provide banks with access to new or expanded markets, revenue sources, and customers. As discussed in more detail below, bank-fintech arrangements also may introduce potential risks through business and legal structures that increase operational complexity, unbundle traditional banking products and services (particularly payments), and increase compliance challenges. The failure of banks to manage these arrangements effectively may present consumer protection, safety and soundness, and compliance concerns.

The following sections of this RFI describe several bank-fintech arrangement structures and use cases, as well as the risks the agencies have seen manifesting and arising from these arrangements. The agencies seek public comment to build on their understanding of these arrangements, including with respect to roles, risks, costs, and revenue allocation. The agencies also seek additional information and stakeholder perspectives relevant to the implications of such arrangements, including for banks' risk management, safety and soundness, and compliance with applicable laws and regulations. The RFI is not intended to impose any obligations or define any rights, and it is not an interpretation of any statute or regulation.

Descriptions of Bank-Fintech Arrangements

The agencies have observed that bank-fintech arrangements vary significantly in structure and product and service offerings, but many commonly fall into one or more categories of facilitating deposit-taking, payment (including card issuance and digital wallet capabilities), and lending activities. Such arrangements may be effectuated either directly between banks and fintech companies or indirectly through the use of an intermediate platform provider. The agencies seek comment on these categories and the attributes of the bank-fintech arrangements described below.

Bank-Fintech Arrangements in Connection With Deposit-Taking Activities

Some non-bank fintech companies provide end users with access to deposit products and services; however, these entities are not Federally insured depository institutions (IDIs). Instead, the fintech company establishes arrangements with one or more IDIs, directly or through an intermediate platform provider, to provide end users with access to banking products and services—such as deposit accounts, debit cards, savings accounts, and other account-related services—through the fintech company's online or mobile platform.[6] Some fintech companies enter into these deposit-taking arrangements with banks to target a specific customer base, such as underserved or younger demographics. Other fintech companies incorporate such deposit-taking arrangements into much larger suites of financial and non-financial products and services and target a much broader customer base.

In arrangements between banks and fintech companies to facilitate an IDI's deposit-taking activities, fintech companies often play a critical role in maintaining a deposit and transaction system of record. These transaction records may not be reflected in the bank's core processing system. Instead, the bank's core deposit ledger may only include omnibus accounts, often titled to reflect that they are held for the benefit of (FBO) end users. The contracts governing these arrangements commonly set forth the operational responsibilities of each party, such as record-keeping and access to records, end-user on-boarding, compliance management, transaction monitoring, and complaint handling. Bank-fintech arrangements involving deposit-taking activities often involve heightened levels of operational complexity, including as it relates to reconciliations and Bank Secrecy Act (BSA) recordkeeping and compliance (*e.g.,* customer identification and due diligence, suspicious activity monitoring, and reporting and sanctions screening).

Bank-Fintech Arrangements in Connection With Payment Activities, Including Card Issuance

Banks may enter a variety of arrangements with fintech companies in connection with fund-transfer services, card issuance, contactless payments, and other payment solutions. While banks and non-banks have entered into payment-related card sponsorship arrangements for decades, the types, number, and complexity of payment-related products and services and associated arrangements between banks and fintech companies have rapidly increased in recent years.

Today, payment-related bank-fintech arrangements can vary widely and may include several different types of payment options, including debit and credit card offerings, fund-transfer services utilizing ACH transactions, wire transfers, prepaid services, and instant payments. Non-cash payments, particularly cards and ACH transactions, have increased significantly in size and volume in recent years due to innovation and the ease, convenience, accessibility, and speed of digital payments. A fintech company may enter into a card offering arrangement with a bank to provide end users with access to bank-issued, fintech-branded debit or credit cards. In some of these card offering arrangements, the partner bank directly operates and manages the cards. In others, the fintech company directly operates and manages the cards with oversight by the partner bank pursuant to a bank sponsorship agreement between the bank and fintech company. In a prepaid services arrangement, a fintech company may offer end users access to bank-operated (and, often, fintech-branded) prepaid accounts that link to end users' accounts with the fintech company. This type of structure allows end users to load and store prepaid funds and transfer such funds to others. A fintech company may also

[5] These arrangements are sometimes referred to as ''banking-as-a-service'' or ''embedded finance'' depending on the structure and parties involved in the arrangement.

[6] Fintech companies that offer these services to end users through such arrangements are sometimes referred to as ''neobanks'' or ''challenger banks.''

enter into a bank-fintech arrangement to offer ACH transactions, wire transfers, or settlement of payment services to end users. For example, a fintech company may enter into an arrangement with a bank to offer ACH services to its end users, such as sending or receiving funds via ACH transfers, which may take place through a bank sponsorship arrangement. Additionally, operators of digital platforms permitting the transmittal and exchange of funds between and among member participants [7] enter into bank-fintech arrangements to offer a range of payment options to end users of the platforms.

Under each of these arrangements, fintech companies also may provide a variety of additional services, including providing end users with personal finance and payment management tools, marketing the branded cards and payment services to end users, or assisting banks with underwriting for credit cards (sometimes using alternative data). Additionally, under each of these arrangements, banks may provide access to various services to or for end users, including card or account issuance, back-end fund-transfer and redemption operations support, access to proprietary electronic platforms, or bill payment services.

Many fintech companies enter these arrangements with banks in order to gain access to existing payment systems and card networks. In these types of structures, a bank may enter into an arrangement with the fintech company (such as a payments platform or a card processor) to ''sponsor'' the fintech company's access to one or more payment systems or card networks to facilitate the availability of specified payment options to end users in exchange for one-time and/or per-transaction fees. In this structure, operators of payment systems and card networks may permit fintech companies to conduct transactions on payment and card networks through the bank's sponsorship arrangements with the operator. Among other things, bank sponsorship may entail the partner bank agreeing with the operators of the payment and card networks to sponsor and pre-approve the proposed payment activities of the fintech company across the payment or card networks, to monitor the fintech company's operations for compliance with operator and relevant network rules, or to accept risk-of-loss liability in connection with transactions effectuated by the fintech company.

A bank that sponsors a fintech company's access to a payment system or card network for these purposes may establish an account for the fintech company at the bank for the acceptance and settlement of end-user payments, which may be effectuated in several different ways depending on the agreement between the fintech company and bank. For example, the bank may agree to open an account FBO the end users and use it to settle payment transactions. In some cases, the fintech may provide recordkeeping functions to facilitate the settlement of end-user transactions.

Several fintech companies have also entered into arrangements with banks in recent years to offer digital wallets, often in conjunction with associated payment applications (sometimes referred to as ''pay apps''). A digital wallet is a software application that permits end users to store card account or other payment credentials in encrypted or tokenized form so that end users may recall and transmit the stored credentials via a digital payment application at physical or digital points of sale. End users may rely on digital wallet functionality, used in combination with payment applications, to make in-person, contactless payments via their mobile devices (sometimes referred to as ''tap-to-pay''). Digital wallet functionalities also may assist end users in making online purchases through web and mobile applications. Some fintech companies make their digital wallets and associated payment applications available for limited use—for instance, to effectuate purchases with a single retailer or group of retailers. Others offer general use digital wallets and associated digital payment applications available to end users at a variety of participating points of sale.

In each case, fintech companies offering combined digital wallet and payment applications typically enter into arrangements with banks that issue the debit and credit cards that end users wish to include in their digital wallets. Many of the arrangements reflect standard terms governed by the payment systems and card networks. Other arrangements may require debit and credit card issuers to pay fintech companies per-transaction fees associated with the end users' reliance on the combined digital wallet and payment applications of the fintech companies.

Bank-Fintech Arrangements in Connection With Consumer and Small Business Lending

Bank-fintech arrangements can also facilitate loans through a fintech company's online platform. Fintech companies may market and distribute a variety of loan products, including those targeted to consumers, students, and small businesses.[8] Banks increasingly engage with fintech companies to access these lending markets. The parties to these arrangements in turn may be assigned to perform various core operational functions in connection with lending, including those relating to the processing, underwriting, closing, delivering, or servicing of loans.

In a typical arrangement, a partner bank agrees to facilitate and fund loans, while the fintech company solicits end users and collects application data. In some arrangements, end-user application data collected by the fintech company is used in the underwriting process within the parameters of underwriting standards agreed upon with the bank. Loans might be retained on the bank's balance sheet, or the loans (or a portion of the loans or an interest in the loan payment streams) might be sold to the fintech company. The fintech company may then securitize any acquired loans for subsequent re-sale into the public or private asset-backed securities markets, although the bank may retain an economic interest in the performance of the loans through a variety of contractual mechanisms. The fintech company or a fourth party often performs loan servicing and collection under these arrangements.

The Role of Intermediate Platform Providers

The growth of bank-fintech arrangements has spurred the development of a new business model whereby some fintech companies provide an intermediate technology platform—sometimes referred to as an ''aggregation layer''—to facilitate relationships between banks and other fintech companies that seek to distribute banking products and services directly

[7] These platforms are sometimes referred to as ''Peer-2-Peer,'' ''Business-2-Consumer,'' or ''Business-2-Business'' platforms.

[8] Such products may also include ''buy now, pay later'' (BNPL) lending, to the extent offered through a bank-fintech arrangement; however, BNPL offerings have to date typically been offered and distributed solely through either a bank, fintech company, or consumer retailer, rather than through a bank-fintech arrangement. BNPL generally refers to point-of-sale installment loans offered to end users that are payable in four or fewer installments, often concurrently with their purchase of non-financial goods and services. For additional information on BNPL, and the risks it may pose to banks, see *Retail Lending: Risk Management of 'Buy Now, Pay Later' Lending,* OCC Bulletin 2023–37 (Dec. 6, 2023).

to end users. These intermediate platform providers enable individual banks to connect to numerous fintech companies and serve the role of introducing banks and fintech companies seeking such relationships. Intermediate platform providers may also market these services together as an ''all-in-one'' solution for fintech companies and banks by providing technological, operational, and information services in one place, enabling fintech companies and banks to connect more seamlessly. An intermediate platform provider may also offer to assist fintech companies in implementing compliance risk management programs and in handling the transfer and flow of funds across deposit-taking, payments, card issuance, or lending activities.

Operators of intermediate platforms may enter into their own arrangements with banks and third parties to provide these services. These arrangements may involve a bank providing an intermediate platform provider with permission to transfer data via, for example, application programming interfaces (APIs). A single intermediate platform provider may have arrangements with multiple banks to provide such access or provide services to banks relating to operational, compliance, data, or other functions in connection with the banks' relationships with fintech companies or the platform provider itself.

Risk Implications

While bank-fintech arrangements may offer banks significant benefits, they also may present the full spectrum of risks facing banks, including, but not limited to, third-party, credit, liquidity, compliance, and operational risk. Risks may also be heightened where the fintech is the distributor of the banking product or service to the end user, or where the fintech or intermediate platform provider performs key functions, such as handling end-user complaints, performing customer identification and due diligence, developing and transmitting disclosures, monitoring transactions, maintaining end-user ledgers, performing certain lending-related activities, developing and deploying marketing materials, or directly communicating with end users.[9] Bank-fintech arrangements may also involve a wide range of practices to deliver banking products and services to end users through a combination of the fintech company's technological capabilities and the bank's infrastructure, including the ability to provide access to deposit accounts, access to payment rails, and extend credit. These facets of bank-fintech arrangements may create heightened or novel risks for banks relative to the risks associated with more traditional third-party vendor relationships. The following discussion of risks in bank-fintech arrangements is meant to be illustrative of certain select concerns and is not meant to be comprehensive.

Accountability

Contractual accountability for different aspects of the end-user relationship may be allocated among the parties to a bank-fintech arrangement. However, banks remain responsible for compliance with applicable law. Failure to conduct sufficient due diligence, ongoing monitoring, and oversight of the bank-fintech arrangement may complicate the bank's ability to ensure such compliance and to identify risk. In addition, contractual division of labor may complicate the bank's ability to establish clear lines of accountability, implement effective risk and compliance management strategies, and address and remediate issues as they arise, especially where novel arrangements place certain traditional banking activities outside of the bank. These factors may expose the bank to compliance, litigation, and other risks.

For example, in a bank-fintech arrangement, the fintech company may maintain the end-user relationship, including by interacting directly with end users, responding to inquiries and complaints, and providing required consumer protection and other disclosures. However, independent of contractual responsibilities, the end user may still qualify as a customer of the bank for certain regulatory purposes.[10] The bank also remains responsible for its various other compliance requirements, such as Anti-Money Laundering and Countering the Financing of Terrorism (AML/CFT) compliance program requirements.[11] Similarly, the fintech company's role in providing disclosures may increase the risk of inaccurate or misleading representations concerning, for example, the applicability, nature, or scope of Federal deposit insurance available to end users.[12] Such risks may be heightened where the fintech company controls the end-user relationship and uses the bank's name and branding in marketing or when an intermediate platform provider is used and further distances the bank from the end user.

Under certain bank-fintech arrangements, it may be difficult for the bank to perform oversight and control functions over the fintech company effectively where the fintech company has substantial negotiating power relative to the bank or where the bank relies on revenue or liquidity from the fintech company. Difficulty in performing this oversight and control function in turn could impede bank staff's ability to provide effective challenge to critical aspects of the bank-fintech relationship, including whether to terminate the contractual arrangement if necessary. These risks may be heightened where the fintech company is not familiar with or has a different risk tolerance concerning the specific requirements of the laws and regulations applicable to it,[13] the bank, or the products and services offered via the arrangement. These risks may be further heightened where an intermediate platform provider assists the fintech company in implementing risk management programs, such as compliance.

[9] A fintech company may also use subcontractors (referred to variously as ''nth-party risk,'' ''nested risk,'' or ''banking services supply chain risk'') in providing these services. Ineffectual oversight of subcontractors (including failure to properly account for subcontractors in the arrangement's business continuity plan) could result in material disruptions of the arrangement. *See generally* Interagency Guidance on Third-Party Relationships: Risk Management, 88 FR 37920 (Jun. 9, 2023).

[10] *See, e.g.,* 12 CFR 1016.3(i) (defining customer relationships for purposes of the Consumer Financial Protection Bureau's (CFPB) Regulation P); OCC (12 CFR part 30, App. B (I)(C)(2)(d); Board (12 CFR part 208, App. D–2 § I.C.2.d) FDIC (12 CFR part 364, App. B § I.C.2.d) (adopting Regulation P's definition of ''customer'' for the Interagency Guidelines Establishing Information Security Standards); 31 CFR 1020.100(b) (defining customer relationships for purposes of a bank's customer identification program).

[11] *See, e.g.,* suspicious activity reporting and BSA/AML program requirements for the OCC (12 CFR 21.11 and 21.21), Board (12 CFR 208.62 and 208.63), and FDIC (12 CFR 326.8 and part 353).

[12] *See, e.g.,* 12 U.S.C. 1828(a)(4); 12 CFR part 328, subpart B; FDIC, FIL–35–2022, ''Advisory to FDIC-Insured Institutions Regarding Deposit Insurance and Dealings with Crypto Companies'' (Jul. 29, 2022); *see also* 12 CFR 7.5010 (requiring banking organizations to distinguish products and services offered by it from those of a third party on co-branded websites and other shared electronic spaces). Even when the parties intend that the financial products or services will benefit from deposit insurance, application of Federal deposit insurance may be complicated in novel arrangements; 12 CFR 330.5, 330.7 (describing requirements for pass-through deposit insurance).

[13] The CFPB (for instance) possesses authority under 12 U.S.C. 5514 to engage in risk-based supervision of non-depository financial institutions participating in certain markets for consumer financial products and services. Fintech companies that are regulated as money services businesses are also subject to certain BSA/AML and state law requirements. *See, e.g.,* 31 CFR part 1022.

End-User Confusion

The fintech company's efforts to provide a seamless end-user experience could make it difficult for end users to know in what capacity they are dealing with the bank or the fintech company. In some cases, marketing materials or other statements by the fintech company or bank may exacerbate end-user confusion. For example, end users may not be well-informed regarding the type of account relationship that the end user is establishing through the fintech and may not understand that Federal deposit insurance does not protect them from a nonbank fintech company's failure. End-user confusion may also complicate compliance efforts and pose other risks to the bank. For example, an end user that is unaware of the bank's presence in the arrangement may direct complaints solely to the fintech company. The bank's ability to comply with its obligations under Federal consumer financial protection laws could be undermined if the fintech company fails to timely communicate to, or coordinate with, the bank on responses to consumer complaints.[14]

Rapid Growth

A bank may experience rapid growth as a result of engaging in a bank-fintech arrangement (*e.g.,* growth in deposits or transaction volume), especially in the case of a community bank. Various risks can emerge from rapid growth and the bank's changing risk profile, including risks that may threaten the bank's safety and soundness or its ability to comply with applicable laws and regulations.[15] These risks may arise from challenges such as appropriately scaling risk and compliance management systems, operational complexities, significant deposit growth, and insufficient capital to support the rapid growth, among other things.

For example, a bank's existing risk and compliance management systems, as well as management's and employees' expertise and roles and responsibilities, may neither be commensurate with the risk profile of the new business model nor be sufficiently scalable without significant investments in resources and training. Failure to scale compliance and risk management functions and resources with the growth resulting from the bank-fintech arrangement may increase the likelihood of the bank violating applicable laws and regulations, including those related to AML/CFT or sanctions, consumer protection, and fair lending.

Bank-fintech arrangements may also pose operational complexities, which may lead to increased risk. For example, potentially significant increases in the volume of payment processing may give rise to increased transaction monitoring alerts. In addition, depending on the integration of the bank's information technology systems with those of the fintech company, security vulnerabilities and other sources of operational disruption may arise, increasing the likelihood of data breaches, privacy incidents, service interruptions, and fraud.[16] In some cases, banks do not have or are unable to develop the infrastructure to adequately address these complexities, and instead rely on manual workarounds, which could lead to operational breakdowns that may implicate various other risks, including compliance and legal risks. These risks may be heightened where the bank-fintech arrangement involves an additional entity (*e.g.,* an intermediate platform provider).[17]

Rapid deposit growth related to a bank-fintech arrangement can also pose risks related to funds management. For example, a bank may need to invest an influx of short-term deposits that greatly exceed amounts the bank has traditionally managed. To the extent that deposits are used to fund growth in longer-term or higher-risk fixed-rate assets, including loans and securities, the bank may be exposed to greater liquidity, interest rate, or credit risk, especially when such investments are concentrated, or the risks are otherwise correlated. The bank may also experience increased liquidity stress should it need to meet material short-term withdrawal requests. Rapid deposit or asset growth also implicates various other risks, including those relating to maintaining sufficient capital to support expansion of the bank's business.[18]

Concentration and Liquidity Management

Bank-fintech arrangements may also result in the bank's business becoming highly concentrated in the arrangement. This concentration risk may amplify other risks to the bank, including from any market stresses or if deposits are used to fund longer-term assets. For example, in a rising interest rate environment, a bank-fintech arrangement involving loan products may see a reduction in originations. This reduction may pose particular risk to a bank whose business has become heavily concentrated in that arrangement and that, as a result, relies on those originations for a material portion of its earnings. Such an environment may increase the bank's exposure to credit risk from the arrangement (*e.g.,* the credit risk of the fintech company or of loans originated under the arrangement, whether still on the bank's balance sheet or for which the bank retains any contractual interest, even if repurchased by the fintech company). Such an environment may also lead to an increase in the credit risk of a bank's overall retail loan portfolio.[19]

Bank-fintech arrangements may also pose liquidity risks if the bank fails to establish adequate liquidity contingency plans and exit strategies, particularly when arrangements represent a funding concentration. An arrangement may be terminated or reduced in amount for any number of reasons, including those over which the bank has little control, and which may result in significant stress on a bank. For example, if the fintech partner or an intermediate platform provider in a deposit-taking bank-fintech arrangement faces a stress event or terminates the contractual arrangement, that could lead to a large withdrawal of end-user-related deposits, resulting in liquidity stress and losses for the bank. Failure to establish adequate liquidity contingency plans and exit strategies could also increase operational and strategic risks for the bank.

[14] For example, the bank's ability to comply with its dispute and error resolution obligations or undertake its risk monitoring capabilities could be impaired.

[15] *See* OCC Bulletin 2017–43, *New, Modified, or Expanded Bank Products and Services: Risk Management Principles* (Oct. 20, 2017) for a general discussion of these risks.

[16] Integration could also introduce security vulnerabilities, including by providing another access point into the bank's systems. Integration may amplify operational risks, such as fraud, cybersecurity, and data privacy incidents occurring at the fintech company that then affect the bank.

[17] The growing prevalence of nested relationships may materially alter the traditional third-party risks present, complicating the bank's ability to provide effective oversight to the arrangement. This is especially so if the additional entity may be contractually allowed to add operating partners or subcontractors without the bank's prior consent. *See* ''Interagency Guidance on Third-Party Relationships,'' *supra* note 9, for more.

[18] Additionally, to the extent that a fintech company meets the definition of a deposit broker under 12 CFR 337.6, any related deposits would be brokered deposits subject to applicable restrictions if the bank becomes less than well capitalized under the prompt corrective action provisions of the agencies' capital rules.

[19] These risks may be heightened where the arrangement results in the bank's risk profile becoming more correlated to or concentrated in a particular market segment or asset type, either directly through its exposure to certain products, or indirectly through its exposure to the fintech company.

Use and Ownership of Data and Customer Information

Bank-fintech arrangements often rely on new, innovative, and potentially untested uses of data to expand or enhance access to financial services, which may in turn lead to risks related to compliance with laws and regulations, operational challenges, and the ownership, use, and nature of that data. For instance, a bank-fintech arrangement may be premised on underwriting credit using alternative data. Introducing alternative data into a bank's existing systems may pose risks. These include, for example, risks related to the bank's ability to address concerns associated with alternative data and its use (including as to accuracy and biases) and to incorporate alternative data types and formats into its information technology systems, credit risk modeling capabilities, and compliance management systems.[20]

Data ownership and use questions may also create risks for the bank. For instance, the fintech company may attempt to limit the bank's access to data generated as part of the arrangement if the fintech company views the data as its proprietary information. Other issues related to data ownership and use may arise where banks are required by law to limit the fintech company's access to and use of certain data. For example, banks are restricted in the sharing, use, and disposal of end user nonpublic information, and end users may have opt-out rights, which could pose operational difficulties and compliance risks.[21] Therefore, the bank may require information on the bank-fintech arrangement's end users to meet its own compliance obligations, including, but not limited to, those related to recordkeeping, AML/CFT or sanctions, fair lending, or state escheatment statutes or regulations. This requirement for information may arise even where the bank lacks a direct relationship with end users or where they are not named account holders with the bank.[22] As discussed in more detail above, these risks may be heightened where aspects of the end-user relationship or compliance-related activities are contractually allocated among multiple entities (*e.g.,* intermediate platform providers).

Request for Comment

In this RFI, the agencies are inviting interested members of the public to comment on the descriptions of bank-fintech arrangements and risks summarized in the document. The agencies are also seeking comment on effective practices for managing these risks. Where questions ask for the ''range of practices,'' respondents are encouraged to describe the practices' advantages and disadvantages.

Bank-Fintech Arrangement Descriptions

1. Do the descriptions and categorizations in this RFI adequately describe the types of bank-fintech arrangements in the industry and the companies involved? If not, why? Are the descriptions or categorizations overly broad or narrow, or are there any types of companies or categories of arrangements missing from the descriptions?

2. Are there any benefits of bank-fintech arrangements that are not addressed by this RFI? What benefits do the bank or the fintech company receive by using an intermediate platform provider?

3. Describe the range of practices regarding banks' use of data [23] to monitor risk, ensure compliance with regulatory responsibilities and obligations, or otherwise manage bank-fintech arrangements. What data and information do banks typically receive in bank-fintech arrangements, including in those involving intermediate platform providers? To what extent is this information different from the information banks would receive when interacting with end users independent of fintech companies? What challenges have banks experienced in bank-fintech arrangements—including those involving intermediate platform providers—related to the timely access to customer information, and what steps have the parties to bank-fintech arrangements taken to assess potential compliance issues associated with such challenges?

4. How do the parties to bank-fintech arrangements determine the end user's status as a customer of the bank, the fintech company, or both, including for purposes of compliance with applicable laws and regulations, and each party's responsibility in complying with contractual requirements? What disputes or uncertainties regarding the status of end users have the parties experienced, and how have they sought to resolve them? How does the type of arrangement impact such determinations?

5. Describe the range of practices regarding the use of a core bank service provider or other third-party providers in bank-fintech arrangements. How do these providers help or hinder bank-fintech arrangements?

6. Describe the range of practices in cases where bank-fintech arrangements involve affiliates of the bank, including fintechs. What are the benefits and risks of these arrangements?

7. Bank-fintech arrangements can involve significant up-front and ongoing costs and resources for the bank involved and may take some time to recoup these costs and resources. What type of up-front and ongoing costs and resources are associated with establishing bank-fintech arrangements? Describe the range of practices regarding how a bank factors such upfront costs and resources into its overall strategy and risk management strategy. Describe the range of practices regarding how revenues and costs resulting from these arrangements are allocated between the bank and fintech company.

Risk and Risk Management

1. Describe the range of practices for maintaining safety and soundness, and compliance with applicable laws and regulations arising from bank-fintech arrangements. How do the practices differ as between different categories of arrangements? Does the RFI adequately identify and describe the potential risks of bank-fintech arrangements?

2. Bank-fintech arrangements can present unique or heightened consumer protection risks, such as risks of discrimination, unfair or deceptive acts or practices under the Federal Trade Commission Act, or privacy concerns. Describe the range of practices for managing any heightened risks.

3. Describe the range of practices parties to a bank-fintech arrangement may use in contractually allocating functions among themselves, including the advantages and disadvantages of each such practice. For example, while the parties to such arrangements remain responsible for their own compliance with applicable laws and regulations, as a matter of contractual allocation, who performs which activities related to risk and compliance management, customer identification and due diligence,

[20] For example, alternative datasets that impact credit decisions could potentially create or heighten consumer protection risks, such as unlawful discrimination in lending.

[21] *See* Title V, subtitle A of the Gramm-Leach Bliley Act, Public Law 106–102, 113 Stat. 1338, codified in relevant part at 15 U.S.C. 6801 *et seq.,* implemented at OCC (12 CFR part 30 Appendix B, including Supplement A), Board (12 CFR part 208 Appendix D–2, including Supplement A), FDIC (12 CFR part 364 (Appendix B, including Supplement A), and 12 CFR part 1016 (Regulation P).

[22] *See, e.g.,* suspicious activity reporting and BSA/AML program requirements for the OCC (12 CFR 21.11 and 21.21), Board (12 CFR 208.62 and 208.63), and FDIC (12 CFR 326.8 and part 353). *See also supra* note 10 and accompanying text.

[23] For example, key performance indicators, product-level data, service levels, end-user information, key risk indicators, consumer complaints, fraud monitoring metrics, or KYC/CIP information.

transaction monitoring, sanctions screening, fraud monitoring, end-user complaint management, dispute resolution, data protection, or credit underwriting, if applicable? Who develops and oversees marketing materials, develops and provides disclosures and account statements, addresses errors, receives and resolves disputes, and responds to complaints? How are contractual breaches and indemnifications typically addressed in these types of arrangements? Describe the range of practices for monitoring compliance with applicable laws and regulations, notwithstanding contractual allocations.

4. How are risks resulting from these arrangements, including those concerning credit, liquidity, concentration, compliance, and operational risk, as well as concerns regarding negative end-user experience managed? What techniques or strategies are most effective in managing the impact of rapid growth, particularly related to deposit-taking and payment-related arrangements?

5. Describe the range of risk management strategies banks and fintech companies use to ensure that required disclosures in bank-fintech arrangements, including those relating to rates and fees associated with end-user banking products and services, are accurately and plainly communicated, and comply with all relevant state and Federal laws and regulations.

6. Describe the range of practices regarding disclosures (*e.g.,* initial, annual, or ongoing) to end users about the involvement of bank-fintech arrangements in the delivery of banking products and service.

7. Describe the range of practices regarding the use of an intermediate platform provider. Describe how the use of an intermediate platform provider may amplify or mitigate risk, and to what extent, if any, intermediate platform providers influence how banks handle operational, compliance, or other issues when dealing with fintech companies within the intermediate platform provider's network.

8. Describe the range of practices regarding how banks manage the risks of connecting to multiple technology platforms and exchanging data in bank-fintech arrangements.

9. Describe the range of practices regarding planning for when a fintech company or intermediate platform provider exits an arrangement, faces a stress event, or experiences a significant operational disruption, such as a cyber-attack. Describe the range of practices regarding how arrangements are structured to minimize harm to end users, meet compliance requirements, and minimize liquidity risks and other risks in the event of such exits, stresses, or disruptions.

10. Describe the range of practices, and challenges, in negotiating contracts with, or conducting due diligence on fintech companies. Describe the range of practices in maintaining ongoing monitoring of bank-fintech arrangements, particularly related to risk management, regulatory compliance, data ownership and use, and information security assessment rights. What impact, if any, does the size and negotiating power of the bank or the fintech company have on these issues? What impact, if any, does the fintech company's or intermediary platform provider's degree of control of operational functions have on these issues? What impact, if any, does bank liquidity or revenues concentration represented by any particular fintech company, intermediary platform provider, or business line have on these issues?

11. Bank-fintech arrangements may involve processing payments transactions unrelated to any specific deposit-taking or credit offering in significant volumes. Describe the range of practices that banks adopt to manage potential risks associated with processing large volumes of otherwise unaffiliated payments transactions. Do banks view bank-fintech arrangements involving such processing differently from other payments-related products and services offered to end users?

12. How do banks ensure bank-fintech arrangements can be suspended or terminated based upon safety and soundness, compliance, or consumer protection concerns? What fees or other costs are typically involved in exiting these arrangements?

13. Are there other techniques or strategies that banks use to manage the various risks bank-fintech arrangements may present? Which of these techniques or strategies are most effective in managing such risks?

14. In the context of bank-fintech arrangements, how are deposit accounts usually titled? Describe the range of practices reconciling bank deposit account records with the fintechs' records. Generally, what party holds and maintains the account records? Describe the structure in place to exchange accurate customer information between the bank and the fintech company and how the agreements between banks and fintech companies generally address these matters. Describe any additional controls, that banks or fintechs may use to provide for accurate reconciliations.

15. Describe the range of practices regarding the maintenance of systems of records and account titling in the context of bank-fintech arrangements. Do certain account structures pose greater risk considerations to banks and end users than others? What additional controls, if any, do banks or fintechs place on these accounts to manage these risks?

16. To what extent would additional clarifications or further guidance be helpful to banks with respect to bank-fintech arrangements? If so, please explain. In what specific areas would additional clarification or further guidance be most helpful?

Trends and Financial Stability

1. What data would be helpful for the agencies in monitoring developments regarding bank-fintech arrangements? For example, this might include data to assist in monitoring developments and trends in bank-fintech arrangement structures and use cases, concentrations, and the number and types of bank-fintech arrangements in the financial services industry.

2. In what ways do or can bank-fintech arrangements support increased access to financial products and services? Alternatively, in what ways do or can these arrangements disadvantage end users?

3. In what ways might bank-fintech arrangements function as transmission mechanisms to amplify financial shocks (*i.e.,* threaten financial stability)? Conversely, how could these arrangements help to contain shocks and reduce contagion?

4. What factors are important in determining whether bank-fintech arrangements support or hinder responsible innovation and a competitive and compliant financial services landscape?

Michael J. Hsu,

Acting Comptroller of the Currency.

By order of the Board of Governors of the Federal Reserve System.

Ann E. Misback,

Secretary of the Board.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on July 23, 2024.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2024–16838 Filed 7–30–24; 8:45 am]

BILLING CODE 4810–33–P; 6210–01–P; 6714–01–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Departmental Offices Information Collection Requests

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice of information collection; request for comment.

SUMMARY: The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

DATES: Comments should be received on or before August 30, 2024 to be assured of consideration.

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

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Spencer W. Clark by emailing *PRA@treasury.gov,* calling (202) 927–5331, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

1. Title: Treasury International Capital Form SLT, ''Aggregate Holdings, Purchases and Sales, and Fair Value Changes of Long-Term Securities by U.S. and Foreign Residents''.

OMB Control Number: 1505–0235.

Type of Review: Extension without change of a currently approved collection.

Description: Form SLT is part of the Treasury International Capital (TIC) reporting system, which is required by law (22 U.S.C. 286f; 22 U.S.C. 3103; E.O. 10033; 31 CFR part 128) for the purpose of providing timely information on international capital movements. Form SLT is used to collect monthly data on cross-border ownership by U.S. and foreign residents of long-term securities, purchases and sales of long-term securities, and changes in fair value of long-term securities, for portfolio investment purposes. These data are used by the U.S. Government in the formulation of international and financial policies and for the preparation of the U.S. balance of payments accounts and the U.S. international investment position. Form SLT is filed by U.S.-resident custodians, U.S.-resident issuers of long-term securities, and U.S.-resident end-investors (including endowments, foundations, pension funds, mutual funds, and other investment managers/advisors/sponsors) in long-term foreign securities.

Form: Treasury International Capital Form SLT.

Affected Public: Businesses or other for-profits, Not-for-profit Institutions.

Estimated Number of Respondents: 429.

Frequency of Response: Monthly.

Estimated Total Number of Annual Responses: 5,148.

Estimated Time per Response: 14.5 hours.

Estimated Total Annual Burden Hours: 74,882.

2. Title: Coronavirus State and Local Fiscal Recovery Funds Program.

OMB Control Number: 1505–0271.

Type of Review: Revision of a currently approved collection.

Description: Sections 602 and 603 of the Social Security Act (the ''Act''), as added by section 9901 of the American Rescue Plan Act of 2021, Public Law 117–2 (Mar. 11, 2021) authorized the Coronavirus State Fiscal Recovery Fund (''CSFRF'') and Coronavirus Local Fiscal Recovery Fund (''CLFRF'') respectively (referred to as the ''Coronavirus State and Local Fiscal Recovery Funds'' or ''SLFRF''). The SLFRF provided $350 billion in total funding for the U.S. Department of the Treasury (''Treasury'') to make payments to States (defined to include the District of Columbia), U.S. Territories (defined to include Puerto Rico, U.S. Virgin Islands, Guam, Northern Mariana Islands, and American Samoa), Tribes, Metropolitan cities, Counties, Consolidated Governments, and (through States) Non-entitlement units of local government (collectively the ''eligible entities'') to (1) respond to the COVID–19 public health emergency or its negative economic impacts, including providing assistance to households, small business, nonprofits, and impacted industries, such as tourism, travel, and hospitality; (2) respond to workers performing essential work during the COVID–19 pandemic by providing premium pay to eligible workers of the State, U.S. Territory, Tribal government, Metropolitan city, County, or Non-entitlement units of local government who are performing essential work or by providing grants to eligible employers that have eligible workers; (3) provide of government services, to the extent COVID–19 caused a reduction of revenues collected in the most recent full fiscal year of the State, U.S. Territory, Tribal government, Metropolitan city, County, or Non-entitlement units of local government; or (4) make necessary investments in water, sewer, or broadband infrastructure, (5) provide emergency relief from natural disasters or the negative economic impacts of natural disasters including temporary emergency housing, food assistance, financial assistance for lost wages, and other immediate needs; (6) use funds for projects eligible under 26 programs administered by the Department of Transportation (''Surface Transportation projects''), or (7) use funds for projects eligible under Title I of the Housing and Community Development Act of 1974 (''Title I projects'').

Title I projects require the implementing recipients to submit to Treasury a National Environmental Review Act (NEPA) Environmental Certification form under certain circumstances. This form can be found on the Treasury website.

To administer the SLFRF program, a Project and Expenditure (P&E) Report is required to be submitted by recipients quarterly or annually based on their ''reporting tier'' provided in the Compliance and Reporting Guidance. The first quarterly reports were due January 31, 2022 for certain recipients. The first annual reports were due April 30, 2022. The P&E Report has been updated periodically to accommodate new reporting needs corresponding to updated program guidance offered through interim final rules (IFRs) and frequently asked questions (FAQs) and will be continuously updated throughout the program's period of performance. Existing and anticipated future updates are reflected in the estimated time per response for reporting.

Final program reports will be due in accordance to guidelines established in *2 CFR 200.344,* and property, real property, and equipment disposition procedures must be followed in accordance with 2 CFR 200.311, 200.313, and 200.314, as well as in accordance with additional guidance issued by Treasury.

Form: Award and Payment Forms and associated forms; Annual Recovery Performance Plan and Distribution Templates; Annual and Quarterly Project and Expenditure Reports, National Environmental Protection Act (NEPA) Review Certification Form for Title I projects, disposition and

associated forms, and the Impact Story submission form.

Affected Public: State, Territorial, Tribal, and certain Local Governments.

Estimated Number of Respondents: 30,000.

Frequency of Response: As required.

Estimated Total Number of Annual Responses: 82,874.

Estimated Time per Response: 15 minutes to 1 hour for Award and Payment forms, up to 100 hours for Annual Recovery Plan Performance Reports, up to 15 hours for annual and quarterly Project and Expenditure Reports, up to 2 hours for Title I NEPA Environmental Reviews, and up to 1 hour for optional impact story submissions, in addition to time spent on previously collected items.

Estimated Total Annual Burden Hours: 628,494.

Authority: 44 U.S.C. 3501 *et seq.*

Spencer W. Clark,

Treasury PRA Clearance Officer.

[FR Doc. 2024–16865 Filed 7–30–24; 8:45 am]

BILLING CODE 4810–AK–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Internal Revenue Service (IRS) Information Collection Requests

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

DATES: Comments should be received on or before August 30, 2024 to be assured of consideration.

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

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Melody Braswell by emailing *PRA@treasury.gov,* calling (202) 622–1035, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Internal Revenue Service (IRS)

1. Title: Payout Requirements for Type III Supporting Organizations that are not Functionally Integrated.

OMB Number: 1545–2157.

Regulation Project Number: TD 9605.

Abstract: This document contains final regulations regarding the requirements to qualify as a Type III supporting organization that is operated in connection with one or more supported organizations. The regulations reflect changes to the law made by the Pension Protection Act of 2006. The regulations will affect Type III supporting organizations and their supported organizations.

Current Actions: There is no change in the paperwork burden previously approved by OMB. However, the estimated number of responses were updated based on current filing data.

Type of Review: Extension of a currently approved collection.

Affected Public: Not-for-profit institutions, State, local or Tribal governments.

Estimated Number of Respondents: 6,089.

Estimated Time per Respondent: 2 hours.

Estimated Total Annual Burden Hours: 12,178.

2. Title: Limited Payability Claim Against the United States for Proceeds of An Internal Revenue Refund Check.

OMB Number: 1545–2024.

Document Number: 13818.

Abstract: Form 13818, *Limited Payability Claim Against the United States for the Proceeds of an Internal Revenue Refund Check,* is sent to the payee (taxpayer). This form is designed to provide taxpayers a method to file a claim for a replacement check when the original check is over 12 months old.

Current Actions: There are no changes to the burden previously approved by OMB. This request is to extend the current approval for another 3 years.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households, Businesses, and other for-profit organizations.

Estimated Number of Respondents: 6,000.

Estimated Time per Respondent: 1 hr.

Estimated Total Annual Burden Hours: 6,000.

3. Title: U.S. Information Return-Trust Accumulation of Charitable Amounts.

OMB Number: 1545–0094.

Form Number: 1041–A.

Abstract: Form 1041–A is used to report the information required in Internal Revenue Code section 6034 concerning accumulation and distribution of charitable amounts. Trusts claiming a contributions deduction under section 642(c) or split-interest trusts described in section 4947(a)(2) use Form 1041–A to report information required by section 6034.

Current Actions: There are changes (reduction in filers) in the paperwork burden previously approved by OMB. The Tax Cuts and Jobs Act of 2017 (Pub. L. 115–97) amended section 641(c)(2). As a result, Electing Small Business Trusts (ESBTs) are no longer subject to the charitable information reporting requirements under section 6034 and do not file Form 1041–A. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit organizations, and individuals.

Estimated Number of Respondents: 6,700.

Estimated Time per Respondent: 36 hours, 40 minutes.

Estimated Total Annual Burden Hours: 245,622.

4. Title: Information Reporting Requirements under Code sec. 6039.

OMB Number: 1545–2129.

Document Number: Forms 3921 and 3922.

Abstract: Form 3921 is a copy of the information return filed with the Internal Revenue Service by the corporation which transferred shares of stock to a recipient. Form 3922 is used by the corporation to record a transfer of the legal title of a share of stock acquired by the employee where the stock was acquired pursuant to the exercise of an option described in Internal Revenue Code section 423(c). Treasury Decision 9470 contains the final regulations relating to the return and information statement requirements under Internal Revenue Code section 6039. These regulations reflect changes to section 6039 made by section 403 of the Tax Relief and Health Care Act of 2006.

Current Actions: There are no changes to the burden previously approved by OMB. This request is to extend the current approval for another 3 years.

Type of Review: Extension of a currently approved collection.

Affected Public: Business and other for-profit organizations.

Estimated Number of Respondents: 6,676,894.

Estimated Time per Respondent: 25 min.

Estimated Total Annual Burden Hours: 1,457,411.

5. Title: Product Liability Losses and Accumulations for Product Liability Losses.

OMB Number: 1545–0863.

Regulation Project Number: T.D. 8096.

Abstract: T.D. 8096 provides final regulations relating to product liability losses and accumulations for the payment of reasonable anticipated product liability losses. Changes to the applicable tax law were made by the Revenue Act of 1978. Generally, a taxpayer who sustains a product liability loss must carry the loss back 10 years. However, a taxpayer may elect to have such loss treated as a regular net operating loss under section 172. If desired, such election is made by attaching a statement to the tax return. This statement will enable the IRS to monitor compliance with the statutory requirements.

Current Actions: There is no change to this existing regulation or to the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 5,000.

Estimated Time per Respondent: 30 minutes.

Estimated Total Annual Burden Hours: 2,500.

6. Title: Low-Income Housing Credit Agencies Report of Noncompliance or Building Disposition.

OMB Number: 1545–1204.

Form Number: 8823.

Abstract: Under Internal Revenue Code section 42(m)(1)(B)(iii), state housing credit agencies are required to notify the IRS of any building disposition or noncompliance with the low-income housing tax credit provisions. A separate form must be filed for each building that is not in compliance. The IRS uses this information to determine whether the low-income housing credit is being correctly claimed and whether there is any credit recapture.

Current Actions: There are no changes being made to the form at this time, changes to the burden estimates are due to IRS most current filing data.

Type of Review: Extension of a currently approved collection.

Affected Public: State or local government housing credit agencies.

Estimated Number of Respondents: 14,474.

Estimated Time per Respondent: 15.16 hours.

Estimated Total Annual Burden Hours: 219,426.

7. Title: Refunds and Credits; Periods of Limitations; Financial Disability.

OMB Number: 1545–1649.

Revenue Procedure: Revenue Procedure 99–21.

Abstract: Generally, under section 6511(a), a taxpayer must file a claim for credit or refund of tax within three years after the date of filing a tax return or within two years after the date of payment of the tax, whichever period expires later. Under section 6511(h), the statute of limitations on claims for credit or refund is suspended for any period of an individual taxpayer's life during which the taxpayer is unable to manage his or her financial affairs because of a medically determinable mental or physical impairment, if the impairment can be expected to result in death, or has lasted (or can be expected to last) for a continuous period of not less than 12 months.

Current Actions: There is no change in the paperwork burden previously approved by OMB. The revenue procedure is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 48,200.

Estimated Time per Response: 30 minutes.

Estimated Total Annual Burden Hours: 24,100.

8. Title: Statement of Liability of Lender, Surety, or Other Person for Withholding Taxes.

OMB Number: 1545–2254.

Form Number: Form 4219.

Abstract: Third parties who directly pay another's payrolls can be held liable for the full amount of taxes required to be withheld but not paid to the Government (subject to the 25% limitation). IRC 3505 deals with persons who supply funds to an employer for the purpose of paying wages. The notification that a third party is paying or supplying wages will usually be made by filing of the Form 4219, Statement of Liability of Lender, Surety, or Other Person for Withholding Taxes. The Form 4219, Statement of Liability of Lender, Surety, or Other Person for Withholding Taxes, is to be submitted and associated with each employer and for every calendar quarter for which a liability under section 3505 is incurred.

Current Actions: There have been no changes to the form that would affect burden.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profit organizations, Not-for-profit institutions, Farms, Federal Government, State, Local, or Tribal Government.

Estimated Number of Respondents: 1,000.

Estimated Time per Respondent: 12 hours, 50 minutes.

Estimated Total Annual Burden Hours: 12,833.

9. Title: Itemized Statement Component of Advisee List.

OMB Number: 1545–1686.

Form Number: Form 13976.

Abstract: Internal Revenue Code (IRC) Section 6112, (as amended by the American Jobs Creation Act of 2004, Pub. L. 108–357), requires that each material advisor with respect to any reportable transaction shall maintain (in such manner as the Secretary may by regulations prescribe) a list identifying each person with respect to whom the advisor acted as a material advisor. Form 13976, Itemized Statement Component of Advisee List, may be used by Material Advisors for the purpose of preparing and maintaining list with respect to reportable transaction under section 6112, but the form is not required to be used under 301.6112–1, but is offered as an option for maintaining the transaction participants list.

Current Actions: There is no change to the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, individuals or households, and not-for-profit institutions.

Estimated Number of Respondents: 500.

Estimated Time per Respondent: 100.

Estimated Total Annual Burden Hours: 50,000 hours.

10. Title: Information Reporting by Passport Applicants.

OMB Number: 1545–1359.

Regulation Number: T.D. 9679.

Abstract: These final regulations provide information reporting rules for certain passport applicants. These final regulations apply to certain individuals applying for passports (including renewals) and provide guidance to such individuals about the information that must be included with their passport application.

Current Actions: There is no change to the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 12,133,537.

Estimated Time per Response: 6 minutes.

Estimated Total Annual Burden Hours: 1,213,354 hours.

11. Title: Manufacturers Excise Taxes on Sporting Goods and Firearms and Other Administrative Provisions of Special Application to Manufacturers and Retailers Excise Taxes Reporting and Recordkeeping Requirements.

OMB Number: 1545–0723.

Regulation Project Number: T.D. 8043.

Abstract: Chapters 31 and 32 of the Internal Revenue Code impose excise taxes on the sale or use of certain articles. Code section 6416 allows a credit or refund of the tax to manufacturers in certain cases. Code sections 6420, 6421, and 6427 allow credits or refunds of the tax to certain users of the articles. This regulation contains reporting and recordkeeping requirements that enable the IRS and taxpayers to verify that the proper amount of tax is reported or excluded.

Current Actions: There is no change in the paperwork burden previously approved by OMB. The regulation is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit or not-for-profit institutions.

Estimated Number of Respondents: 1,500,000.

Estimated Time per Response: 19 minutes.

Estimated Total Annual Burden Hours: 475,000.

12. Title: Guidance under Sections 897, 1445, and 6109 to require use of Taxpayer Identifying Numbers on Submission under the Section 897 and 1445.

OMB Number: 1545–1797.

Document Number: TD 9082, TD 9751.

Abstract: The collection of information relates to applications for withholding certificates under section 1.1445–3 to be filed with the IRS with respect to (1) dispositions of U.S. real property interests that have been used by foreign persons as a principle residence within the prior 5 years and excluded from gross income under section 121 and (2) dispositions of U.S. real property interests by foreign persons in deferred like kind exchanges that qualify for nonrecognition under section 1031.

Current Actions: There are no changes to the burden previously approved by OMB. This request is to extend the current approval for another 3 years.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households and Business or other for-profit.

Estimated Number of Respondents: 50.

Estimated Time per Respondent: 2 hrs.

Estimated Total Annual Burden Hours: 100.

13. Title: Claim for Refund and Request for Abatement.

OMB Number: 1545–0024.

Form Number: 843.

Abstract: Internal Revenue Code section 6402, 6404, and sections 301.6402–2, 301.6404–1, and 301.6404–3 of the regulations allow for refunds of taxes (except income taxes) or refund, abatement, or credit of interest, penalties, and additions to tax in the event of errors or certain actions by the IRS. Form 843 is used by taxpayers to claim these refunds, credits, or abatements.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, individuals or households, not-for-profit institutions, farms, and State, local or Tribal governments.

Estimated Number of Responses: 550,500.

Estimated Time per Respondent: 1 hr., 35 min.

Estimated Total Annual Burden Hours: 875,295.

14. Title: Disclosure of Tax Return Information for Purposes of Quality or Peer Reviews, Due to Incapacity or Death of Tax Return Preparer.

OMB Number: 1545–1209.

Regulation Project Number: TD 8383.

Abstract: These regulations govern the circumstances under which tax return information may be disclosed for purposes of conducting quality or peer reviews, and disclosures that are necessary because of the tax return preparer's death or incapacity.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 250,000.

Estimated Time per Respondent: 1 hour.

Estimated Total Annual Burden Hours: 250,000.

15. Title: Application for Determination of Employee Stock Ownership Plan (ESOP).

OMB Number: 1545–0284.

Form Number: 5309.

Abstract: Internal Revenue Code section 404(a) allows employers an income tax deduction for contributions to their qualified deferred compensation plans. Form 5309 is used to request an IRS determination letter about whether the plan is qualified under Code section 409 or 4975(e)(7).

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 3,655.

Estimated Time per Respondent: 10 hours, 47 minutes.

Estimated Total Annual Burden Hours: 39,437.

16. Title: Special Rules and Certificate of Partner-Level Items to Reduce Section 1446 Withholding.

OMB Number: 1545–1934.

Regulation and Form Number: T.D. 9394 and Form 8404–C.

Abstract: T.D. 9394 contains final regulations regarding when a partnership may consider certain deductions and losses of a foreign partner to reduce or eliminate the partnership's obligation to pay withholding tax under section 1446 on effectively connected taxable income allocable under section 704 to such partner. Form 8804–C is used by a foreign partner that voluntary submit to the partnership if it chooses to provide a certification that could reduce or eliminate the partnership's withholding tax obligation under section 1446 (1446 tax) on the partner's allocable share of effectively connected income (ECTI) from the partnership.

Current Actions: There is no change to the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profit organizations, Individuals or Households, and Not-for-Profit Organizations.

Form 8804–C

Estimated Number of Respondents: 1,000.

Estimated Time per Response: 18.7 hours.

Estimated Total Annual Burden Hours: 18,700 hours.

17. Title: Electronic Deposit of Tax Refund of $1 Million of More.

OMB Number: 1545–1763.

Form Number: Form 8302.

Abstract: Form 8302 is used to report an electronic deposit of a tax refund of $1 millon or more directly into an account at any U.S. bank or other

financial institution that accepts electronic deposits.

Current Actions: There is no change to the existing collection. However, the estimated number of responses was updated based on current filing data.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Responses: 160.

Estimated Time per Respondent: 1 hours, 42 minutes.

Estimated Total Annual Burden Hours: 272.

18. Title: Electronic Filing of Form W–4.

OMB Number: 1545–1435.

Regulation Number: T.D. 8706.

Abstract: Information is required by the Internal Revenue Service to verify compliance with regulation section 31.3402(f)(2)–1(g)(1), which requires submission to the Service of certain withholding exemption certificates. The affected respondents are employers that choose to make electronic filing of Forms W–4 available to their employees.

Current Actions: There is no change to the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, not for-profit institutions, and Federal, State, local or Tribal governments.

Estimated Number of Respondents: 2,000.

Estimated Number of Responses: 160,000.

Estimated Time per Response: 15 minutes.

Estimated Total Annual Burden Hours: 40,000 hours.

19. Title: Cancellation of Debt.

OMB Number: 1545–1424.

Form Number: 1099–C.

Regulation Project Number: TD 9793.

Abstract: This form is used by Federal Government agencies, financial institutions, and credit unions to report the cancellation or forgiveness of a debt of $600 or more, as required by section 6050P of the Internal Revenue Code. The IRS uses the form to verify compliance with the reporting rules and to verify that the debtor has included the proper amount of canceled debt in income on his or her income tax return.

TD 9793

Abstract: These regulations under section 6050P of the Internal Revenue Code (Code), relating to the rule in § 1.6050P–1(b)(2)(iv) that the 36-month non-payment testing period is an identifiable event triggering an information reporting obligation on Form 1099–C for discharge of indebtedness by certain entities.

Current Actions: There are no changes being made to the form or regulation at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, not-for-profit institutions, and the Federal Government.

Estimated Number of Responses: 6,540,900.

Estimated Time per Response: 13 minutes.

Estimated Total Annual Burden Hours: 1,438,998.

20. Title: Credit for Increasing Research Activities.

OMB Number: 1545–0619.

Form Number: 6765.

Abstract: Internal Revenue Code section 38 allows a credit against income tax (Determined under IRC section 41) for an increase in research activities in a trade or business. Form 6765 is used by businesses and individuals engaged in a trade or business to figure and report the credit. The data is used to verify that the credit claimed is correct.

Current Actions: There is no change to the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, individuals, and not-for-profit institutions.

Estimated Number of Respondents: 15,805.

Estimated Time per Respondent: 18 hours, 3 minutes.

Estimated Total Annual Burden Hours: 285,281 hours.

21. Title: Request for Change in Plan/Trust Year (Form 5308).

OMB Number: 1545–0201.

Form Number: Form 5308.

Abstract: Form 5308 is used to request permission to change the plan or trust year for a pension benefit plan. The information submitted is used in determining whether IRS should grant permission of the change.

Current Actions: There is no change to the existing collection. However, the time per respondent was recalculated for a better estimate.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Responses: 3.

Estimated Time per Respondent: 7 hours, 54 minutes.

Estimated Total Annual Burden Hours: 24.

22. Title: Treaty-Based Return Position Disclosure.

OMB Number: 1545–1354.

Document Number: 8833.

Abstract: Revenue Procedure 2010–19 provides guidance for individuals who emigrate from Canada and wish to make an election for U.S. federal income tax purposes. Form 8833 is used by taxpayers to make the treaty-based return position disclosure required by section 6114.

Current Actions: There are no changes to the burden previously approved by OMB. This request is to extend the current approval for another 3 years.

Type of Review: Extension of a currently approved collection.

Affected Public: Business and other for-profit organizations.

Estimated Number of Respondents: 4,100.

Estimated Time per Respondent: 7 hrs., 25 min.

Estimated Total Annual Burden Hours: 25,740.

23. Title: Continuation Coverage Requirements Application to Group Health Plans.

OMB Number: 1545–1581.

Regulation Number: REG–209485–86 (TD 8812).

Abstract: The regulations require group health plans to provide notices to individuals who are entitled to elect COBRA (The Consolidated Omnibus Budget Reconciliation Act of 1985) continuation coverage of their election rights. Individuals who wish to obtain the benefits provided under the statute are required to provide plans notices in the cases of divorce from the covered employee, a dependent child's ceasing to be dependent under the terms of the plan, and disability. Most plans will require that elections of COBRA continuation coverage be made in writing. In cases where qualified beneficiaries are short by an insignificant amount in a payment made to the plan, the regulations require the plan to notify the qualified beneficiary if the plan does not wish to treat the tendered payment as full payment. If a health care provider contacts a plan to confirm coverage of a qualified beneficiary, the regulations require that the plan disclose the qualified beneficiary's complete rights to coverage.

Current Actions: There is no change to the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, individuals or households, and not-for-profit institutions.

Estimated Number of Respondents: 12,079,600.

Estimated Time per Response: Varies from 30 seconds to 330 hours, depending on individual circumstances, with an estimated average of 14 minutes.

Estimated Total Annual Burden Hours: 404,640 hours.

24. Title: Monthly Tax Return for Wagers (Form 730).

OMB Number: 1545–0235.

Form Number: Form 730.

Abstract: Form 730 is used to identify taxable wagers under Internal Revenue Code section 4401 and collect the tax monthly. The information is used to determine if persons accepting wagers are correctly reporting the amount of wagers and paying the required tax.

Current Actions: There is no change to the existing collection. However, the estimated number of responses was updated based on current filing data.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Responses: 17,796.

Estimated Time per Respondent: 8 hours, 11 minutes.

Estimated Total Annual Burden Hours: 145,749.

25. Title: Carryover of Passive Activity Losses and Credits and At-Risk losses to Bankruptcy Estates for Individuals.

OMB Number: 1545–1375.

Regulation Project Number: T.D. 8537.

Abstract: These regulations relate to the application of carryover of passive activity losses and credits and at risk losses to the bankruptcy estates of individuals. The final regulations affect individual taxpayers who file bankruptcy petitions under chapter 7 or chapter 11 of title 11 of the United States Code and have passive activity losses and credits under section 469 or losses under section 465.

Current Actions: There are no changes being made to this existing regulation or to the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 500.

Estimated Time per Respondent: 12 Minutes.

Estimated Total Annual Burden Hours: 100.

26. Title: Adjustments to Basis of Stock and Indebtedness to Shareholders of S Corporations and Treatment of Distributions by S Corporations to Shareholders.

OMB Number: 1545–1139.

Regulation Project Number: TD 9300 and TD 9428.

Abstract: This document contains final regulations relating to the passthrough of items of an S corporation to its shareholders, the adjustments to the basis of stock of the shareholders, and the treatment of distributions by an S corporation. Changes to the applicable law were made by the Subchapter S Revision Act of 1982, the Tax Reform Act of 1984, the Tax Reform Act of 1986, the Technical and Miscellaneous Revenue Act of 1988, and the Small Business Job Protection Act of 1996. These regulations provide the public with guidance needed to comply with the applicable law and will affect S corporations and their shareholders.

Current Actions: There are no changes being made to this existing regulation or to the paperwork burden previously approved by OMB.

Type of Review: Extension of currently approved collection.

Affected Public: Business or other for-profit organizations and individuals.

Estimated Number of Responses: 2,000.

Estimated Time per Respondent: 6 minutes.

Estimated Total Annual Burden Hours: 200.

27. Title: Salary Reduction Simplified Employee Pension—Individual Retirement Accounts Contribution Agreement.

OMB Number: 1545–1012.

Document Number: 5305A SEP.

Abstract: Form 5305A–SEP is used by an employer to make an agreement to provide benefits to all employees under a Simplified Employee Pension (SEP) described in Internal Revenue Code section 408(k). This form is not to be filed with the IRS, but is to be retained in the employer's records as proof of establishing a SEP and justifying a deduction for contributions made to the SEP.

Current Actions: There are no changes to the burden previously approved by OMB. This request is to extend the current approval for another 3 years.

Type of Review: Extension of a currently approved collection.

Affected Public: Business and other for-profit organizations.

Estimated Number of Respondents: 100,000.

Estimated Time per Respondent: 9 hrs., 43 min.

Estimated Total Annual Burden Hours: 972,000.

28. Title: PTIN Supplemental Application for U.S. Citizens Without A Social Security Number Due to Conscientious Religious Objection.

OMB Number: 1545–2188.

Form Number: 8945.

Abstract: Form 8945 is used by U.S. citizens who are members of certain recognized religious groups that want to prepare tax returns for compensation. Most individuals applying for a Preparer Tax Identification Number (PTIN) will have a social security number, which will be used to help establish their identity. However, there exists a population of U.S. residents that are religious objectors and do not have social security numbers. Form 8945 was created to assist that population in establishing their identity while applying for a PTIN.

Current Actions: There is no change in the paperwork burden previously approved by OMB. This form is being submitted for renewal purposes.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profit organizations.

Estimated Number of Respondents: 500.

Estimated Time per Respondent: 7 hours, 11 min.

Estimated Total Annual Burden Hours: 3,590.

29. Title: Diesel Fuel and Kerosene Excise Tax; Dye Injection.

OMB Number: 1545–1418.

Regulation Project Number: TD 9199.

Abstract: This document contains regulations relating to the diesel fuel and kerosene excise tax. These regulations reflect changes made by the American Jobs Creation Act of 2004 regarding mechanical dye injection systems for diesel fuel and kerosene. These regulations affect certain enterers, refiners, terminal operators, and through putters.

Current Actions: There are no changes to the burden previously approved by OMB. This request is to extend the current approval for another 3 years.

Type of Review: Extension of a currently approved collection.

Affected Public: Business and other for-profit organizations.

Estimated Number of Respondents: 1.

Estimated Time per Respondent: 1 hr.

Estimated Total Annual Burden Hours: 1.

30. Title: Acquisition or Abandonment of Secured Property.

OMB Number: 1545–0877.

Form Number: 1099–A.

Abstract: This form is used by persons who lend money in connection with a trade or business, and who acquire an interest in the property that is security for the loan or who have reason to know that the property has been abandoned, to report the acquisition or abandonment.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Responses: 466,000.

Estimated Time per Response: 10 minutes.

Estimated Total Annual Burden Hours: 74,560.

31. Title: Sales of Business Property.

OMB Number: 1545–0184.

Form Number: Form 4797.

Abstract: Form 4797 is used by taxpayers to report sales, exchanges, or involuntary conversions of assets used in a trade or business. It is also used to compute ordinary income from recapture and the recapture of prior year losses under section 1231 of the Internal Revenue Code.

Current Actions: There are no changes being made to the form at this time. The forms are being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, individuals or households, and farms.

Estimated Number of Respondents: 211,536.

Estimated Time per Response: 51 hours, 7 minutes.

Estimated Total Annual Burden Hours: 10,813,730.

32. Title: Information Regarding Beneficiaries Acquiring Property From a Decedent.

OMB Number: 1545–2264.

Form Number: 8971.

Abstract: The Surface Transportation and Veterans Health Care Choice Improvement Act of 2015 requires executors of an estate and other persons who are required to file a Form 706, Form 706–NA, or Form 706–A, to report to the Internal Revenue Service (IRS) and to each beneficiary receiving property from an estate tax value of the property, if the return is filed after July 31, 2015. Form 8971 is used to report to the IRS and a Schedule A will be sent to each beneficiary and a copy of each Schedule A will be attached to the Form 8971. Some property received by a beneficiary may have a consistency requirement, meaning that the beneficiary must use the value reported on the Schedule A as the beneficiary's initial basis of the property. A beneficiary is an individual, trust, or other estate who has acquired (or is expected to acquire) property from the estate. If the executor is also a beneficiary who has acquired (or is expected to acquire) property from the estate, the executor is a beneficiary for purposes of the Form 8971 and the attached Schedule A.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals, business or other for-profit organization, and not-for-profit institutions.

Estimated Number of Responses: 10,000.

Estimated Time per Response: 20 hours.

Estimated Total Annual Burden Hours: 200,000.

33. Title: ABLE Account Contribution Information; Distributions from ABLE Accounts.

OMB Number: 1545–2262.

Form Numbers: 5498–QA; 1099–QA.

Abstract: Form 5498–QA, ABLE Account Contributions Information. Public Law 113–295, ABLE Act of 2014 allows individuals and families to set money aside in this special account for the purpose of supporting individuals with disabilities to maintain health, independence, and quality of life, without impacting eligibility for other social service financial assistance programs such as Medicaid. Form 1099–QA allows these individuals and families to draw from the special account.

Current Actions: There are no changes being made to the forms at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Responses: 20,000.

Estimated Time per Respondent: 22 minutes.

Estimated Total Annual Burden Hours: 3,600.

34. Title: Mortgage Credit Certificates (MCCs).

OMB Number: 1545–0922.

Regulation Project Number: Form 8329 and Form 8330.

Abstract: Mortgage Credit Certificates provide qualified holders of the certificates with a credit against income tax liability. In general, an Issuer elects to establish a mortgage credit certificate program in lieu of issuing qualified mortgage revenue bonds. Section 25 of the Code permits states and political subdivisions to elect to issue Mortgage Credit Certificates in lieu of qualified mortgage revenue bonds. Form 8329 is used by lending institutions and Form 8330 is used by state and local governments to provide the IRS with information on the issuance of mortgage credit certificates (MCCs) authorized under Internal Revenue Code section 25. IRS matches the information supplied by lenders and issuers to ensure that the credit is computed properly.

Current Actions: There is no change to the burden previously approved.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: Form 8329—10,000; Form 8330—2,000.

Estimated Time per Respondent: Form 8329—5 hrs. 53 min.; Form 8330—7 hrs. 28 min.

Estimated Total Annual Burden Hours: Form 8329—58,800; Form 8330—14,920.

35. Title: Passive Activity Loss Limitations.

OMB Number: 1545–1008.

Form Number: 8582.

Abstract: Internal Revenue Code section 469 limits the passive activity losses that a taxpayer may deduct. The passive activity losses from passive activities, to the extent that they exceed income from passive activities, cannot be deducted against nonpassive income. Form 8582 is used to figure the passive activity loss allowed and the actual loss to be reported on the tax returns.

Current Actions: There is no change to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households, estates, and trusts.

Estimated Number of Respondents: 400,000.

Estimated Time per Respondent: 3 hours, 12 minutes.

Estimated Total Annual Burden Hours: 1,280,000.

36. Title: Payments from Qualified Education Programs (Under Sections 529 and 530).

OMB Number: 1545–1760.

Form Number: Form 1099–Q.

Abstract: Form 1099–Q is used to report distributions from private and state qualified tuition programs as required under Internal Revenue Code sections 529 and 530.

Current Actions: There are no changes to the burden previously approved by OMB. This submission is for renewal purposes.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Responses: 3,649,000.

Estimated Time per Respondent: 13 minutes.

Estimated Total Annual Burden Hours: 802,780.

37. Title: Optional Election to Make Monthly 706(a) Computations.

OMB Number: 1545–1768.

Revenue Procedure Number: 2003–84.

Abstract: This procedure allows certain partnerships that invest in tax-exempt obligations to make an election that enables the partners to take into account monthly the inclusions required under sections 702 and 707(c) of the Code and provides rules for partnership income tax reporting under section 6031 for such partnerships. Rev. Proc. 2002–68 modified and superseded.

Current Actions: There are no changes being made to the revenue procedure at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 1,000.

Estimated Time per Respondent: 30 mins.

Estimated Total Annual Burden Hours: 500.

38. Title: Excise Tax on Certain Transfers of Qualifying Geothermal or Mineral Interests.

OMB Number: 1545–2099.

Form Number: 8924.

Abstract: This form is required by Section 403 of the Tax Relief and Health Care Act of 2006 which imposes an excise tax on certain transfers of qualifying mineral or geothermal interests.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Respondents: 20.

Estimated Time per Respondent: 5 hours, 32 minutes.

Estimated Total Annual Burden Hours: 111.

Authority: 44 U.S.C. 3501 *et seq.*

Melody Braswell,

Treasury PRA Clearance Officer.

[FR Doc. 2024–16844 Filed 7–30–24; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Solicitation of Nomination for Appointment to the Advisory Committee on Women Veterans

ACTION: Notice.

SUMMARY: The Department of Veterans Affairs (VA) is seeking nominations of qualified candidates to be considered for membership on the Advisory Committee on Women Veterans (''the Committee'') for the 2024 membership cycle.

DATES: Nominations for membership on the Committee must be received by August 12, 2024, no later than 4:00 p.m., eastern standard time. Packages received after this time will not be considered for the current membership cycle.

ADDRESSES: All nomination packages should be sent to the Advisory Committee Management Office at *vaadvisorycmte@va.gov* with subject line: Nomination to Women Veterans.

FOR FURTHER INFORMATION CONTACT: Shannon Middleton, Assistant Designated Federal Officer, Center for Women Veterans, Department of Veterans Affairs, 810 Vermont Avenue NW, (00W), Washington, DC 20420, telephone 202–461–6194.

SUPPLEMENTARY INFORMATION: In carrying out the duties set forth, the Committee provides a Congressionally-mandated report to the Secretary each year, which includes:

(1) An assessment of the needs of women Veterans with respect to compensation, health care, rehabilitation, outreach, and other benefits and programs administered by VA;

(2) A review of the programs and activities of VA designed to meet such needs;

(3) An assessment of the effects of intimate partner violence on women Veterans; and

(4) Recommendations (including recommendations for administrative and legislative action) as the Committee considers appropriate. The Committee reports to the Secretary, through the Director of the Center for Women Veterans.

Authority: The Committee is authorized by 38 U.S.C. 542, to provide advice to the Secretary of Veterans Affairs (Secretary) on: the administration of VA's benefits and services (health care, rehabilitation benefits, compensation, outreach, and other relevant programs) for women Veterans; reports and studies pertaining to women Veterans; and the needs of women Veterans. In accordance with the statute and the Committee's current charter, the majority of the membership shall consist of non-Federal employees appointed by the Secretary from the general public, serving as special government employees.

The Secretary appoints Committee members and determines the length of terms in which Committee members serve. A term of service for any member may not exceed three (3) years. However, the Secretary can reappoint members for additional terms. Each year, there are several vacancies on the Committee, as members' terms expire.

Membership Criteria: The Committee is currently comprised of 12 members. By statute, the Committee consists of members appointed by the Secretary from the general public, including: representatives of women Veterans; individuals who are recognized authorities in fields pertinent to the needs of women Veterans, including the gender specific health-care needs of women Veterans; representatives of both female and male Veterans with service-connected disabilities, including at least one female Veteran with a service-connected disability and at least one male Veteran with a service-connected disability; and women Veterans who are recently separated from service in the Armed Forces. Non-Veterans are also eligible for nomination.

The Committee meets at least two times annually, which may include a site visit to a VA field location. In accordance with Federal travel regulation, VA will cover travel expenses—to include per diem—for all members of the Committee, for any travel associated with official Committee duties. A copy of the Committee's most recent charter and a list of the current membership can be found at *www.va.gov/ADVISORY/* or *www.va.gov/womenvet/*.

In accordance with revised guidance regarding the ban on lobbyists serving as members of advisory boards and commissions, Federally-registered lobbyists are prohibited from serving on Federal advisory committees in an individual capacity. Additional information regarding this issue can be found at *www.federalregister.gov/articles/2014/08/13/2014-19140/revised-guidance-on-appointment-of-lobbyists-to-federal-advisory-committees-boards-and-commissions*.

Requirements for Nomination Submission: Nomination packages must be typed (12-point font) and include: (1) a cover letter from the nominee and (2) a current resume that is no more than four pages in length. The cover letter must summarize: the nominee's interest in serving on the Committee and contributions she/he can make to the Committee's work; any relevant Veterans' service activities she/he is currently engaged in; and the military branch affiliation and timeframe of military service (if applicable). To promote inclusion and demographic balance of membership, please include as much information related to your race, national origin, disability status,

minority Veteran status, or any other factors that may give you a diverse perspective on women Veterans matters. Finally, the cover letter *must* include the nominee's complete contact information (name, address, email address and phone number); and a statement confirming that she/he is not a Federally-registered lobbyist. The resume should show professional and/or work experience and Veterans' service involvement—especially service that involves women Veterans' issues.

Self-nominations are acceptable. Any letters of nomination from organizations or other individuals *must* accompany the package when it is submitted. Letters of nomination submitted without a complete nomination package *will not* be considered. If you are submitting a package on behalf of an individual, it *must* include all of the required components and complete contact information. Do not submit a package without the nominee's consent or awareness.

The Department makes every effort to ensure that the membership of its advisory committees is fairly balanced, in terms of points of view represented. In the review process, consideration is given to nominees' potential to address the Committee's demographic needs (regional representation, race/ethnicity/minority representation, professional expertise, war era service, gender, former enlisted or officer status, branch of service, for example). Other considerations to promote a balanced membership include longevity of military service, significant deployment experience, ability to handle complex issues, experience running large organizations and ability to contribute to the gender-specific health care and benefits needs of women Veterans.

Dated: July 25, 2024.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2024–16793 Filed 7–30–24; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Research Advisory Committee on Gulf War Veterans' Illnesses, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. ch. 10., that the Research Advisory Committee on Gulf War Veterans' Illnesses will meet at The Benson Hotel & Faculty Club, 13025 E Montview Blvd., Aurora, CO 80045 in the Ballroom. The meeting sessions will begin and end as follows:

Dates	Times
August 20, 2024	11:00 a.m. to 5:00 p.m. Eastern Time (ET).
August 21, 2024	11:00 a.m. to 2:00 p.m. (ET).

All sessions will be open to the public. For interested parties who cannot attend in person, this meeting will also be available by videoconference by connecting to Webex at the following URLs:

August 20, 2024, 11:00 a.m. to 5:00 p.m. (ET): *https://veteransaffairs.webex.com/veteransaffairs/j.php?MTID=mf8041252f79288e6e3dae062aa7d856c* or join by phone: 1–833–558–0712 Toll-free; meeting number (access code): 2828 129 4501. Meeting password: GWVET1991!

August 21, 2024, 11:00 a.m. to 2:00 p.m. (ET): *https://veteransaffairs.webex.com/veteransaffairs/j.php?MTID=m6a2eeeff9e182753391e8f5dbc0a3571* or join by phone: 1–833–558–0712 Toll-free; meeting number (access code): 2824 038 6205. Meeting password: GWVETS1991!

The purpose of the Committee is to provide advice and make recommendations to the Secretary of Veterans Affairs on proposed research studies, research plans, and research strategies relating to the health consequences of military service in the Southwest Asia theater of operations during the Gulf War in 1990–91.

The Committee will review VA program activities related to Gulf War Veterans' illnesses and updates on relevant scientific research published since the last Committee meeting. This meeting will focus in part on (1) diversity, equity, inclusion, and women's health research, (2) research project updates, (3) updates on committee membership and recommendations, and (4) a report from the Veteran Engagement Subcommittee.

The meeting will include time reserved for public comments before the meeting closes each day. Individuals wishing to make public comments should contact *VARACGWVI@va.gov.* Public comment speakers are requested to submit a 1–2-page summary of their comments for inclusion in the official meeting record. Written comments will also be accepted for the record. Members of the public who have confirmed public speaker registrations will be allowed to provide public comment first followed by non-registered speakers time permitting. Each public comment speaker will be held to a 5-minute time limit. Individuals wishing to seek additional information should contact Dr. Karen Block, Designated Federal Officer, at *Karen.Block@va.gov.*

Dated: July 26, 2024.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2024–16829 Filed 7–30–24; 8:45 am]

BILLING CODE 8320–01–P



FEDERAL REGISTER

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Book 2 of 2 Books

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 401, 405, et al.

Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 401, 405, 410, 411, 414, 423, 424, 425, 427, 428, and 491

[CMS–1807–P]

RIN 0938–AV33

Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This major proposed rule addresses: changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; codification of, and proposing policies for, the Medicare Prescription Drug Inflation Rebate Program under the Inflation Reduction Act of 2022; updates to the Medicare Diabetes Prevention Program expanded model; payment for dental services inextricably linked to specific covered medical services; updates to drugs and biological products paid under Part B including immunosuppressive drugs and clotting factors; Medicare Shared Savings Program requirements; updates to the Quality Payment Program; Medicare coverage of opioid use disorder services furnished by opioid treatment programs; updates to policies for Rural Health Clinics and Federally Qualified Health Centers; electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or a Medicare Advantage Prescription Drug (MA–PD) plan under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act); update to the Ambulance Fee Schedule regulations; codification of the Inflation Reduction Act and Consolidated Appropriations Act, 2023 provisions; updates to Clinical Laboratory Fee Schedule regulations; updates to the diabetes payment structure and PHE flexibilities; expansion of colorectal cancer screening and Hepatitis B vaccine coverage and payment; establishing payment for drugs covered as additional preventive services; Medicare Parts A and B Overpayment Provisions of the Affordable Care Act.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 9, 2024.

ADDRESSES: In commenting, please refer to file code CMS–1807–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *https://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1807–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1807–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT:

MedicarePhysicianFeeSchedule@cms.hhs.gov, for any issues not identified below. Please indicate the specific issue in the subject line of the email.

Michael Soracoe, (410) 786–6312, Morgan Kitzmiller, (410) 786–1623, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to practice expense, work RVUs, conversion factor, and PFS specialty-specific impacts.

Kris Corwin, (410) 786–8864, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to strategies for updates to practice expense data collection and methodology.

Hannah Ahn, (814) 769–0143, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to potentially misvalued services under the PFS.

Kris Corwin, (410) 786–8864, Patrick Sartini, (410) 786–9252, Mikayla Murphy, (667) 414–0093, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to direct supervision using two-way audio/video communication technology, telehealth, and other services involving communications technology.

Tamika Brock, (312) 886–7904, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to teaching physician billing for services involving residents in teaching settings.

Sarah Leipnik, (410) 786–3933, Mikayla Murphy, (667) 414–0093, Regina Walker-Wren, (410) 786–9160, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to payment for caregiver training services and addressing health-related social needs (community health integration, principal illness navigation, and social determinants of health risk assessment).

Erick Carrera, (410) 786–8949, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to office/outpatient evaluation and management visit inherent complexity add-one.

Sarah Irie, (410) 786–1348, Emily Parris (667) 414–0418, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to payment for advanced primary care management service.

Sarah Leipnik, (410) 786–3933, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to global surgery payment accuracy.

Pamela West, (410) 786–2302, for issues related to supervision of outpatient therapy services in private practices, certification of therapy plans of care, and KX modifier threshold.

Lindsey Baldwin, (410) 786–1694, Regina Walker-Wren, (410) 786–9160, Erick Carrera, (410) 786–8949, Mikayla Murphy, (667) 414–0093, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to advancing access to behavioral health services.

Laura Ashbaugh, (410) 786–1113, and Erick Carrera, (410) 786–8949, Zehra Hussain, (214) 767–4463, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to dental services inextricably linked to specific covered medical services.

Zehra Hussain, (214) 767–4463, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to payment of skin substitutes.

Laura Kennedy, (410) 786–3377, Adam Brooks, (202) 205–0671, Rachel Radzyner, (410) 786–8215, Rebecca Ray, (667) 414–0879, and Jae Ryu, (667) 414–0765 for issues related to Drugs and Biological Products Paid Under Medicare Part B.

MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to complex drug administration.

Glenn McGuirk, (410) 786–5723, or *CLFS_Inquiries@cms.hhs.gov* for issues related to Clinical Laboratory Fee Schedule.

Lisa Parker, (410) 786–4949, or *FQHC–PPS@cms.hhs.gov,* for issues related to FQHC payments.

Heidi Oumarou, (410) 786–7942, for issues related to the FQHC market basket.

Michele Franklin, (410) 786–9226, or *RHC@cms.hhs.gov,* for issues related to RHC payments.

Kianna Banks (410) 786–3498 and Cara Meyer (667) 290–9856, for issues related to RHCs and FQHCs and Conditions for Certification or Coverage.

Colleen Barbero (667) 290–8794, for issues related to Medicare Diabetes Prevention Program.

Ariana Pitcher, (667) 290–8840, or *OTP_Medicare@cms.hhs.gov,* for issues related to Medicare coverage of opioid use disorder treatment services furnished by opioid treatment programs.

Sabrina Ahmed, (410) 786–7499, or *SharedSavingsProgram@cms.hhs.gov,* for issues related to the Medicare Shared Savings Program (Shared Savings Program) Quality performance standard and quality reporting requirements.

Janae James, (410) 786–0801, or *SharedSavingsProgram@cms.hhs.gov,* for issues related to Shared Savings Program beneficiary assignment and benchmarking methodology.

Richard (Chase) Kendall, (410) 786–1000, or *SharedSavingsProgram@cms.hhs.gov,* for issues related to reopening ACO payment determinations, and mitigating the impact of significant, anomalous, and highly suspect billing activity on Shared Savings Program financial calculations.

Lucy Bertocci, (410) 786–3776, or *SharedSavingsProgram@cms.hhs.gov,* for issues related to Shared Savings Program prepaid shared savings, advance investment payments, beneficiary notice and eligibility requirements.

Rachel Radzyner, (410) 786–8215, for issues related to payment for preventative services, including preventive vaccine administration and drugs covered as additional preventive services.

Elisabeth Daniel, (667) 290–8793, for issues related to the Medicare Prescription Drug Inflation Rebate Program.

Genevieve Kehoe, *Ambulatoryspecialtycare@cms.hhs.gov,* or 1–844–711–2664 (Option 4) for issues related to the Request for Information: Building upon the MIPS Value Pathways (MVPs) Framework to Improve Ambulatory Specialty Care.

Kimberly Long, (410) 786–5702, for issues related to expanding colorectal cancer screening.

Rachel Katonak, (410) 786–8564, for issues related to expanding Hepatitis B vaccine coverage.

Mei Zhang, (410) 786–7837, for issues related to requirement for electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan (section 2003 of the SUPPORT Act).

Katie Parker, (410) 786–0537, for issues related to Parts A and B overpayment provisions of the Affordable Care Act.

Amy Gruber, (410) 786–1542, for issues related to low titer O+ whole blood transfusion therapy during ground ambulance transport.

Renee O'Neill, (410) 786–8821, or Sophia Sugumar, (410) 786–1648, for inquiries related to Merit-based Incentive Payment System (MIPS) track of the Quality Payment Program.

Danielle Drayer, (516) 965–6630, for inquiries related to Alternative Payment Models (APMs).

SUPPLEMENTARY INFORMATION:

Addenda Available Only Through the Internet on the CMS website: The PFS Addenda along with other supporting documents and tables referenced in this proposed rule are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.* Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2025 PFS proposed rule, refer to item CMS–1807–P. Readers with questions related to accessing any of the Addenda or other supporting documents referenced in this proposed rule and posted on the CMS website identified above should contact *MedicarePhysicianFeeSchedule@cms.hhs.gov.*

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I. Executive Summary

A. Purpose

This major annual rule proposes to revise payment policies under the Medicare PFS and makes other policy changes, including proposals to implement certain provisions of the Further Continuing Appropriations and Other Extensions Act of 2024 (Pub. L. 118–22, November 16, 2023), Consolidated Appropriations Act, 2023 (Pub. L. 117–328, September 29, 2022), Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169, August 16, 2022), Consolidated Appropriations Act, 2022 (Pub. L. 117–103, March 15, 2022), Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116–260, December 27, 2020), Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, February 9, 2018) and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271, October 24, 2018), related to Medicare Part B payment. In addition, this major proposed rule includes proposals regarding other Medicare payment policies described in sections III. and IV.

This rulemaking also proposes to codify policies previously established in guidance for the Medicare Prescription Drug Inflation Rebate Program at new parts 427 and 428, including clarifications to certain existing policies, consistent with sections 1847A(i) and 1860D–14B of the Act. This rulemaking also proposes new policies for the Medicare Prescription Drug Inflation Rebate Program, including removal of units of drugs subject to discarded drug refunds from the Part B rebate amounts, exclusion of units for which a manufacturer provides a discount under the 340B Program from the Part D inflation rebate amount starting on January 1, 2026, the process for reconciliation of a Part B or Part D rebate amount to incorporate certain revised information, and procedures for imposing civil money penalties on manufacturers that do not pay Part B or Part D inflation rebate amounts within a specified period of time.

This rulemaking proposes to update the Rural Health Clinic (RHC) and Federally Qualified Health Clinic (FQHC) Conditions for Certification and Conditions for Coverage (CfCs), respectively, by clarifying the requirements and intent of the program regarding the provision of services. We also aim to ensure RHCs are provided flexibility in the services they offer, including specialty and laboratory services.

This rulemaking also proposes to further advance Medicare's overall value-based care strategy of growth, alignment, and equity through the Medicare Shared Savings Program (Shared Savings Program) and the Quality Payment Program. The structure of the programs enables us to develop a set of tools for measuring and encouraging improvements in care, which may support a shift to clinician payment over time into Advanced Alternative Payment Models (APMs) and accountable care arrangements which reduce care fragmentation and unnecessary costs for patients and the health system.

This rulemaking also proposes changes to Medicare regulations regarding requirements for reporting and returning Parts A and B overpayments.

B. Summary of the Major Provisions

Please note, some sections of this proposed rule contain a request for information (RFI). In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), these general solicitations are exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA. Respondents are encouraged to provide complete but concise responses. These RFIs are issued solely for information and planning purposes; they do not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. These RFIs do not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through these RFIs and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to these RFIs; all costs associated with responding to these RFIs will be solely at the interested party's expense. Not responding to these RFIs does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor these RFI announcements for additional information pertaining to these requests. Please note that CMS will not respond to questions about the policy issues raised in these RFIs. CMS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to this notice are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of these RFIs may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. These RFIs should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. CMS may publicly post the comments received, or a summary thereof.

Section 1848 of the Social Security Act (the Act) requires us to establish payments under the PFS, based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: work, practice expense (PE), and malpractice (MP) expense. In addition, the statute requires that each year we establish, by regulation, the payment amounts for physicians' services paid under the PFS, including geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas.

In this major proposed rule, we are proposing to establish RVUs for CY 2025 for the PFS to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This proposed rule also includes discussions and provisions regarding several other Medicare Part B payment policies, Medicare and Medicaid provider and supplier enrollment policies, and other policies regarding programs administered by CMS.

Specifically, this proposed rule addresses:

- Background (section II.A.)
- Determination of PE RVUs (section II.B.)
- Potentially Misvalued Services Under the PFS (section II.C.)
- Payment for Medicare Telehealth Services Under Section 1834(m) of the Act (section II.D.)
- Valuation of Specific Codes (section II.E.)
- Evaluation and Management (E/M) Visits (section II.F.)
- Enhanced Care Management (section II.G.)
- Supervision of Outpatient Therapy Services in Private Practices, Certification of Therapy Plans of Care with a Physician or NPP Order, and KX Modifier Thresholds (section II.H.)
- Advancing Access to Behavioral Health Services (section II.I.)
- Proposals on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Services (section II.J.)
- Payment for Skin Substitutes (section II.K.)
- Drugs and Biological Products Paid Under Medicare Part B (section III.A.)
- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (section III.B.)
- Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Conditions for Certification and Conditions for Coverage (CfCs) (section III.C.)
- Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions (section III.D.)
- Medicare Diabetes Prevention Program (MDPP) (section III.E.)
- Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs) (section III.F.)
- Medicare Shared Savings Program (section III.G.)
- Medicare Part B Payment for Preventive Services (§§ 410.10, 410.57, 410.64, 410.152) (section III.H.)
- Medicare Prescription Drug Inflation Rebate Program (section III.I.)
- Request for Information: Building upon the MIPS Value Pathways (MVPs) Framework to Improve Ambulatory Specialty Care (section III.J.)
- Expand Colorectal Cancer Screening (section III.K.)
- Requirements for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA–PD Plan (section III.L.)
- Expand Hepatitis B Vaccine Coverage (section III.M.)
- Low Titer O+ Whole Blood Transfusion Therapy During Ground Ambulance Transport (section III.N.)
- Medicare Parts A and B Overpayment Provisions of the Affordable Care Act (section III.O.)
- Updates to the Quality Payment Program (section IV.)

- Collection of Information Requirements (section V.)
- Response to Comments (section VI.)
- Regulatory Impact Analysis (section VII.)

C. Summary of Costs and Benefits

We have determined that this proposed rule is economically significant. We estimate the CY 2025 PFS conversion factor to be 32.3562 which reflects a 0.05 percent positive budget neutrality adjustment required under section 1848(c)(2)(B)(ii)(II) of the Act, the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act, and the removal of the temporary 2.93 percent payment increase for services furnished from March 9, 2024, through December 31, 2024, as provided in the CAA, 2024. For a detailed discussion of the economic impacts, see section VII., Regulatory Impact Analysis, of this proposed rule.

II. Provisions of the Proposed Rule for the PFS

A. Background

In accordance with section 1848 of the Social Security Act (the Act), CMS has paid for physicians' services under the Medicare physician fee schedule (PFS) since January 1, 1992. The PFS relies on national relative values that are established for work, practice expense (PE), and malpractice (MP), which are adjusted for geographic cost variations. These values are multiplied by a conversion factor (CF) to convert the relative value units (RVUs) into payment rates. The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) (Pub. L. 101–239, December 19, 1989), and the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) (Pub. L. 101–508, November 5, 1990). The final rule published in the November 25, 1991 **Federal Register** (56 FR 59502) set forth the first fee schedule used for Medicare payment for physicians' services.

We note that throughout this proposed rule, unless otherwise noted, the term ''practitioner'' is used to describe both physicians and nonphysician practitioners (NPPs) who are permitted to bill Medicare under the PFS for the services they furnish to Medicare beneficiaries.

B. Determination of PE RVUs

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice (MP) expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physicians' service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service specific PE RVUs. We refer readers to the CY 2010 Physician Fee Schedule (PFS) final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the American Medical Association (AMA) Relative Value Scale Update Committee (RUC) and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the 5-year review of work RVUs under the PFS and proposed changes to the PE methodology in the CY 2007 PFS proposed rule (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense Per Hour Data

We use survey data on indirect PEs incurred per hour worked to develop the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the PE/HR by specialty obtained from the AMA's Socioeconomic Monitoring System (SMS). The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of physicians and NPPs paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare-recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology or how the PE/HR data are used. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs nor independent labs participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the Medicare Economic Index (MEI) to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties are not

separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare-recognized specialty data.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS based PE/HR. We use crosswalks for specialties that did not participate in the PPIS. These crosswalks have been generally established through notice and comment rulemaking and are available in the file titled ''CY 2025 PFS proposed rule PE/HR'' on the CMS website under downloads for the CY 2025 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

For CY 2025, we have incorporated the available utilization data for two new specialties, Marriage and Family Therapist (MFT) and Mental Health Counselor (MHC), which we recognized effective January 1, 2024, in accordance with section 4121 of the CAA, 2023. We are proposing to use proxy PE/HR values for these new specialties, as there are no PPIS data for these specialties, by crosswalking the PE/HR as follows from specialties that furnish similar services in the Medicare claims data:

- Marriage and Family Therapist (MFT) from Licensed Clinical Social Workers; and
- Mental Health Counselor (MHC) from Licensed Clinical Social Workers

These updates are reflected in the ''CY 2025 PFS proposed rule PE/HR'' file available on the CMS website under the supporting data files for the CY 2025 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

We allocate the indirect costs at the code level based on the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporate the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. That is, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represent 25 percent of total costs for the specialties that furnish the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVU of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).
- Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had a work RVU of 4.00 and the clinical labor portion of the direct PE RVU was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.
- Then, we incorporate the specialty specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

(3) Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a facility setting, where Medicare makes a separate payment to the facility for its costs in furnishing a service, we establish two PE RVUs: facility and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs but is applied independently to yield two separate PE RVUs. In calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service. For this reason, the facility PE RVUs are generally lower than the nonfacility PE RVUs.

(4) Services With Technical Components and Professional Components

Diagnostic services are generally comprised of two components: a professional component (PC); and a technical component (TC). The PC and TC may be furnished independently or by different healthcare providers, or they may be furnished together as a global service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this, we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global.)

(5) PE RVU Methodology

For a more detailed description of the PE RVU methodology, we direct readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746). We also direct readers to the file titled ''Calculation of PE RVUs under Methodology for Selected Codes'' which is available on our website under downloads for the CY 2025 PFS proposed rule at *https://www.cms.gov/*

Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html. This file contains a table that illustrates the calculation of PE RVUs as described in this proposed rule for individual codes.

(a) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty specific PE/HR data calculated from the surveys.

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. We set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the projected aggregate work RVUs.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregate direct costs for all services from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3, use the CF to calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling adjustment to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to an RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs as long as the same CF is used in Step 4 and Step 5. Different CFs would result in different direct PE scaling adjustments, but this has no effect on the final direct cost PE RVUs since changes in the CFs and the associated direct scaling adjustments offset one another.

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

We generally use an average of the three most recent years of available Medicare claims data to determine the specialty mix assigned to each code. Codes with low Medicare service volume require special attention since billing or enrollment irregularities for a given year can result in significant changes in specialty mix assignment. We finalized a policy in the CY 2018 PFS final rule (82 FR 52982 through 59283) to use the most recent year of claims data to determine which codes are low volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). For codes that fall into this category, instead of assigning a specialty mix based on the specialties of the practitioners reporting the services in the claims data, we use the expected specialty that we identify on a list developed based on medical review and input from expert interested parties. We display this list of expected specialty assignments as part of the annual set of data files we make available as part of notice and comment rulemaking and consider recommendations from the RUC and other interested parties on changes to this list annually. Services for which the specialty is automatically assigned based on previously finalized policies under our established methodology (for example, ''always therapy'' services) are unaffected by the list of expected specialty assignments. We also finalized in the CY 2018 PFS final rule (82 FR 52982 through 52983) a policy to apply these service-level overrides for both PE and MP, rather than one or the other category.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: the direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

For most services the indirect allocator is: indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs.

(*Note:* For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs would be allocated using the work RVUs, and for the TC service, indirect PEs would be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes, in the examples in the download file titled ''Calculation of PE RVUs under Methodology for Selected Codes'', the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the result of step 8 by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty specific indirect PE/HR data, calculate specialty specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the work time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (Note: For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(d) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 5 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment. The final PE BN adjustment is calculated by comparing the sum of steps 5 and 17 to the aggregate work RVUs scaled by the ratio of current aggregate PE and work RVUs. This adjustment ensures that all PE RVUs in the PFS account for the fact that certain specialties are excluded from the calculation of PE RVUs but included in maintaining overall PFS BN. (See ''Specialties excluded from ratesetting calculation'' later in this proposed rule.)

Step 19: Apply the phase-in of significant RVU reductions and its associated adjustment. Section 1848(c)(7) of the Act specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period. In implementing the phase-in, we consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach limits the year one reduction for the service to the maximum allowed amount (that is, 19 percent), and then phases in the remainder of the reduction. To comply with section 1848(c)(7) of the Act, we adjust the PE RVUs to ensure that the total RVUs for all services that are not new or revised codes decrease by no more than 19 percent, and then apply a relativity adjustment to ensure that the total pool of aggregate PE RVUs remains relative to the pool of work and MP RVUs. For a more detailed description of the methodology for the phase-in of significant RVU changes, we refer readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70931).

(e) Setup File Information

- Specialties excluded from ratesetting calculation: To calculate the PE and MP RVUs, we exclude certain specialties, such as NPPs paid at a percentage of the PFS and low volume specialties, from the calculation. These specialties are included to calculate the BN adjustment. They are displayed in Table 1.

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TABLE 1: Specialties Excluded from Ratesetting Calculation

Specialty Code	Specialty Description
49	Ambulatory surgical center
50	Nurse practitioner
51	Medical supply company with certified orthotist
52	Medical supply company with certified prosthetist
53	Medical supply company with certified prosthetist-orthotist
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist
56	Individual certified prosthetist
57	Individual certified prosthetist-orthotist
58	Medical supply company with registered pharmacist
59	Ambulance service supplier, e.g., private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies
61	Voluntary health or charitable agencies
73	Mass immunization roster biller
74	Radiation therapy centers
87	All other suppliers (e.g., drug and department stores)
88	Unknown supplier/provider specialty
89	Certified clinical nurse specialist
96	Optician
97	Physician assistant
A0	Hospital
A1	SNF
A2	Intermediate care nursing facility
A3	Nursing facility, other
A4	HHA
A5	Pharmacy
A6	Medical supply company with respiratory therapist
A7	Department store
A8	Grocery store
B1	Supplier of oxygen and/or oxygen related equipment (eff. 10/2/2007)
B2	Pedorthic personnel
B3	Medical supply company with pedorthic personnel
B4	Rehabilitation Agency
B5	Ocularist
C1	Centralized Flu
C2	Indirect Payment Procedure
C5	Dentistry

BILLING CODE C

- *Crosswalk certain low volume physician specialties:* Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.
- *Physical therapy utilization:* Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.
- *Identify professional and technical services not identified under the usual TC and 26 modifiers:* Flag the services that are PC and TC services but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).
- *Payment modifiers:* Payment modifiers are accounted for in creating the file consistent with the current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the work time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time accordingly. Table 2 details the

manner in which the modifiers are applied.

TABLE 2: Application of Payment Modifiers to Utilization Files

Modifier	Description	Volume Adjustment	Time Adjustment
80,81,82	Assistant at Surgery	16%	Intraoperative portion
AS	Assistant at Surgery – Physician Assistant	14% (85% * 16%)	Intraoperative portion
50 or LT and RT	Bilateral Surgery	150%	150% of work time
51	Multiple Procedure	50%	Intraoperative portion
52	Reduced Services	50%	50%
53	Discontinued Procedure	50%	50%
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims	Preoperative + Intraoperative portion
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims	Postoperative portion
62	Co-surgeons	62.5%	50%
66	Team Surgeons	33%	33%
CO, CQ	Physical and Occupational Therapy Assistant Services	88%	88%

We also adjust volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPRs). We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the BN calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

Beginning in CY 2022, section 1834(v)(1) of the Act required that we apply a 15 percent payment reduction for outpatient occupational therapy services and outpatient physical therapy services that are provided, in whole or in part, by a physical therapist assistant (PTA) or occupational therapy assistant (OTA). Section 1834(v)(2)(A) of the Act required CMS to establish modifiers to identify these services, which we did in the CY 2019 PFS final rule (83 FR 59654 through 59661), creating the CQ and CO payment modifiers for services provided in whole or in part by PTAs and OTAs, respectively. These payment modifiers are required to be used on claims for services with dates of service beginning January 1, 2020, as specified in the CY 2020 PFS final rule (84 FR 62702 through 62708). We applied the 15 percent payment reduction to therapy services provided by PTAs (using the CQ modifier) or OTAs (using the CO modifier), as required by statute. Under sections 1834(k) and 1848 of the Act, payment is made for outpatient therapy services at 80 percent of the lesser of the actual charge or applicable fee schedule amount (the allowed charge). The remaining 20 percent is the beneficiary copayment. For therapy services to which the new discount applies, payment will be made at 85 percent of the 80 percent of allowed charges. Therefore, the volume discount factor for therapy services to which the CQ and CO modifiers apply is: (0.20 + (0.80* 0.85), which equals 88 percent.

We note that for CY 2025, we are proposing mandatory use of the 54 and 55 modifiers when practitioners furnishing global surgery procedures share in patient care and intend only to furnish preoperative/intraoperative or postoperative portions of the total global procedure. If finalized, this proposal will likely increase the number of claims subject to the adjustment described in the discussion above. We discuss this proposal in section II.G. of this proposed rule.

For anesthesia services, we do not apply adjustments to volume since we use the average allowed charge when simulating RVUs; therefore, the RVUs as calculated already reflect the payments as adjusted by modifiers, and no volume adjustments are necessary. However, a time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where a single practitioner is involved with multiple beneficiaries concurrently, so that counting each service without regard to the overlap with other services would overstate the amount of time spent by the practitioner furnishing these services.

- *Work RVUs:* The setup file contains the work RVUs from this proposed rule.

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

(1/(minutes per year * usage)) * price * ((interest rate/(1 (1/((1 + interest rate)^ life of equipment)))) + maintenance)

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage=1); generally, 150,000 minutes.
usage = variable, see discussion below in this proposed rule.
price = price of the particular piece of equipment.
life of equipment = useful life of the particular piece of equipment.
maintenance = factor for maintenance; 0.05.
interest rate = variable, see discussion below in this proposed rule.

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic

imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

Useful Life: In the CY 2005 PFS final rule we stated that we updated the useful life for equipment items primarily based on the AHA's ''Estimated Useful Lives of Depreciable Hospital Assets'' guidelines (69 FR 66246). The most recent edition of these guidelines was published in 2018. This reference material provides an estimated useful life for hundreds of different types of equipment, the vast majority of which fall in the range of 5 to 10 years, and none of which are lower than two years in duration. We believe that the updated editions of this reference material remain the most accurate source for estimating the useful life of depreciable medical equipment.

In the CY 2021 PFS final rule, we finalized a proposal to treat equipment life durations of less than 1 year as having a duration of 1 year for the purpose of our equipment price per minute formula. In the rare cases where items are replaced every few months, we noted that we believe it is more accurate to treat these items as disposable supplies with a fractional supply quantity as opposed to equipment items with very short equipment life durations. For a more detailed discussion of the methodology associated with very short equipment life durations, we refer readers to the CY 2021 PFS final rule (85 FR 84482 through 84483).

- *Maintenance:* We finalized the 5 percent factor for annual maintenance in the CY 1998 PFS final rule with comment period (62 FR 33164). As we previously stated in the CY 2016 PFS final rule with comment period (80 FR 70897), we do not believe the annual maintenance factor for all equipment is precisely 5 percent, and we concur that the current rate likely understates the true cost of maintaining some equipment. We also noted that we believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding data sources containing equipment maintenance rates, commenters could not identify an auditable, robust data source that CMS could use on a wide scale. We noted that we did not believe voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining a different maintenance factor, we did not propose a variable maintenance factor for equipment cost per minute pricing as we did not believe that we have sufficient information at present. We noted that we would continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.
- *Interest Rate:* In the CY 2013 PFS final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation (see 77 FR 68902 for a thorough discussion of this issue). The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). The Interest rates are listed in Table 3.

TABLE 3: SBA Maximum Interest Rates

Price	Useful Life	Interest Rate
<$25K	<7 Years	7.50%
$25K to $50K	<7 Years	6.50%
>$50K	<7 Years	5.50%
<$25K	7+ Years	8.00%
$25K to $50K	7+ Years	7.00%
>$50K	7+ Years	6.00%

We are not proposing any changes to the equipment interest rates for CY 2025.

3. Adjusting RVUs To Match the PE Share of the Medicare Economic Index (MEI)

In the past, we have stated that we believe that the MEI is the best measure available of the relative weights of the three components in payments under the PFS—work, practice expense (PE), and malpractice (MP). Accordingly, we believe that to ensure that the PFS payments reflect the relative resources in each of these PFS components as required by section 1848(c)(3) of the Act, the RVUs used in developing rates should reflect the same weights in each component as the cost share weights in the Medicare Economic Index (MEI). In the past, we have proposed (and subsequently finalized) to accomplish this by holding the work RVUs constant and adjusting the PE RVUs, MP RVUs, and CF to produce the appropriate balance in RVUs among the three PFS components and payment rates for individual services, that is, that the total RVUs on the PFS are proportioned to approximately 51 percent work RVUs, 45 percent PE RVUs, and 4 percent MP RVUs. As the MEI cost shares are updated, we would typically propose to modify steps 3 and 10 to adjust the aggregate pools of PE costs (direct PE in step 3 and indirect PE in step 10) in proportion to the change in the PE share in the rebased and revised MEI cost share weights, and to recalibrate the relativity adjustment that we apply in step 18 as described in the CY 2023 PFS final rule (87 FR 69414 and 69415) and CY 2014 PFS final rule (78 FR 74236 and 74237). The most recent recalibration was done for the CY 2014 RVUs.

In the CY 2014 PFS proposed rule (78 FR 43287 through 43288) and final rule (78 FR 74236 through 74237), we detailed the steps necessary to accomplish this result (see steps 3, 10, and 18). The CY 2014 proposed and final adjustments were consistent with our longstanding practice to make adjustments to match the RVUs for the PFS components with the MEI cost share weights for the components, including the adjustments described in the CY 1999 PFS final rule (63 FR 58829), CY 2004 PFS final rule (68 FR 63246 and 63247), and CY 2011 PFS final rule (75 FR 73275).

In the CY 2023 PFS final rule (87 FR 69688 through 69711), we finalized to rebase and revise the MEI to reflect more current market conditions faced by physicians in furnishing physicians' services (referred to as the ''2017-based MEI''). We also finalized a delay of the adjustments to the PE pools in steps 3

and 10 and the recalibration of the relativity adjustment in step 18 until the public had an opportunity to comment on the rebased and revised MEI (87 FR 69414 through 69416). Because we finalized significant methodological and data source changes to the MEI in the CY 2023 PFS final rule and significant time has elapsed since the last rebasing and revision of the MEI in CY 2014, we believed that delaying the implementation of the finalized CY 2023 rebased and revised MEI was consistent with our efforts to balance payment stability and predictability with incorporating new data through more routine updates. We refer readers to the discussion of our comment solicitation in the CY 2023 PFS final rule (87 FR 69429 through 69432), where we reviewed our ongoing efforts to update data inputs for PE to aid stability, transparency, efficiency, and data adequacy. We also solicited comment in the CY 2023 PFS proposed rule on when and how to best incorporate the CY 2023 rebased and revised MEI into PFS ratesetting, and whether it would be appropriate to consider a transition to full implementation for potential future rulemaking. We presented the impacts of implementing the rebased and revised MEI in PFS ratesetting through a 4-year transition and through full immediate implementation, that is, with no transition period in the CY 2023 PFS proposed rule. We also solicited comment on other implementation strategies for potential future rulemaking in the CY 2023 PFS proposed rule. In the CY 2023 PFS final rule, we discussed that many commenters supported our proposed delayed implementation, and many commenters expressed concerns with the redistributive impacts of the implementation of the rebased and revised MEI in PFS ratesetting. Many commenters also noted the AMA's intent to collect practice cost data from physician practices, which could be used to derive cost share weights for the MEI and RVU shares.

In light of the AMA's current data collection efforts and because the methodological and data source changes to the MEI finalized in the CY 2023 PFS final rule would have significant impacts on PFS payments, similar to our discussion of this topic in the CY 2024 PFS rulemaking cycle (88 FR 78829 through 78831), we continue to believe that delaying the implementation of the finalized 2017-based MEI cost share weights for the RVUs is consistent with our efforts to balance payment stability and predictability with incorporating new data through more routine updates. For these reasons, we did not propose to incorporate the 2017-based MEI in PFS ratesetting for CY 2024. As we noted in the CY 2024 PFS final rule, many commenters on the CY 2024 PFS proposed rule supported our continued delayed implementation of the 2017-based MEI in PFS ratesetting (88 FR 78830). Most of these commenters urged us to pause consideration of other sources for the MEI until the AMA's efforts to collect practice cost data from physician practices have concluded, although a few commenters recommended that we implement the MEI for PFS ratesetting as soon as possible. We agree with the commenters that it would be prudent, and avoid potential duplication of effort, to wait to consider other data sources for the MEI while the AMA's data collection activities are ongoing. As we discussed in the CY 2024 PFS final rule, we continue to monitor the data available related to physician services' input expenses, but we are not proposing to update the data underlying the MEI cost weights at this time. Given our previously described policy goal to balance PFS payment stability and predictability with incorporating new data through more routine updates to the MEI, we are not proposing to incorporate the 2017-based MEI in PFS ratesetting for CY 2025. We invite comments on this approach as well as any information on the timing of the AMA's practice cost data collection efforts and other sources of data we could consider for updating the MEI.

4. Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2025 direct PE input public use files, which are available on the CMS website under downloads for the CY 2025 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

a. Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS final rule with comment period (79 FR 67640 through 67641), we continue to make improvements to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the preservice, service, and post service periods for each code. In addition to increasing the transparency of the information used to set PE RVUs, this level of detail would allow us to compare clinical labor times for activities associated with services across the PFS, which we believe is important to maintaining the relativity of the direct PE inputs. This information would facilitate the identification of the usual numbers of minutes for clinical labor tasks and the identification of exceptions to the usual values. It would also allow for greater transparency and consistency in the assignment of equipment minutes based on clinical labor times. Finally, we believe that the detailed information can be useful in maintaining standard times for particular clinical labor tasks that can be applied consistently to many codes as they are valued over several years, similar in principle to physician preservice time packages. We believe that setting and maintaining such standards would provide greater consistency among codes that share the same clinical labor tasks and could improve the relativity of values among codes. For example, as medical practice and technologies change over time, standards could be updated simultaneously for all codes with the applicable clinical labor tasks instead of waiting for individual codes to be reviewed.

In the CY 2016 PFS final rule with comment period (80 FR 70901), we solicited comments on the appropriate standard minutes for the clinical labor tasks associated with services that use digital technology. After consideration of comments received, we finalized standard times for clinical labor tasks associated with digital imaging at 2 minutes for ''Availability of prior images confirmed'', 2 minutes for ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'', 2 minutes for ''Review examination with interpreting MD'', and 1 minute for ''Exam documents scanned into PACS'' and ''Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.'' In the CY 2017 PFS final rule (81 FR 80184 through 80186), we finalized a policy to establish a range of appropriate standard minutes for the clinical labor activity, ''Technologist QCs images in PACS, checking for all images, reformats, and dose page.'' These standard minutes will be applied to new and revised codes that make use of this clinical labor activity when they are reviewed by us for valuation. We finalized a policy to establish 2 minutes as the standard for the simple case, 3 minutes as the standard for the intermediate

case, 4 minutes as the standard for the complex case, and 5 minutes as the standard for the highly complex case. These values were based upon a review of the existing minutes assigned for this clinical labor activity; we determined that 2 minutes is the duration for most services and a small number of codes with more complex forms of digital imaging have higher values. We also finalized standard times for a series of clinical labor tasks associated with pathology services in the CY 2016 PFS final rule with comment period (80 FR 70902). We do not believe these activities would be dependent on number of blocks or batch size, and we believe that the finalized standard values accurately reflect the typical time it takes to perform these clinical labor tasks.

In reviewing the RUC-recommended direct PE inputs for CY 2019, we noticed that the 3 minutes of clinical labor time traditionally assigned to the ''Prepare room, equipment and supplies'' (CA013) clinical labor activity were split into 2 minutes for the ''Prepare room, equipment and supplies'' activity and 1 minute for the ''Confirm order, protocol exam'' (CA014) activity. We proposed to maintain the 3 minutes of clinical labor time for the ''Prepare room, equipment and supplies'' activity and remove the clinical labor time for the ''Confirm order, protocol exam'' activity wherever we observed this pattern in the RUC-recommended direct PE inputs. Commenters explained in response that when the new version of the PE worksheet introduced the activity codes for clinical labor, there was a need to translate old clinical labor tasks into the new activity codes, and that a prior clinical labor task was split into two of the new clinical labor activity codes: CA007 (*Review patient clinical extant information and questionnaire*) in the preservice period, and CA014 (*Confirm order, protocol exam*) in the service period. Commenters stated that the same clinical labor from the old PE worksheet was now divided into the CA007 and CA014 activity codes, with a standard of 1 minute for each activity. We agreed with commenters that we would finalize the RUC-recommended 2 minutes of clinical labor time for the CA007 activity code and 1 minute for the CA014 activity code in situations where this was the case. However, when reviewing the clinical labor for the reviewed codes affected by this issue, we found that several of the codes did not include this old clinical labor task, and we also noted that several of the reviewed codes that contained the CA014 clinical labor activity code did not contain any clinical labor for the CA007 activity. In these situations, we believe that the three total minutes of clinical staff time would be more accurately described by the CA013 ''Prepare room, equipment and supplies'' activity code, and we finalized these clinical labor refinements. We direct readers to the discussion in the CY 2019 PFS final rule (83 FR 59463 through 59464) for additional details.

Following the publication of the CY 2020 PFS proposed rule, one commenter expressed concern with the published list of common refinements to equipment time. The commenter stated that these refinements were the formulaic result of applying refinements to the clinical labor time and did not constitute separate refinements; the commenter requested that CMS no longer include these refinements in the table published each year. In the CY 2020 PFS final rule, we agreed with the commenter that these equipment time refinements did not reflect errors in the equipment recommendations or policy discrepancies with the RUC's equipment time recommendations. However, we believed it was important to publish the specific equipment times that we were proposing (or finalizing in the case of the final rule) when they differed from the recommended values due to the effect these changes can have on the direct costs associated with equipment time. Therefore, we finalized the separation of the equipment time refinements associated with changes in clinical labor into a separate table of refinements. We direct readers to the discussion in the CY 2020 PFS final rule (84 FR 62584) for additional details.

Historically, the RUC has submitted a ''PE worksheet'' that details the recommended direct PE inputs for our use in developing PE RVUs. The format of the PE worksheet has varied over time, and among the medical specialties developing the recommendations. These variations have made it difficult for the RUC's development and our review of code values for individual codes. Beginning with its recommendations for CY 2019, the RUC mandated the use of a new PE worksheet for its recommendation development process that standardizes the clinical labor tasks and assigns them a clinical labor activity code. We believe the RUC's use of the new PE worksheet in developing and submitting recommendations helps us simplify and standardize the hundreds of clinical labor tasks currently listed in our direct PE database. As in previous calendar years, to facilitate rulemaking for CY 2025, we are continuing to display two versions of the Labor Task Detail public use file: one version with the old listing of clinical labor tasks and one with the same tasks crosswalked to the new listing of clinical labor activity codes. These lists are available on the CMS website under downloads for the CY 2025 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

b. Updates to Prices for Existing Direct PE Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking, beginning with the CY 2012 PFS proposed rule. Beginning in CY 2019 and continuing through CY 2022, we conducted a market-based supply and equipment pricing update using information developed by our contractor, StrategyGen, which updated pricing recommendations for approximately 1300 supplies and 750 equipment items currently used as direct PE inputs. Given the potentially significant changes in payment that would occur, in the CY 2019 PFS final rule, we finalized a policy to phase in our use of the new direct PE input pricing over a 4-year period using a 25/75 percent (CY 2019), 50/50 percent (CY 2020), 75/25 percent (CY 2021), and 100/0 percent (CY 2022) split between new and old pricing. We believed that implementing the proposed updated prices with a 4-year phase-in would improve payment accuracy while maintaining stability and allowing interested parties to address potential concerns about changes in payment for particular items. This 4-year transition period to update supply and equipment pricing concluded in CY 2022; for a more detailed discussion, we refer readers to the CY 2019 PFS final rule with comment period (83 FR 59473 through 59480).

For CY 2025, we are proposing to update the price of 17 supplies and one equipment item in response to the public submission of invoices following the publication of the CY 2024 PFS final rule. The 18 supply and equipment items with proposed updated prices are listed in the valuation of specific codes section of the preamble under Table 16, CY 2025 Invoices Received for Existing Direct PE Inputs.

An interested party submitted 30 invoices to update pricing for the human amniotic membrane allograft

mounted on a non-absorbable self-retaining ring (SD248) supply. We previously updated the price of this supply in the CY 2024 final rule (88 FR 78901) based on averaging together the price of the Prokera Slim, Prokera Classic, and Prokera Plus devices. The interested party submitted new invoices for all three of these devices which averaged to a new price of $1149.00 which we are proposing for the SD248 supply. We are soliciting additional comments from interested parties regarding the price of the SD248 supply as well as any information as far as whether one of these three devices (the Prokera Slim, Prokera Classic, and Prokera Plus) would be more typical than the other two for use as a supply in CPT code 65778.

In the case of the indocyanine green (25ml uou) (SL083) supply, we noticed that there was a clear bimodal distribution of prices on the eight submitted invoices, clustered around $91.00 and $141.67, respectively, with no pricing in between $100 and $140. We are proposing the updated total average price of $125.11 based on the eight submitted invoices for the SL083 supply, however, we are soliciting comments on why there was such divergence in the pricing on the submitted invoices, as well as whether these may represent pricing for two different supplies.

Regarding the Reaction buffer 10X (Ventana 950–300) (SL478) supply, we are proposing to update the price from $0.037 to $0.045, which is less than the $0.075 contained on the invoice submitted by interested parties. We were able to find this product readily available for purchase online at a quantity of 10 liters for $453 or a price of $0.045. We do not believe that it would be typical for providers to pay a higher price based on smaller unit quantities; therefore, we are proposing to update the price of the SL478 supply but only to $0.045, which is the price to purchase this supply online, as stated above.

Interested parties also alerted CMS to a technical correction for pricing the Atomizer tips (disposable) (SL464) supply. We previously finalized a price of $2.66 for the SL464 supply, which was included in the table of Invoices Received for Existing Direct PE Inputs in the CY 2018 final rule (82 FR 53162). However, due to a technical error, the updated pricing for the SL464 supply was never implemented. We are proposing to make this correction for CY 2025; the corrected price of $2.66 for the SL464 supply is included in Table 16.

We are not proposing to update the price of another ten supplies, which were the subject of public submission of invoices. Our reasons for not proposing updates to these prices are detailed below, and we are seeking additional information from interested parties for assistance in pricing these supplies:

- *Liposorber supplies: Tubing set (SC083), Plasma LDL adsorption column (SD186), and Plasma separator (SD188):* We received invoices for these three Liposorber supplies from an interested party. However, it was unclear from the invoice submissions what the unit quantity size is for each product. We require additional information regarding the unit size of each supply included on these invoices to establish updated pricing, and therefore, we are not proposing updates to the prices for these supplies. We are seeking additional comments regarding the pricing of these supplies and whether the pricing has increased so dramatically, as it seems unlikely that prices have tripled in the five years since we most recently updated the pricing for these supplies.
- *Congo Red kits (SA110):* We received three invoices from interested parties requesting an increase in the price of the SA110 supply from $6.80 to $18.78. However, we were able to find Congo Red staining kits readily available online at a price of 100 for $410 or $4.10 per kit. The unit size of these kits was also unclear, which made price comparisons with the submitted invoices difficult. Based on the three invoices and the online price of 100 for $410 or $4.10 per kit, we do not believe there is enough pricing data to support an increase in the price of the SA110 supply from $6.80 to $18.78, and we are not proposing an increase in the price of this supply.
- *Gauze, non-sterile 4in x 4in (SG051):* We received one invoice from interested parties requesting an increase in the price of the SG051 supply from $0.03 to $0.04. However, the submitted invoice price appeared to be for surgical gauze, not non-sterile gauze. We were able to find the 4x4 non-sterile gauze readily available online at less than the invoice price. Based on this information, we do not believe there is enough pricing data to support an increase in the price of the SG051 supply from $0.03 to $0.04, and we are not proposing an increase in the price of this supply.
- *Permanent marking pen (SL477):* We received one invoice from interested parties requesting an increase in the price of the SL477 supply from $2.81 to $4.62. However, we found black marking pens, such as Sharpies, widely available at unit prices around $2.00 when purchased in larger quantities. Based on this information, we do not believe there is enough pricing data to support an increase in the price of the SL477 supply from $2.81 to $4.62, and we are not proposing an increase in the price of this supply.
- *Hematoxylin II (Ventana 790–2208) (SL483):* We received four invoices from interested parties requesting an increase in the price of the SL483 supply from $0.780 to $2.722. However, we were able to find hematoxylin II stains readily available online at cheaper prices, such as $52.00 for 500 ml ($0.104 per ml). Based on this information, we do not believe there is enough pricing data to support an increase in the price of the SL483 supply from $0.780 to $2.722, and we are not proposing an increase in the price of this supply.
- *Bluing reagent (Ventana 760–2037) (SL484):* We received three invoices from interested parties requesting an increase in the price of the SL484 supply from $4.247 to $6.130. While researching the pricing of the SL484 supply, we were unable to determine the unit quantity size on invoices, which made it difficult to evaluate if the requested price accurately reflected market pricing. As best we could tell, the requested price increase to $6.130 was more expensive than comparable online bluing reagents available for purchase. Based on this information, we do not believe there is enough pricing data to support an increase in the price of the SL484 supply from $4.247 to $6.130, and we are not proposing an increase in the price of this supply.
- *EZ Prep (10X) (Ventana 950–102) (SL481) and 250 Test Prep Kit # 78 (Ventana 786–3034) (SL486):* In each of these cases, we received invoices from interested parties requesting substantial increases in the price of the associated supplies, from $0.034 to $0.509 for the SL481 supply and from $0.309 to $2.134 for the SL486 supply. We do not believe that it is reasonable to expect that the typical market prices for these supplies have increased by 1400 percent and 600 percent, respectively, in the 5 years since we most recently updated the pricing for these supplies. The limited pricing information we could find online for each product also failed to support these drastic increases in pricing. Based on this information, we do not believe there is enough pricing data to support the requested increases for the SL481 and SL486 supplies, and we are not proposing increases to the prices for these supplies.

(1) Invoice Submission

We remind readers that we routinely accept public submissions of invoices as part of our process for developing payment rates for new, revised, and

potentially misvalued codes. Often, these invoices are submitted in conjunction with the RUC-recommended values for the codes. To be included in a given year's proposed rule, we generally need to receive invoices by the same February 10th deadline we noted for consideration of RUC recommendations. However, we will consider invoices submitted as public comments during the comment period following the publication of the PFS proposed rule and would consider any invoices received after February 10th or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices. Interested parties are encouraged to submit invoices with their public comments or, if outside the notice and comment rulemaking process, via email at *PE_Price_Input_Update@cms.hhs.gov.*

In recent years, we have noticed a growing number of invoice submissions for use in updating supply and equipment pricing. Although we continue to believe in the importance of using the most recent and accurate invoice data to reflect current market pricing, we do have some concerns that the increased use of these submissions may distort relativity across the fee schedule. Relying on voluntary invoice submissions to update pricing for a small subset of the total number of supply and equipment items in our database, while leaving the overwhelming majority of prices untouched, could be distorting pricing in favor of the most recent submissions. We believe that it may be more efficient, and more accurate, to update supply and equipment pricing in a more comprehensive fashion similar to the pricing update that took place from CY 2019 to CY 2022. For example, future updates to supply and equipment pricing could take place in tandem with updates to clinical labor pricing after the current clinical labor update concludes in CY 2025. We welcome public comments on this general topic of more comprehensive updates to supply and equipment pricing, and we may consider comments we receive to inform future rulemaking.

(2) Supply Pack Pricing Update

Interested parties previously notified CMS that they identified numerous discrepancies between the aggregated cost of some supply packs and the individual item components contained within. The interested parties indicated that CMS should rectify these mathematical errors as soon as possible to ensure that the sum correctly matches the totals from the individual items, and they recommended that we resolve these pricing discrepancies in the supply packs during CY 2024 rulemaking. The AMA RUC convened a workgroup on this subject and submitted recommendations to update pricing for a series of supply packs along with the RUC's comment letter for the CY 2024 rule cycle.

We appreciated the additional information and RUC workgroup recommendations regarding discrepancies in the aggregated cost of some supply packs. However, due to the projected significant cost revisions in the pricing of supply packs and because we did not propose to address supply pack pricing in the CY 2024 proposed rule, we stated that this issue would be better addressed in future rulemaking. For example, the cleaning and disinfecting endoscope pack (SA042) is included as a supply input in more than 300 HCPCS codes, which could have a sizable impact on the overall valuation of these services, and which was not incorporated into the proposed RVUs published for the CY 2024 proposed rule. We stated that interested parties would be better served if we comprehensively addressed this topic during future rulemaking in which commenters could provide feedback in response to proposed pricing updates (88 FR 78833 through 78834).

For CY 2025, we are proposing to implement the supply pack pricing update and associated revisions as recommended by the RUC's workgroup. We are proposing to update the pricing of the ''pack, cleaning and disinfecting, endoscope'' (SA042) supply from $19.43 to $31.29, to update the pricing of the ''pack, drapes, cystoscopy'' (SA045) supply from $17.33 to $14.99, to update the pricing of the ''pack, ocular photodynamic therapy'' (SA049) supply from $16.35 to $26.35, to update the pricing of the ''pack, urology cystoscopy visit'' (SA058) supply from $113.70 to $37.63, and to update the pricing of the ''pack, ophthalmology visit (w-dilation)'' (SA082) supply from $3.91 to $2.33. As recommended by the RUC workgroup, we are also proposing to delete the ''pack, drapes, laparotomy (chest-abdomen)'' (SA046) supply entirely. The proposed updated prices for these supply packs are listed in the valuation of specific codes section of the preamble under Table 16, CY 2025 Invoices Received for Existing Direct PE Inputs.

In accordance with the RUC workgroup's recommendations, we are also proposing to create eight new supply codes, including components contained within previously existing supply packs. Aside from the SB056 supply, which is a replacement in several HCPCS codes for the deleted SA046 supply pack, all of these new supplies are not included as standalone direct PE inputs in any current HCPCS codes, as they are, again, components contained within previously existing supply packs. We are proposing to add:

- The kit, ocular photodynamic therapy (PDT) (SA137) supply at a price of $26.00 as a component of the SA049 supply pack;
- The Abdominal Drape Laparotomy Drape Sterile (100 in x 72 in x 124 in) (SB056) supply at a price of $8.049 as a replacement for the SA046 supply pack;
- The drape, surgical, legging (SB057) supply at a price of $3.284 as a component of the SA045 supply pack;
- The drape, surgical, split, impervious, absorbent (SB058) supply at a price of $8.424 as a component of the SA045 supply pack;
- The post-mydriatic spectacles (SB059) supply at a price of $0.328 as a component of the SA082 supply pack;
- The y-adapter cap (SD367) supply at a price of $0.352 as a component of the SA049 supply pack;
- The ortho-phthalaldehyde 0.55% (*e.g.,* Cidex OPA) (SM030) supply at a price of $0.554 as a component of the SA042 supply pack; and
- The ortho-phthalaldehyde test strips (SM031) supply at a price of $1.556 as a component of the SA042 supply pack.

The proposed new supply pack component items are listed in the valuation of specific codes section of the preamble under Table 17, CY 2025 New Invoices.

We are also proposing the following additional supply substitutions based on the recommendations of the RUC workgroup. We are proposing to remove the deleted SA046 supply pack and replace it with the drape, sterile, fenestrated 16in x 29in (SB011) supply for CPT codes 19020, 19101, 19110, 19112, 20101, and 20102. We are proposing to remove the deleted SA046 supply pack and replace it with two supplies—the drape, sterile, three-quarter sheet (SB014) and the drape, towel, sterile 18in x 26in (SB019)—for CPT codes 19000 and 60300. We are proposing to remove the deleted SA046 supply pack and replace it with two supplies—the drape, towel, sterile 18in × 26in (SB019) and the newly created Abdominal Drape Laparotomy Drape Sterile (100 in × 72 in × 124 in) (SB056) supply—for CPT codes 22510, 22511, 22513, and 22514. We are proposing to remove the deleted SA046 supply pack without replacing it with anything for CPT code 22526; the RUC workgroup

did not make a recommendation on what to do with CPT code 27278, which also previously contained the SA046 supply pack. Therefore, we are also proposing not to replace the SA046 supply pack with any supplies for this code. The RUC workgroup also recommended removing the SA046 supply pack from CPT code 64595 with no replacement; however, this code was recently reviewed at the April 2022 RUC meeting and it no longer includes the SA046 supply.

The RUC workgroup also reviewed the issue of skin adhesives and identified several generic alternatives to using the skin adhesive (Dermabond) (SG007) supply. The workgroup stated that there are multiple skin adhesive products, at different price points, available that work similarly to Dermabond and requested that generic alternatives be used overall in place of brand names in the CMS direct PE database. The workgroup made a series of suggestions for CMS to create new medical supply item codes to encompass the generic formulations of cyanoacrylate skin adhesive in multidose form and single use sterile application.

We appreciate the recommendations from the RUC workgroup and concur that generic alternatives be used in place of brand names, where appropriate, in the CMS direct PE database. However, we have no pricing information or submitted invoices for the four generic formulations of cyanoacrylate skin adhesive requested by the RUC workgroup (2-Octyl-cyanoacrylate, n-Butyl-2-cyanoacrylate, Combined n-Butyl and 2-Octylcyanoacrylate, and Ethyl-2-cyanoacrylate). Since these four potential new supplies have no pricing information and are not currently included as direct PE inputs for any HCPCS codes, we have not added them to our direct PE database for the CY 2025 proposed rule due to lack of available information.

c. Clinical Labor Pricing Update

Section 220(a) of the PAMA provides that the Secretary may collect or obtain information from any eligible professional or any other source on the resources directly or indirectly related to furnishing services for which payment is made under the PFS and that such information may be used in the determination of relative values for services under the PFS. Such information may include the time involved in furnishing services; the amounts, types, and prices of PE inputs; overhead and accounting information for practices of physicians and other suppliers, and any other elements that would improve the valuation of services under the PFS.

Beginning in CY 2019, we updated the supply and equipment prices used for PE as part of a market-based pricing transition; CY 2022 was the final year of this 4-year transition. We initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the supply and equipment pricing for CY 2019, and we finalized a policy in CY 2019 to phase in the new pricing over a period of 4 years. However, we did not propose to update the clinical labor pricing, and the pricing for clinical labor has remained unchanged during this pricing transition. Clinical labor rates were last updated for CY 2002 using Bureau of Labor Statistics (BLS) data and other supplementary sources where BLS data were not available; we refer readers to the full discussion in the CY 2002 PFS final rule for additional details (66 FR 55257 through 55262).

Interested parties raised concerns that the long delay since clinical labor pricing was last updated created a significant disparity between CMS' clinical wage data and the market average for clinical labor. In recent years, several interested parties suggested that certain wage rates were inadequate because they did not reflect current labor rate information. Some interested parties also stated that updating the supply and equipment pricing without updating the clinical labor pricing could create distortions in the allocation of direct PE. They argued that since the pool of aggregated direct PE inputs is budget neutral, if these rates are not routinely updated, clinical labor may become undervalued over time relative to equipment and supplies, especially since the supply and equipment prices are in the process of being updated. There was considerable interest among interested parties in updating the clinical labor rates, and when we solicited comment on this topic in past rules, such as in the CY 2019 PFS final rule (83 FR 59480), interested parties supported the idea.

Therefore, we proposed to update the clinical labor pricing for CY 2022, in conjunction with the final year of the supply and equipment pricing update (86 FR 39118 through 39123). We believed updating the clinical labor pricing was important to maintain relativity with the recent supply and equipment pricing updates. We proposed to use the methodology outlined in the CY 2002 PFS final rule (66 FR 55257), which draws primarily from BLS wage data, to calculate updated clinical labor pricing. As we stated in the CY 2002 PFS final rule, the BLS' reputation for publishing valid estimates that are nationally representative led to the choice to use the BLS data as the main source. We believe that the BLS wage data continues to be the most accurate source to use as a basis for clinical labor pricing and this data will appropriately reflect changes in clinical labor resource inputs for setting PE RVUs under the PFS. We used the most current BLS survey data (2019) as the main source of wage data for our CY 2022 clinical labor proposal.

We recognized that the BLS survey of wage data does not cover all the staff types contained in our direct PE database. Therefore, we crosswalked or extrapolated the wages for several staff types using supplementary data sources for verification whenever possible. In situations where the price wages of clinical labor types were not referenced in the BLS data, we used the national salary data from the Salary Expert, an online project of the Economic Research Institute that surveys national and local salary ranges and averages for thousands of job titles using mainly government sources. (A detailed explanation of the methodology used by Salary Expert to estimate specific job salaries can be found at *www.salaryexpert.com*.) We previously used Salary Expert information as the primary backup source of wage data during the last update of clinical labor pricing in CY 2002. If we did not have direct BLS wage data available for a clinical labor type, we used the wage data from Salary Expert as a reference for pricing, then crosswalked these clinical labor types to a proxy BLS labor category rate that most closely matched the reference wage data, similar to the crosswalks used in our PE/HR allocation. For example, there is no direct BLS wage data for the Mammography Technologist (L043) clinical labor type; we used the wage data from Salary Expert as a reference and identified the BLS wage data for Respiratory Therapists as the best proxy category. We calculated rates for the ''blend'' clinical labor categories by combining the rates for each labor type in the blend and then dividing by the total number of labor types in the blend.

As in the CY 2002 clinical labor pricing update, the proposed cost per minute for each clinical staff type was derived by dividing the average hourly wage rate by 60 to arrive at the per minute cost. In cases where an hourly wage rate was not available for a clinical staff type, the proposed cost per minute for the clinical staff type was derived by

dividing the annual salary (converted to 2021 dollars using the Medicare Economic Index) by 2080 (the number of hours in a typical work year) to arrive at the hourly wage rate and then again by 60 to arrive at the per minute cost. We ultimately finalized the use of median BLS wage data instead of mean BLS wage data in response to comments in the CY 2022 PFS final rule. To account for the employers' cost of providing fringe benefits, such as sick leave, we finalized a benefits multiplier of 1.296 based on a BLS release from June 17, 2021 (USDL–21–1094). As an example of this process, for the Physical Therapy Aide (L023A) clinical labor type, the BLS data reflected a median hourly wage rate of $12.98, which we multiplied by the 1.296 benefits modifier and then divided by 60 minutes to arrive at the finalized per-minute rate of $0.28.

After considering the comments on our CY 2022 proposals, we agreed with commenters that the use of a multi-year transition would help smooth out the changes in payment resulting from the clinical labor pricing update, avoiding potentially disruptive changes in payment for affected interested parties, and promoting payment stability from year-to-year. We believed it would be appropriate to use a 4-year transition, as we have for several other broad-based updates or methodological changes. While we recognized that using a 4-year transition to implement the update means that we will continue to rely in part on outdated data for clinical labor pricing until the change is fully completed in CY 2025, we agreed with the commenters that these significant updates to PE valuation should be implemented in the same way, and for the same reasons, as for other major updates to pricing such as the recent supply and equipment update. Therefore, we finalized the clinical labor pricing update implementation over four years to transition from current prices to the final updated prices in CY 2025. We finalized the implementation of this pricing transition over 4 years, such that one-quarter of the difference between the current price and the fully phased-in price is implemented for CY 2022, one-third of the difference between the CY 2022 price and the final price is implemented for CY 2023, and one-half of the difference between the CY 2023 price and the final price is implemented for CY 2024, with the new direct PE prices fully implemented for CY 2025. (86 FR 65025) An example of the transition from the current to the fully-implemented new pricing that we finalized in the CY 2022 PFS final rule is provided in Table 4.

TABLE 4: Example of Clinical Labor Pricing Transition

Current Price	$1.00	
Final Price	$2.00	
Year 1 (CY 2022) Price	$1.25	1/4 difference between $1.00 and $2.00
Year 2 (CY 2023) Price	$1.50	1/3 difference between $1.25 and $2.00
Year 3 (CY 2024) Price	$1.75	1/2 difference between $1.50 and $2.00
Final (CY 2025) Price	$2.00	

(1) CY 2023 Clinical Labor Pricing Updates

For CY 2023, we received information from one interested party regarding the pricing of the Histotechnologist (L037B) clinical labor type. The interested party provided data from the 2019 Wage Survey of Medical Laboratories which supported an increase in the per-minute rate from the $0.55 finalized in the CY 2022 PFS final rule to $0.64. This rate of $0.64 for the L037B clinical labor type is a close match to the online salary data that we had for the Histotechnologist and matches the $0.64 rate that we initially proposed for L037B in the CY 2022 PFS proposed rule. Based on the wage data provided by the commenter, we proposed this $0.64 rate for the L037B clinical labor type for CY 2023; we also proposed a slight increase in the pricing for the Lab Tech/Histotechnologist (L035A) clinical labor type from $0.55 to $0.60 as it is a blend of the wage rate for the Lab Technician (L033A) and Histotechnologist clinical labor types. We also proposed the same increase to $0.60 for the Angio Technician (L041A) clinical labor type, as we previously established a policy in the CY 2022 PFS final rule that the pricing for the L041A clinical labor type would match the rate for the L035A clinical labor type (86 FR 65032).

Based on comments received on the CY 2023 proposed rule, we finalized a change in the descriptive text of the L041A clinical labor type from ''Angio Technician'' to ''Vascular Interventional Technologist''. We also finalized an update in the pricing of three clinical labor types: from $0.60 to $0.84 for the Vascular Interventional Technologist (L041A), from $0.63 to $0.79 for the Mammography Technologist (L043A), and from $0.76 to $0.78 for the CT Technologist (L046A) based on submitted wage data from the 2022 Radiologic Technologist Wage and Salary Survey (87 FR 69422 through 69425).

(2) CY 2024 Clinical Labor Pricing Updates

We did not receive new wage data or other additional information for use in clinical labor pricing from interested parties prior to the publication of the CY 2024 PFS proposed rule. Therefore, our proposed clinical labor pricing for CY 2024 was based on the clinical labor pricing that we finalized in the CY 2023 PFS final rule, incremented an additional step for Year 3 of the update. Based on comments received on the CY 2024 proposed rule, we finalized an update in the clinical labor pricing of the cytotechnologist (L045A) clinical labor type from $0.76 to $0.85 based on submitted data from the 2021 American Society of Clinical Pathologists (ASCP) Wage Survey of Medical Laboratories (88 FR 78838).

(3) CY 2025 Clinical Labor Pricing Update Proposals

We did not receive new wage data or other additional information for use in clinical labor pricing from interested parties prior to the publication of the CY 2025 PFS proposed rule. Therefore, our proposed clinical labor pricing for CY 2025 in Table 5 is based on the clinical labor pricing that we finalized in the CY 2024 PFS final rule, incremented an additional step for the final Year 4 of the update:

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TABLE 5: Proposed CY 2025 Clinical Labor Pricing

Labor Code	Labor Description	Source	CY 2021 Rate Per Minute	Final Y4 Rate Per Minute	Total % Change
L023A	Physical Therapy Aide	BLS 31-2022	0.23	0.28	22%
L026A	Medical/Technical Assistant	BLS 31-9092	0.26	0.36	38%
L030A	Lab Tech/MTA	L033A, L026A	0.30	0.46	53%
L032B	EEG Technician	BLS 29-2098	0.32	0.44	38%
L033A	Lab Technician	BLS 29-2010	0.33	0.55	67%
L033B	Optician/COMT	BLS 29-2081, BLS 29-2057	0.33	0.39	18%
L035A	Lab Tech/Histotechnologist	L033A, L037B	0.35	0.60	70%
L037A	Electrodiagnostic Technologist	BLS 29-2098	0.37	0.44	19%
L037B	Histotechnologist	BLS 29-2010	0.37	0.64	73%
L037C	Orthoptist	BLS 29-1141	0.37	0.76	105%
L037D	RN/LPN/MTA	L051A, BLS 29-2061, L026A	0.37	0.54	46%
L037E	Child Life Specialist	BLS 21-1021	0.37	0.49	32%
L038A	COMT/COT/RN/CST	BLS 29-2057, BLS 29-2055, L051A, BLS 19-4010	0.38	0.52	37%
L038B	Cardiovascular Technician	BLS 29-2031	0.38	0.60	58%
L038C	Medical Photographer	BLS 29-2050	0.38	0.38	0%
L039A	Certified Retinal Angiographer	BLS 29-9000	0.39	0.52	33%
L039B	Physical Therapy Assistant	BLS 31-2021	0.39	0.61	56%
L039C	Psychometrist	BLS 21-1029	0.39	0.64	62%
L041A	Vascular Interventional Technologist	ASRT Wage Data	0.41	0.84	104%
L041B	Radiologic Technologist	BLS 29-2034	0.41	0.63	54%
L041C	Second Radiologic Technologist for Vertebroplasty	BLS 29-2034	0.41	0.63	54%
L042A	RN/LPN	L051A, BLS 29-2061	0.42	0.63	50%
L042B	Respiratory Therapist	BLS 29-1126	0.42	0.64	52%
L043A	Mammography Technologist	ASRT Wage Data	0.43	0.79	84%
L045A	Cytotechnologist	BLS 29-9092	0.45	0.85	89%
L045B	Electron Microscopy Technologist	BLS 29-1124	0.45	0.89	98%
L045C	CORF social worker/psychologist	BLS 21-1022, BLS 19-3031	0.45	0.70	56%
L046A	CT Technologist*	ASRT Wage Data	0.46	0.78	70%
L047A	MRI Technologist	BLS 29-2035	0.47	0.76	62%
L047B	REEGT (Electroencephalographic Tech)	BLS 29-2035	0.47	0.76	62%
L047C	RN/Respiratory Therapist	L051A, L042B	0.47	0.70	49%
L047D	RN/Registered Dietician	L051A, BLS 29-1031	0.47	0.70	49%
L049A	Nuclear Medicine Technologist	BLS 29-2033	0.62	0.81	32%
L050A	Cardiac Sonographer	BLS 29-2032	0.50	0.77	54%
L050B	Diagnostic Medical Sonographer	BLS 29-2032	0.50	0.77	54%
L050C	Radiation Therapist	BLS 29-1124	0.50	0.89	78%
L050D	Second Radiation Therapist for IMRT	BLS 29-1124	0.50	0.89	78%
L051A	RN	BLS 29-1141	0.51	0.76	49%
L051B	RN/Diagnostic Medical Sonographer	L051A, BLS 29-2032	0.51	0.77	51%
L051C	RN/CORF	L051A	0.51	0.76	49%
L052A	Audiologist	BLS 29-1181	0.52	0.81	56%
L053A	RN/Speech Pathologist	L051A, L055A	0.53	0.79	49%
L054A	Vascular Technologist	BLS 19-1040	0.54	0.91	69%
L055A	Speech Pathologist	BLS 29-1127	0.55	0.82	49%
L056A	RN/OCN	BLS 29-2033	0.79	0.81	3%
L057A	Genetics Counselor	BLS 29-9092	0.57	0.85	50%
L057B	Behavioral Health Care Manager	BLS 21-1018	0.57	0.57	0%
L063A	Medical Dosimetrist	BLS 19-1040	0.63	0.91	44%

Labor Code	Labor Description	Source	CY 2021 Rate Per Minute	Final Y4 Rate Per Minute	Total % Change
L107A	Medical Dosimetrist/Medical Physicist	L063A, L152A	1.08	1.52	41%
L152A	Medical Physicist	AAPM Wage Data	1.52	2.14	41%

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As was the case for the market-based supply and equipment pricing update, the clinical labor rates will remain open for public comment during the 60-day comment period for this CY 2025 PFS proposed rule. We expect to set the updated clinical labor rates for CY 2025 in the final rule. We updated the pricing of some clinical labor types in the CY 2022, CY 2023, and CY 2024 PFS final rules in response to information provided by commenters. For the full discussion of the clinical labor pricing update, we direct readers to the CY 2022 PFS final rule (86 FR 65020 through 65037).

5. Development of Strategies for Updates to Practice Expense Data Collection and Methodology

a. Background

The AMA PPIS was first introduced in 2007 as a means to collect comprehensive and reliable data on the direct and indirect PEs incurred by physicians (72 FR 66222). In considering the use of PPIS data, the goal was to improve the accuracy and consistency of PE RVUs used in the PFS. The data collection process included a stratified random sample of physicians across various specialties, and the survey was administered between August 2007 and March 2008. Data points from that period of time are integrated into PFS calculations today. In the CY 2009 PFS proposed rule (73 FR 38507 through 3850), we discussed the indirect PE methodology that used data from the AMA's survey that predated the PPIS. In CY 2010 PFS rulemaking, we announced our intent to incorporate the AMA PPIS data into the PFS ratesetting process, which would first affect the PE RVU. In the CY 2010 PFS proposed rule, we outlined a 4-year transition period, during which we would phase in the AMA PPIS data, replacing the existing PE data sources (74 FR 33554). We also explained that our proposals intended to update survey data only (74 FR 33530 through 33531). In our CY 2010 final rule, we finalized our proposal, with minor adjustments based on public comments (74 FR 61749 through 61750). We responded to the comments we received about the transition to using the PPIS to inform indirect PE allocations (74 FR 61750). In the responses, we acknowledged concerns about potential gaps in the data, which could impact the allocation of indirect PE for certain physician specialties and suppliers, which are issues that remain important today. The CY 2010 PFS final rule explains that section 212 of the Balanced Budget Refinement Act of 1999 (Pub. L. 106–113, November 29, 1999) (BBRA) directed the Secretary to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. BBRA required us to establish criteria for accepting supplemental survey data. Since the supplemental surveys were specific to individual specialties and not part of a comprehensive multispecialty survey, we had required that certain precision levels be met in order to ensure that the supplemental data was sufficiently valid, and acceptable for use in the development of the PE RVUs. At the time, our rationale included the assumption that because the PPIS is a contemporaneous, consistently collected, and comprehensive multispecialty survey, we do not believe similar precision requirements are necessary, and we did not propose to establish them for the use of the PPIS data (74 FR 61742). We noted potential gaps in the data, which could impact the allocation of indirect PE for certain physician and suppliers. The CY 2010 final rule adopted the proposal, with minor adjustments based on public comments, and explained that these minor adjustments were in part due to non-response bias that results when the characteristics of survey respondents differ in meaningful ways, such as in the mix of practices sizes, from the general population (74 FR 61749 through 61750).

Throughout the 4-year transition period, from CY 2010 to CY 2013, we gradually incorporated the AMA PPIS data into the PFS rates, replacing the previous data sources. The process involved addressing concerns and making adjustments as necessary, such as refining the PFS ratesetting methodology in consideration of interested party feedback. For background on the refinements that we considered after the transition began, we refer readers to discussions in the CY 2011 through 2014 final rules (75 FR 73178 through 73179; 76 FR 73033 through 73034; 77 FR 98892; 78 FR 74272 through 74276).

In the CY 2011 PFS proposed rule, we requested comments on the methodology for calculating indirect PE RVUs, explicitly seeking input on using survey data, allocation methods, and potential improvements (75 FR 40050). In our CY 2011 PFS final rule, we addressed comments regarding the methodology for indirect PE calculations, focusing on using survey data, allocation methods, and potential improvements (75 FR 73178 through 73179). We recognized some limitations of the current PFS ratesetting methodology but maintained that the approach was the most appropriate at the time. In the CY 2012 PFS final rule, we responded to comments related to indirect PE methodology, including concerns about allocating indirect PE to specific services and using the AMA PPIS data for certain specialties (76 FR 73033 through 73034). We indicated that CMS would continue to review and refine the methodology and work with interested parties to address their concerns. In the CY PFS 2014 final rule, we responded to comments about fully implementing the AMA PPIS data. By 2014, the AMA PPIS data had been fully integrated into the PFS, serving as the primary source for determining indirect PE inputs (78 FR 74235). We continued to review data and the PE methodology annually, considering interested party feedback and evaluating the need for updates or refinements to ensure the accuracy and relevance of PE RVUs (79 FR 67548). In the years following the full implementation of the AMA PPIS data, we further engaged with interested parties, thought leaders and subject matter experts to improve our PE inputs' accuracy and reliability. For further background, we refer readers to our discussions in final rules for CY 2016 through 2022 (80 FR 70892; 81 FR 80175; 82 FR 52980 through 52981; 83 FR 59455 through 59456; 84 FR 62572; 85 FR 84476 through 84478; 86 FR 62572).

In our CY 2023 PFS final rule, we issued an RFI to solicit public comment

on strategies to update PE data collection and methodology (87 FR 69429 through 69432). We solicited comments on current and evolving trends in health care business arrangements, the use of technology, or similar topics that might affect or factor into PE calculations. We reminded readers that we have worked with interested parties and CMS contractors for years to study the landscape and identify possible strategies to reshape the PE portion of physician payments. The fundamental issues are clear but thought leaders and subject matter experts have advocated for more than one tenable approach to updating our PE methodology.

As described in previous rulemaking, we have continued interest in developing a roadmap for updates to our PE methodology that account for changes in the health care landscape. Of various considerations necessary to form a roadmap for updates, we reiterate that allocations of indirect PE continue to present a wide range of challenges and opportunities. As discussed in multiple cycles of previous rulemaking, our PE methodology relies on AMA PPIS data, which may represent the best aggregated available source of information at this time. However, we acknowledge the limitations and challenges interested parties have raised about using the current data for indirect PE allocations, which we have also examined in related ongoing research. We noted in our CY 2023 and CY 2024 rules that there are several competing concerns that CMS must take into account when considering updated data sources, which also should support and enable ongoing refinements to our PE methodology.

b. Preparation for Incorporating Refreshed Data and Request for Information on Timing To Effectuate Routine Updates

In the CY 2024 PFS proposed rule, we continued to encourage interested parties to provide feedback and suggestions to CMS that give an evidentiary basis to shape optimal PE data collection and methodological adjustments over time. Considering our ratesetting methodology and prior experiences implementing new data, we issued a follow-up from the CY 2023 comment solicitation for general information. We solicited comments from interested parties on strategies to incorporate information that could address known challenges we experienced in implementing the initial AMA PPIS data. Our current methodology relies on the AMA PPIS data, legislatively mandated supplemental data sources (for, example, we use supplemental survey data collected in 2003, as required by section 1848(c)(2)(H)(i) of the Act to set rates for oncology and hematology specialties), and in some cases crosswalks to allocate indirect PE as necessary for certain specialties and provider types. We also sought to understand whether, upon completion of the updated PPIS data collection effort by the AMA, contingencies or alternatives may be necessary and available to address the lack of data availability or response rates for a given specialty, set of specialties, or specific service suppliers who are paid under the PFS.

In response to last year's RFI, most commenters stated that CMS should defer significant changes until the AMA PPIS results become available. For further background, refer to 88 FR 78841 to 78843. In responding to our RFI, the AMA RUC provided a set of responses, which many other commenters repeated in their separate, individual comments. In summary, the AMA RUC letter submission from CY 2024 suggested that CMS should not consider further changes until PPIS data collection and analysis is complete. Overall, the AMA comments generally do not support any change to the methodology and stated that CMS should wait to consider any further changes until PPIS updates become available. Further, we noted that through its contractor, Mathematica, the AMA secured an endorsement for the PPIS updates from each State society, national medical specialty society, and others prior to fielding the survey (88 FR 78843). Refer to the AMA's summary of the PPIS, available at *https://www.ama-assn.org/system/files/physician-practice-information-survey-summary.pdf.* The AMA expects analysis, reporting, and documentation to complete by the end of CY 2024, and the AMA would share data with CMS when results become available.

We believe the AMA's approach may possibly mitigate nonresponse bias, which created challenges using previous PPIS data. However, we remain uncertain about whether endorsements prior to fielding the survey may inject other types of bias in the validity and reliability of the information collected. We believe it remains important to reflect on the challenges with our current methodology, and to continue to consider alternatives that improve the stability and accuracy of our overall PE methodology. We reiterate our discussion summarizing the responses to previous years' RFIs in each of the CY 2023 and CY 2024 final rules (refer to 87 FR 69429 through 69432 and 88 FR 78841 to 78843). We have started new work under contract with the RAND Corporation to analyze and develop alternative methods for measuring PE and related inputs for implementation of updates to payment under the PFS. We continue to study possible alternatives, and would include analysis of updated PPIS data, as part of our ongoing work. In the meantime, we request general information from the public on ways that CMS may continue work to improve the stability and predictability of any future updates. Specifically, we request feedback from interested parties regarding scheduled, recurring updates to PE inputs for supply and equipment costs.

We believe that establishing a cycle of timing to update supply and equipment cost inputs every 4 years may be one means of advancing shared goals of stability and predictability. CMS would collect available data, including, but not limited to, submissions and independent third-party data sources, and propose a phase-in period over the following 4 years. The phase-in approach maps to our experience with previous updates. Additionally, we believe that more frequent updates may have the unintended consequence of disproportionate effects of various supplies and equipment that have newly updated costs.

Further, we seek feedback on possible mechanisms to establish a balance whereby our methodology would account for inflation and deflation in supply and equipment costs. We remain uncertain how economies of scale (meaning a general principle that cost per unit of production decreases as the scale of production increases) should or should not factor into future adjustments to our methodology. There remains a diversity of perspectives among interested parties about such effects. We seek information about specific mechanisms that may be appropriate, and in particular, approaches that would leverage verifiable and independent, third-party data that is not managed or controlled by active market participants.

C. Potentially Misvalued Services Under the PFS

1. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the relative value units (RVUs) established under the PFS. Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using

certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) of the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section II.E. of this proposed rule, under Valuation of Specific Codes, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the American Medical Association (AMA) Resource-Based Relative Value Scale (RBRVS) Update Committee (RUC), MedPAC, and other interested parties. For many years, the RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process as authorized by statute. We may also consider analyses of work time, work RVUs, or direct PE inputs using other data sources, such as the Veterans Health Administration (VHA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Merit-based Incentive Payment System (MIPS) data. In addition to considering the most recently available data, we assess the results of physician surveys and specialty recommendations submitted to us by the RUC for our review. We also consider information provided by other interested parties such as from the general medical-related community and the public. We conduct a review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available and requires us to take into account the results of consultations with organizations representing physicians who provide the services. In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs.

In its March 2006 Report to the Congress (*https://www.medpac.gov/document/report-to-the-congress-2006-medicare-payment-policy/*), MedPAC discussed the importance of appropriately valuing physicians' services, noting that misvalued services can distort the market for physicians' services, as well as for other health care services that physicians order, such as hospital services. In that same report, MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, ''When a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.'' We believe services can also become overvalued when PE costs decline. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases, or PE costs rise.

As MedPAC noted in its March 2009 Report to Congress (*https://www.medpac.gov/docs/default-source/reports/march-2009-report-to-congress-medicare-payment-policy.pdf*), in the intervening years since MedPAC made the initial recommendations, CMS and the RUC have taken several steps to improve the review process. Also, section 1848(c)(2)(K)(ii) of the Act augments our efforts by directing the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following categories:

- Codes that have experienced the fastest growth.
- Codes that have experienced substantial changes in PE.
- Codes that describe new technologies or services within an appropriate time-period (such as 3 years) after the relative values are initially established for such codes.
- Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes that have not been subject to review since implementation of the fee schedule.
- Codes that account for the majority of spending under the PFS.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the same service between different sites of service.
- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high intraservice work per unit of time.
- Codes with high PE RVUs.
- Codes with high cost supplies.
- Codes as determined appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using current processes for consideration of coding changes), which may involve consolidating individual services into bundled codes for payment under the PFS.

2. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous potentially misvalued codes as specified in section 1848(c)(2)(K)(ii) of the Act, and we intend to continue our work examining potentially misvalued codes in these areas over the upcoming years. As part of our current process, we identify potentially misvalued codes for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially

misvalued codes established in the CY 2012 PFS final rule with comment period (76 FR 73026, 73058 through 73059), other individuals and groups submit nominations for review of potentially misvalued codes as well. Individuals and groups may submit codes for review under the potentially misvalued codes initiative to CMS in one of two ways. Nominations may be submitted to CMS via email or through postal mail. Email submissions should be sent to the CMS emailbox at *MedicarePhysicianFeeSchedule@cms.hhs.gov,* with the phrase ''Potentially Misvalued Codes'' and the referencing CPT code number(s) and/or the CPT descriptor(s) in the subject line. Physical letters for nominations should be sent via the U.S. Postal Service to the Centers for Medicare & Medicaid Services, Mail Stop: C4–01–26, 7500 Security Blvd., Baltimore, Maryland 21244. Envelopes containing the nomination letters must be labeled ''Attention: Division of Practitioner Services, Potentially Misvalued Codes.'' Nominations for consideration in our next annual rule cycle should be received by our February 10th deadline. Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed over 1,700 potentially misvalued codes to refine work RVUs and direct PE inputs. We have assigned appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the CY 2012 PFS final rule with comment period (76 FR 73052 through 73055). In the same CY 2012 PFS final rule with comment period, we finalized our policy to consolidate the review of physician work and PE at the same time and established a process for the annual public nomination of potentially misvalued services.

In the CY 2013 PFS final rule with comment period (77 FR 68892, 68896 through 68897), we built upon the work we began in CY 2009 to review potentially misvalued codes that have not been reviewed since the implementation of the PFS (so-called ''Harvard-valued codes'' [1]). In the CY 2019 PFS proposed rule (73 FR 38589), we requested recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume, low intensity codes. In the fourth Five-Year Review of Work RVUs proposed rule (76 FR 32410, 32419), we requested recommendations from the RUC to aid in our review of Harvard-valued codes with annual utilization of greater than 30,000 services. In the CY 2013 PFS final rule with comment period, we identified specific Harvard-valued services with annual allowed charges that total at least $10,000,000 as potentially misvalued. In addition to the Harvard-valued codes, in the CY 2013 PFS final rule with comment period we finalized for review a list of potentially misvalued codes that have stand-alone PE (codes with physician work and no listed work time and codes with no physician work that have listed work time). We continue each year to consider and finalize a list of potentially misvalued codes that have or will be reviewed and revised as appropriate in future rulemaking.

3. CY 2025 Identification and Review of Potentially Misvalued Services

In the CY 2012 PFS final rule with comment period (76 FR 73058), we finalized a process for the public to nominate potentially misvalued codes. In the CY 2015 PFS final rule with comment period (79 FR 67548, 67606 through 67608), we modified this process whereby the public and interested parties may nominate potentially misvalued codes for review by submitting the code with supporting documentation by February 10th of each year. Supporting documentation for codes nominated for the annual review of potentially misvalued codes may include the following:

- Documentation in peer reviewed medical literature or other reliable data that demonstrate changes in physician work due to one or more of the following: technique, knowledge and technology, patient population, site-of-service, length of hospital stay, and work time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of work time, work RVU, or direct PE inputs using other data sources (for example, VA, NSQIP, the STS National Database, and the MIPS data).
- National surveys of work time and intensity from professional and management societies and organizations, such as hospital associations.

We evaluate the supporting documentation submitted with the nominated codes and assess whether the nominated codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate for each nominated code whether we agree with its inclusion as a potentially misvalued code. The public has the opportunity to comment on these and all other proposed potentially misvalued codes. In each year's final rule, we finalize our list of potentially misvalued codes.

a. Public Nominations

In each proposed rule, we seek nominations from the public and from interested parties of codes that they believe we should consider as potentially misvalued. We receive public nominations for potentially misvalued codes by February 10th and we display these nominations on our public website, where we include the submitter's name, their associated organization, and the submitted studies for full transparency. We sometimes receive submissions for specific, PE-related inputs for codes, and discuss these PE-related submissions, as necessary under the Determination of PE RVUs section of the rule. We summarize below this year's submissions under the potentially misvalued code initiative. For CY 2025, we received 5 nominations concerning various codes. The nominations are as follows:

(1) CPT Codes 22210, 22212, 22214, 22216

An interested party nominated CPT codes 22210 (*Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; cervical*) (090 day global code), 22212 (*Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; thoracic*) (090 day global code), 22214 (*Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; lumbar*) (090 day global code), and 22216 (*Osteotomy of*

[1] The research team and panels of experts at the Harvard School of Public Health developed the original work RVUs for most CPT codes, in a cooperative agreement with the Department of Health and Human Services (HHS). Experts from both inside and outside the Federal Government obtained input from numerous physician specialty groups. This input was incorporated into the initial PFS, which was implemented on January 1, 1992.

spine, posterior or posterolateral approach, 1 vertebral segment; each additional vertebral segment (List separately in addition to primary procedure) (add-on ZZZ) as potentially misvalued for six reasons: (1) incorrect global period; (2) incorrect inpatient days; (3) incorrect intraservice work description; (4) overvalued intraservice times; (5) changed surgical practice; and (6) incorrect use of posterior osteotomy codes. The posterior osteotomy codes were last valued by the RUC in 1995. Currently, CPT code 22210 has a work RVU of 25.38, CPT code 22212 has a work RVU of 20.99, CPT code 22214 has a work RVU of 21.02, and CPT code 22216 has a work RVU of 6.03. CPT codes 22210, 22212, and 22214 have 7 inpatient days each, while CPT code 22216 has 0 inpatient days, and it is an add-on code.

First, the nominator stated that these posterior osteotomies are always performed as an optional addition to a spinal fusion and should be valued as add-on services and not as 90-day global services. We note that no references are provided to support the statement that the service is always performed as an optional addition to a spinal fusion. Second, the nominator explained that the average hospital stay for scoliosis fusion with osteotomy is 4 to 5 days according to the current literature,[2] [3] [4] in contrast with the currently included 7 inpatient days. We note that the majority of the medical literature submitted by the nominator presented outcome information on adolescent patients, which may be different from the Medicare population. Furthermore, the nominator stated that the intraservice work description for CPT code 22216 describes removal of the pedicle, which is not a typical part of a Ponte/Schwab II osteotomy. Among the posterior osteotomy codes, only CPT code 22216 had vignettes and we do not have information to decide whether the code descriptor is correct. We believe this issue would benefit from further review by the medical community and welcome comments and considerations, including from the AMA CPT.

The nominator also asserted that intraservice times were too high, particularly for these osteotomy services furnished with scoliosis fusion procedures. The nominator explained that a typical scoliosis fusion would be billed with an intraservice time of up to 840 minutes for pediatric scoliosis fusion and 915 minutes for adult cases. However, referencing current literature, they observed that a typical scoliosis fusion in a child requires approximately 278 minutes (243–296 minutes),[5] [6] [7] which contrasts significantly with the durations indicated for the current codes. The nominator provided no studies to support a typical scoliosis fusion time in adults. Drawing from the literature, the nominators assert that intraservice times are overvalued for these services and propose that these times should be adjusted to align more closely with average and/or typical surgery times.

The nominator further asserted that this code family is potentially misvalued because surgical practice for these procedures has evolved since 1995. Approximately 30 years ago, osteotomies were infrequently performed and usually reserved for addressing completely ankylosed or fused spinal segments.[8] However, according to the nominator, contemporary surgical techniques often involve posterior osteotomies to release multiple stiff vertebral segments, thereby enhancing coronal correction and reducing thoracic hypokyphosis. In addition to changes in surgical techniques over time, there are notable shifts in the trends regarding the utilization of osteotomies. For instance, between 2007 and 2015, the use of posterior osteotomies in scoliosis cases nearly doubled, increasing from 17 percent to 35 percent.[9] Additionally, 73 percent of patients undergoing scoliosis surgery received posterior osteotomies.[4] This information supports the nominator's assertion that there have been notable changes in the surgical practice for these codes over time.

Lastly, the nominator highlighted incorrect usage of posterior osteotomy codes. They noted instances where facet/soft tissue releases, such as Schwab type I osteotomies, are inaccurately reported with these codes. According to the nominator, isolated partial facetectomy and soft tissue release are already included in spinal fusion procedures and should not be separately billed with an osteotomy code. Additionally, CMS in reviewing data for these services identified potential bundling of services within this code family. For instance, CPT code 22210 is frequently billed alongside CPT code 22600 (*Arthrodesis, posterior or posterolateral technique, single interspace; cervical below C2 segment*) (090-day global code), approximately 83 percent of the time. This indicates a common billing pattern, suggesting potential for coding revisions, including the consideration of consolidating individual services into bundled codes. Overall, based on the six reasons provided by the nominator, along with the fact that these codes were last valued almost 30 years ago, and given the identified billing practices, we concur that CPT codes 22210, 22212, 22214, and 22216 are potentially misvalued. The nominator suggested two options to address this concern: (1) developing add-on codes to differentiate between the number of vertebral segments involved in the osteotomy procedure and whether it occurs in the cervical, thoracic, or lumbar regions; and (2) removing the current posterior osteotomy codes and incorporating osteotomies into new deformity fusion codes, both with and without osteotomy. We are proposing to consider this code family as potentially misvalued and we appreciate the detailed information submitted by the nominator with sufficient supporting evidence. We believe that this code family would benefit from a comprehensive review by the RUC, and we welcome comments on a broader understanding of these codes. Additionally, we seek input on current standard billing practices. For example, information on whether the standard of

[2] Halanski, Matthew Aaron, and Jeffrey A Cassidy. ''Do multilevel Ponte osteotomies in thoracic idiopathic scoliosis surgery improve curve correction and restore thoracic kyphosis?'' Journal of spinal disorders & techniques vol. 26,5 (2013): 252–5. *doi:10.1097/BSD.0b013e318241e3cf.*

[3] Floccari, Lorena V et al. ''Ponte osteotomies in a matched series of large AIS curves increase surgical risk without improving outcomes.'' Spine deformity vol. 9,5 (2021): 1411–1418. *doi:10.1007/s43390–021–00339–x.*

[4] Buckland, Aaron J et al. ''Ponte Osteotomies Increase the Risk of Neuromonitoring Alerts in Adolescent Idiopathic Scoliosis Correction Surgery.'' Spine vol. 44,3 (2019): E175–E180. *doi:10.1097/BRS.0000000000002784.*

[5] Samdani, Amer F et al. ''Do Ponte Osteotomies Enhance Correction in Adolescent Idiopathic Scoliosis? An Analysis of 191 Lenke 1A and 1B Curves.'' Spine deformity vol. 3,5 (2015): 483–488. *doi:10.1016/j.jspd.2015.03.002.*

[6] Pizones, Javier et al. ''Ponte osteotomies to treat major thoracic adolescent idiopathic scoliosis curves allow more effective corrective maneuvers.'' European spine journal: official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society vol. 24,7 (2015): 1540–6. *doi:10.1007/s00586–014–3749–1.*

[7] Feng, Jing et al. ''Clinical and radiological outcomes of the multilevel Ponte osteotomy with posterior selective segmental pedicle screw constructs to treat adolescent thoracic idiopathic scoliosis.'' Journal of orthopaedic surgery and research vol. 13,1 305. 29 Nov. 2018, *doi:10.1186/s13018–018–1001–0.*

[8] Ponte, Alberto et al. ''The True Ponte Osteotomy: By the One Who Developed It.'' Spine deformity vol. 6,1 (2018): 2–11. *doi:10.1016/j.jspd.2017.06.006.*

[9] Shaheen, Mohammed et al. ''Complication risks and costs associated with Ponte osteotomies in surgical treatment of adolescent idiopathic scoliosis: insights from a national database.'' Spine deformity vol. 10,6 (2022): 1339–1348. *doi:10.1007/s43390–022–00534–4.*

practice has evolved over time, and if so, how it has evolved, could aid in identifying potential coding issues related to this matter.

(2) CPT Code 27279

CPT code 27279 (*Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device*) (090 day global code) has been re-nominated as potentially misvalued based on the absence of separate direct PE inputs for this 090 day global code in the nonfacility setting. Currently, CPT code 27279 is only priced under the PFS in the facility setting, but the nominator is requesting that we establish separate direct PE inputs for this service to value the service when performed in the nonfacility/office setting (for example, in an office-based lab). The nominator stated that establishing payment for direct PE inputs in the nonfacility/office setting would increase access to this service for Medicare patients.

We did not nominate CPT code 27279 as potentially misvalued in the CY 2024 PFS final rule, mainly due to a lack of consensus on whether these services may be safely and effectively furnished in the nonfacility/office setting. In this year's submission, the nominator provided three post-market surveillance publications and two independent reviews of minimally invasive sacroiliac (SI) joint fusion procedures to support their assertion that this 90-day surgical service could be safely and effectively furnished in the nonfacility/office setting. Based on the studies, the nominator stated that the current medical literature provides evidence supporting the conclusion that percutaneous or minimally invasive SI joint arthrodesis (CPT code 27279) carries a complication rate that is acceptably low, comparable to other spinal procedures commonly performed in the office-based lab (OBL). For instance, the risk of major complications during lateral trans iliac (LTI) SI joint fusion (CPT code 27279) is lower than the risks associated with other OBL procedures. These include the risk of iliac perforation during angioplasty, the risk of death, myocardial infarction (MI), and stroke during diagnostic cardiac catheterization. The nominator did not reference literature regarding the rates of major complications for other OBL procedures in their submission.

Based on the information submitted we recognize the possibility that CPT code 27279 may be potentially misvalued, given the nominator's assertion that its complication rate is acceptably low based on the five studies they submitted. The results of the studies may suggest that CPT code 27279 can be safely performed in the office-based lab setting, as asserted by the nominator, with a relatively low complication rate. However, upon reviewing the submitted information, we also note that these studies collectively report heterogeneous safety outcomes. The large variabilities in safety outcomes reported in the studies, coupled with several unreported outcomes, may indicate that we have little knowledge about the effect of the service on safety outcomes, prompting the need for further investigation. Therefore, we are not proposing to consider this code as potentially misvalued, and we are instead seeking comments and additional studies from the broader medical community regarding whether this code should be priced under the PFS for the non-facility/office setting.

(3) CPT code 95800

An interested party re-nominated CPT code 95800 (*Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (e.g., by airflow or peripheral arterial tone), and sleep time*) to update practice expenses that were last reviewed in 2017. This code was nominated as potentially misvalued in the CY 2024 PFS proposed rule (88 FR 52283). For the CY 2024 final rule, we stated that we were unable to properly assess whether CPT code 95800 is potentially misvalued based on the evidence submitted with the original nominations and subsequent comments that CMS received (88 FR 78849–78850). This year, an interested party re-nominated CPT code 59800 noting two significant changes: (1) in the technologies available to perform home sleep apnea testing (HSAT) services; and (2) in clinical practice that leads to the typical procedure reported with the CPT code 95800. According to the nominator, the current practice utilizes disposable HSAT technology, such as the WatchPat One device, more often than the reusable equipment currently included in the procedure's direct practice expense (PE) inputs.

To account for these changes, the nominator requested the deletion of three direct PE input codes: (1) equipment code EQ335 (*WatchPAT 200 Unit with strap, cables, charger, booklet, and patient video*); (2) equipment code EQ336 (*Oximetry and Airflow Device*); and (3) supply code SD263 (*WatchPAT pneumo-opt sleep probes), which are WatchPAT probes used with the reusable WatchPAT unit. Instead, the nominator requested the addition of a supply code SD362 (the WatchPAT ONE device*), a disposable HSAT technology, as a replacement. According to our PE supply list, the combined price of the items that the nominator requested to delete (EQ335, EQ336, and SD263) is $4.71 + $4.55 + $73.32 = $82.58, which is $15.62 less than the price of the item that the nominator requested to add (SD362), priced at $98.20. The price of $98.20 is mentioned in the nomination letter without an accompanying specific invoice. Last year, the nominator submitted invoices, showing a price of $99.00 each (a case of 12 totaling $1,188.00) for the WatchPat One Device (SD362) (see Table 6).

TABLE 6: Listing of Nominator's Practice Expense items for addition or deletion to CPT code 95800

Current Equipment/Supply Code	Equipment/Supply Description	Non-Facility/ Office Equipment/Supply PE Cost	Recommended Equipment/ Supply Status
EQ335	WatchPAT 200 Unit with strap, cables, charger, booklet and patient video	$4.71	Delete
EQ336	Oximetry and Airflow Device	$4.55	Delete
SD263	WatchPAT pneumo-opt slp probes (reusable)	$73.32	Delete
SD362	WatchPAT ONE device (disposable)	$98.20	Add

The nominator asserted that testing trends have shifted away from traditional airflow-based tests, with a noticeable rise in peripheral arterial tone (PAT)-based (non-airflow) tests. The traditional airflow-based tests use the reusable supplies and equipment, whereas the PAT-based non-airflow tests use the disposable HSAT device. While describing these changes in trends, the nominator did not provide us with their internal data, thus we are unable to verify its validity. The nominator also stated that disposable HSAT devices were used for nearly 50 percent of CPT code 95800 services in 2023 and attributed the increased use of disposable devices to the COVID–19 public health emergency (PHE). Furthermore, the nominator projected that over 50 percent of CPT code 95800 services will be furnished using disposable devices in 2024 and 2025. Explaining the patterns and predictions, the nominator concluded that the pandemic significantly altered the delivery of HSAT services, with many sleep physicians transitioning to single-use, disposable sleep tests as an alternative to the reusable testing equipment that is shipped from patient-to-patient after post-use cleaning. The nominator believes that, going forward, the typical procedure described by CPT code 95800 in CY 2024 and beyond will be furnished using disposable HSAT devices rather than reusable equipment.

Since the COVID–19 PHE ended in 2023, we are still unclear as to whether the typical procedure reported with CPT code 95800 involves the use of a reusable or disposable HSAT device. Given that we only have access to the nominator's summary of their internal data to observe changes in usage trends, which may not be generalizable, we propose to maintain the current direct PE supply and equipment inputs for CPT code 95800. While we are not currently proposing to review CPT code 95800 as potentially misvalued for CY 2025, we seek public comments on this nomination. In particular, we seek comments on whether the typical procedure described by CPT code 95800 now involves the use of a disposable HSAT device rather than reusable equipment.

(4) CPT codes 10021, 10004, 10005, 10006

An interested party nominated the CPT code 10021 (*Fine needle aspiration biopsy, without imaging guidance; first lesion*), CPT code 10004 (*Fine needle aspiration biopsy, without imaging guidance; each additional lesion*), CPT code 10005 (*Fine needle aspiration biopsy, including ultrasound guidance; first lesion*) and CPT code 10006 (*Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion*) as potentially misvalued. We note that this code family has been nominated several times in recent years. We discussed our review of these codes and our rationale for finalizing the current values extensively in the CY 2019 PFS final rule (83 FR 59517), and CY 2021 PFS final rule (85 FR 84602). Furthermore, this code family was nominated as potentially misvalued and discussed in the CY 2020 PFS final rule (84 FR 62625). For more information we encourage the interested parties to go to our previous PFS final rules.

The nominator specifically requested that we revisit our work RVU decisions for these codes, stating that the underpinnings of the reduction in work RVUs from the RUC-recommended values were flawed. The nominator suggested that CMS should adopt the RUC-recommended work RVUs. For CPT code 10021, the RUC recommended a work RVU of 1.20, but we adopted a lower value of 1.03. Similarly, for CPT code 10005, the RUC recommended a work RVU of 1.63, but we adopted 1.46. The nominator disagreed with these reductions from the RUC-recommended values by CMS, raising particular concerns about our choice for the RVU crosswalk for CPT code 36440 (*Push blood transfusion, patient 2 years or younger*). According to the nominator, the CPT code we chose is not comparable to fine needle aspiration in any respect other than service time. The nominator raised several points, including that CPT code 36440 is rarely utilized and is almost never billed to Medicare because it pertains to a pediatric procedure conducted on neonates, while CPT code 10021 is never performed on neonates. They further asserted that the training and experience levels required to properly perform these procedures differ significantly; neonatal transfusions can be conducted by less experienced personnel, while performing a thyroid fine needle aspiration demands more experience. Specifically, they argued that there is a notable difference in the work intensity between the two procedures. The thyroid is closely positioned to vital structures such as the carotid artery, jugular vein, lymphatic vessels, nerves, trachea, and esophagus. When sampling thyroid nodules, they are often in proximity to the carotid artery, jugular vein, or both. According to the nominator, even a slight deviation of 1–2 millimeters during the sampling procedure can result in accidental puncture of these critical blood vessels or other nearby structures. Factors such as respiratory movements, patient swallowing, or anxiety may cause the thyroid to move, further increasing the

risk during the procedure. In contrast, neonatal phlebotomy does not require such measures. Also, the CPT code 36440 is designated as facility-only, meaning it does not include any clinical staff pre-service time and has no associated practice expense inputs. According to the nominator, fine needle aspiration is a very complex and high-risk procedure that may require significant physician work and a higher level of clinical expertise to furnish the service, which is very different from CPT code 36440. We appreciated the survey (N=74) results that the nominator submitted to support their statements. The nominator-conducted survey, and their survey questions aimed to gather information on the practitioners' experiences, opinions, and practices related to fine needle aspiration procedures. However, no other references such as peer reviewed medical literature or other nationally representative survey data were provided to reinforce their argument.

The nominator further stated that thyroid fine needle aspiration should exclusively be performed as an outpatient procedure and does not require hospitalization. The nominator emphasized that the reduction in payment for the code family due to the reduction in work RVUs from the RUC-recommended values has led endocrinologists in office-based practices, those who are not affiliated with facilities, to discontinue furnishing this service. According to the nominator, as a consequence of this payment decrease, patients are now being referred to hospital-based radiology practices, despite the fact that thyroid fine needle aspiration should ideally be conducted exclusively in nonfacility outpatient settings. The nominator asserted that radiologists in hospital settings are often unfamiliar with the patient's medical history and risk factors for suspected thyroid cancer. The nominator further noted that radiologists' training in thyroid cancer primarily emphasizes imaging and procedures, rather than considering the patient's overall health perspective. This result may further lead to an increase in medically unnecessary procedures. Additionally, the nominator believes that the payment reduction for this code family has the potential to diminish the specialist workforce trained to perform these procedures, thereby presenting future challenges in patient care and access to specialized services.

Overall, we appreciate the comprehensive information and level of detail provided by the nominator. The nominator disagreed with the choice of crosswalk CPT code 36440 made by CMS, emphasizing the differences in provider training, procedure risk, and patient population. They noted the rarity of Medicare billing for this code. Additionally, they emphasized the importance of outpatient thyroid fine needle aspiration being performed by endocrinologists. The shift to facility settings, prompted by reduced work RVUs, could raise Medicare costs. This, along with a potential decline in specialist workforce, may hinder patient access. However, in discussing this group of codes, we must note that these codes have been recently reviewed multiple times through the annual PFS rulemaking process. We would like to clarify once again that we disagree with the nominator that this code family is potentially misvalued. We acknowledge the possibility that there could be significant changes in the practice of delivering services described by these codes that were not fully reflected in the current work RVU. In such cases, it would be appropriate to refer the codes to the RUC to conduct a new survey to capture these changes accurately. However, we note that these codes underwent thorough RUC survey and review processes during the October 2017 and January 2018 RUC meetings. Based on these considerations, we disagree with the assertion that this code family is potentially misvalued. Nevertheless, we welcome comments on whether these codes should be re-reviewed in light of the arguments made by the nominator.

(5) Tympanostomy codes

CMS routinely interacts with interested parties, and in our most recent review, we have observed several new devices that could be beneficial for populations but are not currently included in our coding system. While there are variations in the described devices, they commonly share the following descriptions. This device uses an innovative surgical technology that combines the separate functions of creating a myringotomy (incision in the eardrum), and positioning and placing a ventilation tube across the tympanic membrane. The new device is intended to deliver a tympanostomy tube (also referred to as a ventilation tube) through the tympanic membrane of the patient and is indicated to be used in office settings for pediatric patients 6 months and older. This device allows the tympanostomy service to be furnished to patients without general anesthesia and the service could therefore be performed in the office setting.

Regarding the delivery of this service using innovative surgical technology, CMS recognizes that CPT code 69433 (*Tympanostomy (requiring insertion of ventilating tube), local or topical anesthesia*) (010-day global code) may serve as a sufficient base code, adequately describing the majority of the surgeon's work and facility resources. However, a practitioner may incur additional resources, due to the higher expected intraservice work driven by both time and intensity factors, especially when furnishing a service to a child, and the cost of the device when using these devices as part of the performed procedure. While the existing CPT code 69433 is not age-specific, both the vignette and the RVU associated with this procedure are established for adult patients who can respond to surgeon direction, and do not have risk of movement during the procedure. We believe that potentially establishing additional coding and payment for tympanostomy services may enable the provision of these services utilizing new technologies to a broader patient population who may benefit from innovative surgical technology. To improve the accuracy of the payment for these services, we are soliciting comments on several alternatives that we are considering for adoption in the CY 2025 PFS final rule or future rulemaking. First, we are seeking comment on whether to establish a new G code that accounts for the work and practice expense for a procedure involving the positioning and placement of a ventilation tube across the tympanic membrane using an innovative surgical technology that combines the separate functions of creating a myringotomy (incision in the eardrum). We could assign contractor pricing to this potential G code for generalizable innovative tympanostomy tube delivery devices and/or systems falling under emerging technology and services categories. Alternatively, we are seeking comment on whether we should establish an add-on payment for the service using inputs from CPT code 69433 as a crosswalk reference, plus direct costs from invoices for the surgical devices referenced above. We are seeking comments regarding these potential approaches, particularly on whether there is additional information we should consider if we were to establish additional coding and payment for these services.

D. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

As discussed in prior rulemaking, several conditions must be met for Medicare to make payment for telehealth services under the PFS. See

further details and full discussion of the scope of Medicare telehealth services in the CY 2018 PFS final rule (82 FR 53006), the CY 2021 PFS final rule (85 FR 84502) and the CY 2024 PFS final rule (88 FR 78861 through 78866) and in 42 CFR 410.78 and 414.65. For a discussion of Telemedicine Evaluation and Management (E/M) Services, we refer readers to section II.E.4.18 of this proposed rule.

1. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

a. Changes to the Medicare Telehealth Services List

In the CY 2003 PFS final rule with comment period (67 FR 79988), we established a regulatory process for adding services to or deleting services from the Medicare Telehealth Services List in accordance with section 1834(m)(4)(F)(ii) of the Act. This process provides the public with an ongoing opportunity to submit requests for adding services, which are then reviewed by us and assigned to categories established through notice and comment rulemaking. Under the process we established beginning in CY 2003, we evaluated whether a service meets the following criteria:

- *Category 1:* Services similar to professional consultations, office visits, and office psychiatry services currently on the Medicare Telehealth Services List. In reviewing these requests, we looked for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site, and, if necessary, the telepresenter, a practitioner who was present with the beneficiary in the originating site. We also looked for similarities in the telecommunications system used to deliver the service, for example, the use of interactive audio and video equipment.
- *Category 2:* Services that are not similar to those on the current Medicare Telehealth Services List. Our review of these requests included assessing whether the service was accurately described by the corresponding code when furnished via telehealth and whether using a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient. Submitted evidence should have included both a description of relevant clinical studies that demonstrated the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer-reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit did not include minor or incidental benefits. Some examples of other clinical benefits that we considered include the following:
  - Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
  - Treatment option for a patient population without access to clinically appropriate in-person treatment options.
  - Reduced rate of complications.
  - Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
  - Decreased number of future hospitalizations or physician visits.
  - More rapid beneficial resolution of the disease process treatment.
  - Decreased pain, bleeding, or other quantifiable signs or symptoms.
  - Reduced recovery time.

In the CY 2021 PFS final rule (85 FR 84507), we created a third category of criteria for adding services to the Medicare Telehealth Services List on a temporary basis following the end of the PHE for the COVID–19 pandemic. This new category described services that were added to the Medicare Telehealth Services List during the PHE, for which there was likely to be clinical benefit when furnished via telehealth, but there was not yet sufficient evidence available to consider the services for permanent addition under the Category 1 or Category 2 criteria. Services added on a temporary, Category 3 basis ultimately needed to meet the criteria under Category 1 or 2 in order to be permanently added to the *Medicare Telehealth* Services List. To add specific services on a Category 3 basis, we would conduct a clinical assessment to identify those services for which we could foresee a reasonable potential likelihood of clinical benefit when furnished via telehealth.

In the CY 2024 PFS final rule (88 FR 78861 through 78866), we consolidated these three categories and implemented a revised 5-step process for making additions, deletions, and changes to the Medicare Telehealth Services List (5-step process), beginning for the CY 2025 Medicare Telehealth Services List. Rather than categorizing a service as ''Category 1'' or ''Category 2,'' each service is now assigned a ''permanent'' or ''provisional'' status. As described further below, a service is assigned a ''provisional'' status if there is not enough evidence to demonstrate that the service is of clinical benefit, but there is enough evidence to suggest that further study may demonstrate such benefit. The 5-step process review criteria are set forth in the CY 2024 PFS final rule (88 FR 78861 through 78866), listed at *https://www.cms.gov/medicare/coverage/telehealth/criteria-request*, and summarized below. Consistent with the deadline for our receipt of code valuation recommendations from the American Medical Association's Relative Value Scale Update Committee (AMA RUC) and other interested parties (83 FR 59491) and with the process set forth in prior calendar years, for CY 2025, requests to add services to the Medicare Telehealth Services List must have been submitted to and received by CMS by February 10, 2024. Each request to add a service to the Medicare Telehealth Services List must have included any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process to make changes to the Medicare Telehealth Services List, requesters are advised that any information submitted as part of a request is subject to public disclosure for this purpose. For more information on submitting a request to add services to the Medicare Telehealth Services List, including where to send these requests, and to view the current Medicare Telehealth Service List, see our website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

Step 1. Determine whether the service is separately payable under the PFS.

When considering whether to add, remove, or change the status of a service on the Medicare Telehealth Services List, we first determine whether the service, as described by the individual HCPCS code, is separately payable under the PFS because, as further discussed in CY 2024 PFS final rule (88 FR 78861 through 78866), Medicare telehealth services are limited to those services for which separate Medicare payments can be made under the PFS. Before gathering evidence and preparing to submit a request to add a service to the Medicare Telehealth Services List, the submitter should therefore first check the payment status for a given service and ensure that the service (as identified by a HCPCS code), is a covered and separately payable service under the PFS (as identified by payment status indicators A, C, T, or R on our public use files).

Step 2. Determine whether the service is subject to the provisions of section 1834(m) of the Act.

If we determine at Step 1 that a service is separately payable under the PFS, we apply Step 2 under which we determine whether the service at issue is subject to the provisions of section 1834(m) of the Act. Section 1834(m) of the Act provides for payment to a physician (or other practitioner) for a service furnished via an interactive telecommunications system, notwithstanding that the furnishing practitioner and patient are not in the same location, at the same amount that would have been paid if the service was furnished without the telecommunications system. We have historically interpreted this to mean that only services that are ordinarily furnished with the furnishing practitioner and patient in the same location can be classified as a ''telehealth service'' for which payment can be made under section 1834(m) of the Act. Given that there may be a range of services delivered using certain telecommunications technology that, though they are separately payable under the PFS, do not fall within the definition of telehealth service set forth in section 1834(m) of the Act, the aim of Step 2 is therefore to determine whether the service at issue is, in whole or in part, inherently a face-to-face service. Such services generally include services that do not require the presence of, or involve interaction with, the patient (for example, remote interpretation of diagnostic imaging tests, and certain care management services). Other examples include virtual check-ins, e-visits, and remote patient monitoring services which involve the use of telecommunications technology to facilitate interactions between the patient and practitioner, but do not serve as a substitute for an in-person encounter, for example, to assess whether an in-person or telehealth visit is needed or to transmit health information to the practitioner.

In determining whether a service is subject to the provisions of section 1834(m) of the Act, we therefore review during this Step 2 whether one or more of the elements of the service, as described by the particular HCPCS code at issue, ordinarily involve direct, face-to-face interaction between the patient and practitioner such that the use of an interactive telecommunications system to deliver the service would be a substitute for an in-person visit.

Step 3. Review the elements of the service as described by the HCPCS code and determine whether each of them is capable of being furnished using an interactive telecommunications system as defined in § 410.78(a)(3).

Step 3 is corollary to Step 2, and is used to determine whether one or more elements of a service are capable of being delivered via an interactive telecommunication system as defined in § 410.78(a)(3). In Step 3, we consider whether one or more face-to-face component(s) of the service, if furnished via audio-video communications technology, would be equivalent to the service being furnished in-person, and we seek information from requesters to demonstrate evidence of substantial clinical improvement in different beneficiary populations that may benefit from the requested service when furnished via telehealth, including, for example, in rural populations. The services are not equivalent when the clinical actions, or patient interaction, would not be of similar content as an in-person visit, or could not be completed.

Step 4. Consider whether the service elements of the requested service map to the service elements of a service on the list that has a permanent status described in previous final rulemaking.

The purpose of Step 4 is to simplify and reduce the administrative burden of submission and review. For Step 4, we review whether the service elements of a code that we are considering for addition to, or removal from, the Medicare Telehealth Services List map to the service elements of a service that is already on the list and is assigned permanent status. Any code that satisfies this criterion would require no further analysis. If the service elements of a code maps to the service elements of a code that is already included on the Medicare Telehealth Services List and is assigned permanent basis, we will add the code to the Medicare Telehealth Services List and assign it permanent status. While we have not previously found that the service elements of a code we are considering for addition to the list map to the elements of a service that was previously added to the list and assigned permanent basis, we believe that it is appropriate to apply this step 4 analysis to compare the candidate service with any permanent code that is on the list on a permanent basis. When Step 4 is met, further evidence review is not necessary. We continue to Step 5 if Step 4 is not met.

Step 5. Consider whether there is evidence of clinical benefit analogous to the clinical benefit of the in-person service when the patient, who is located at a telehealth originating site, receives a service furnished by a physician or practitioner located at a distant site using an interactive telecommunications system.

Similar to Steps 3, 4, and 5 above, the purpose of the proposed step 5 is to simplify and reduce the administrative burden. Under Step 5, we review the evidence provided with a submission to determine the clinical benefit of a service. We then compare the clinical benefit of that service, when provided via telehealth, to the clinical benefit of the service if it were to be furnished in person. If there is enough evidence to suggest that further study may demonstrate that the service, when provided via telehealth, is of clinical benefit, CMS will assign the code a ''provisional'' status on the Medicare Telehealth Services List. Where the clinical benefit of a service, when provided via telehealth, is clearly analogous to the clinical benefit of the service when provided in person, CMS will assign the code ''permanent'' status on the Medicare Telehealth Services List, even if the code's service elements do not map to the service elements of a service that already has permanent status. We reminded readers that our evidentiary standard of demonstrated clinical benefit does not include minor or incidental benefits (81 FR 80194). We review the evidence submitted by interested parties, and other evidence that CMS has on hand. The evidence should indicate that the service can be safely delivered using two-way interactive audio-video communications technology. Clinical practice guidelines, peer-reviewed literature, and similar materials, should illustrate specifically how the methods and findings within the material establish a foundation of support that each element of the defined, individual service described by the existing face-to-face service code has been studied in the typical setting of care, typical population of beneficiaries, and typical clinical scenarios that practitioners would encounter when furnishing the service using only interactive, two-way audio-video communications technology to complete the visit or encounter with Medicare beneficiaries. General evidence may also answer the question of whether a certain beneficiary population requiring care for a specific illness or injury may benefit from receiving a service via telehealth versus receiving no service at all, but must establish that the service is a substitute for an equivalent in-person service. Evidence should demonstrate how all elements described by the individual service code can be met when two-way, interactive audio-video communications technology is used as a complete substitute for any face-to-face interaction required between the patient and practitioner that are described in the individual code descriptor. We further remind readers that submissions

reflecting practitioner services furnished to Medicare beneficiaries are helpful in our considerations.

b. Requests To Add Services to the Medicare Telehealth Services List for CY 2025

We received several requests to permanently add various services to the Medicare Telehealth Services List, effective for CY 2025. The requested services are listed in Table 7.

BILLING CODE P

TABLE 7: CY 2025 Requests for Permanent Addition to the Medicare Telehealth Services List

Category	HCPCS	Short Descriptor
Radiation Treatment Mgmt	77427	Radiation tx management x5
Psych Testing	96130	Psycl tst eval phys/qhp 1st
	96136	Psycl/nrpsyc tst phy/qhp 1st
	96137	Psycl/nrpsyc tst phy/qhp ea
Intensive Cardiac Rehab	G0422	Intens cardiac rehab w/exerc
	G0423	Intens cardiac rehab no exer
Developmental Testing	96112	Devcl tst phys/qhp 1st hr
	96113	Devel tst phys/qhp ea addl
Health and Well Being Coaching	0591T	Hlth&wb coaching indiv 1st
	0592T	Hlth&wb coaching indiv f-up
	0593T	Hlth&wb coaching group
Outpatient Pulmonary Rehab	94625	Phy/qhp op pulm rhb w/o mntr
	94626	Phy/qhp op pulm rhb w/mntr
Cardiac Rehab	93797	Cardiac rehab
	93798	Cardiac rehab/monitor
Caregiver Training	97550	Caregiver traing 1st 30 min
	97551	Caregiver traing ea addl 15
Physical Therapy	97161	Physical therapy evaluation, low complexity
	97162	Physical therapy evaluation, moderate complexity
	97163	Physical therapy evaluation, high complexity
	97164	Physical therapy re-evaluation
	97110	Therapeutic exercises, each 15 mins
	97112	Neuromuscular re-education, each 15 mins
	97116	Gait training, each 15 mins
	97530	Therapeutic activities, each 15 mins
	97535	Self-care home management
OT Evaluation	97165	Ot eval low complex 30 min
	97166	Ot eval mod complex 45 min
	97167	Ot eval high complex 60 min
	97168	Ot re-eval est plan care
Speech, Language, and Voice Evaluation and Treatment	92507	Speech/hearing therapy
	92508	Speech/hearing therapy
	92521	Evaluation of speech fluency
	92522	Evaluate speech production
	92523	Speech sound lang comprehen
	92524	Behavral qualit analys voice
	96105	Assessment of aphasia
	92626	Eval aud funcj 1st hour
	92627	Eval aud funcj ea addl 15
	96125	Cognitive test by hc pro
	97129	Ther ivntj 1st 15 min
	97130	Ther ivntj ea addl 15 min
SGD Evaluation and Treatment	92607	Ex for speech device rx 1hr
	92608	Ex for speech device rx addl
	92609	Use of speech device service
Swallowing Evaluation and Treatment	92526	Oral function therapy
	92610	Evaluate swallowing function
Diagnostic Audiologic Testing	92550	Tympanometry & reflex thresh
	92552	Pure tone audiometry air
	92553	Audiometry air & bone

BILLING CODE C

Category	HCPCS	Short Descriptor
	92555	Speech threshold audiometry
	92556	Speech audiometry complete
	92557	Comprehensive hearing test
	92563	Tone decay hearing test
	92565	Stenger test pure tone
	92567	Tympanometry
	92568	Acoustic refl threshold tst
	92570	Acoustic immitance testing
	92587	Evoked auditory test limited
	92588	Evoked auditory tst complete
	92625	Tinnitus assessment
	92626	Eval aud funcj 1st hour
	92627	Eval aud funcj ea addl 15
Diagnostic CI Testing	92601	Cochlear implt f/up exam <7
	92602	Reprogram cochlear implt <7
	92603	Cochlear implt f/up exam 7/>
	92604	Reprogram cochlear implt 7/>

Many services were added to the Medicare Telehealth Services List on a temporary basis as discussed in the March 31st COVID–19 interim final rule with comment period (IFC) (85 FR 19235 through 19237) for the PHE for Covid-19, and we subsequently retained these services on a provisional basis. All of the received submissions were requests for addition on a permanent basis. We believe that, rather than selectively adjudicating only those services for which we received requests for potential permanent status, it would be appropriate to complete a comprehensive analysis of all provisional codes currently on the Medicare Telehealth Services List before determining which codes should be made permanent. We are therefore not making determinations to recategorize provisional codes as permanent until such time as CMS can complete a comprehensive analysis of all such provisional codes which we expect to address in future rulemaking.

The following is a discussion of the requests received for addition of services to the Medicare Telehealth Services List:

(1) Continuous Glucose Monitoring

We received a request to add CPT code 95251 (*Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report*) to the Medicare Telehealth Services List and assign it permanent status. This code is not on the Medicare Telehealth Services List, nor had it been previously added and removed. The requester stated that the ability of the practitioner to interpret continuous glucose monitoring data and communicate changes in the diabetes care plan to our patients is enhanced by the availability of video visits, and the code should therefore be added to the Medicare Telehealth Services List. This service does not meet the criteria described by Step 2 of the 5-step process: determination of whether the service is subject to the provisions of section 1834(m) of the Act. Section 1834(m) of the Act limits the definition of Medicare telehealth services to those services that would ordinarily be furnished with the furnishing practitioner and patient in the same location (88 78863). In other words, as stated above, for a service to be considered a Medicare telehealth service subject to and payable under section 1834(m) of the Act, the service must be so analogous to in-person care such that the telehealth service, as defined in § 410.78, is essentially a substitute for a face-to-face encounter. We do not consider this service a Medicare telehealth service because it is not an inherently face-to-face service; the patient does not need to be present for the service to be furnished in its entirety. CPT code 95251 describes sensor placement and monitoring over a 72-hour period. We do not consider CPT code 95251 a telehealth service under section 1834(m) of the Act or our regulation at § 410.78. Therefore, we are not proposing to add this service to the Medicare Telehealth Services List.

(2) Cardiovascular and Pulmonary Rehabilitation

We received requests to permanently add cardiovascular *rehabilitation* services (CPT codes 93797 and 93798) and *pulmonary rehabilitation* services (CPT codes 94625 and 94626) to the Medicare Telehealth Services List. These services are currently on the Medicare Telehealth List and are assigned provisional status. We had originally added CPT codes 93797 and 93798 and HCPCS codes G0422 and G0423 on a temporary basis in the CY 2022 PFS final rule (FR 86 65054 through 65055). A requester cited studies that they say demonstrate that the availability of these services via telehealth enhances access and patient equity. Another requester cited evidence of improved outcomes for patients that had access to these services via telehealth. As explained previously, we are not proposing to revise the status of codes from provisional to permanent in this proposed rule because we intend to conduct a comprehensive review. While considering these issues for future rulemaking, we are not proposing to assign CPT codes 93797 and 93798 or CPT codes 94625 and 94626 permanent status on the Medicare Telehealth Services List and would instead maintain the services on the Medicare Telehealth Services List on a provisional basis for CY 2025.

(3) Health and Well Being-Coaching

We received a request to add Health and Well-Being Coaching (CPT codes 0591T–0593T) to the Medicare Telehealth Services List with permanent status. These services are currently on the Medicare Telehealth Services List and are assigned a provisional status. We originally added these codes on a provisional basis in the CY 2024 PFS final rule (FR 88 78859 and 78860). One requester stated that health and well-being coaching, including content education, delivered in a telehealth modality is an evidence-based, cost-

effective, sustainable, and common sense approach to facilitating lifestyle/behavioral intervention and treating the Medicare population with or at heightened risk for chronic diseases. As explained previously, we are not proposing to revise the status of codes from provisional to permanent in this proposed rule because we intend to conduct a comprehensive review. Therefore, we are not proposing to assign them to the Medicare Telehealth Services List with permanent status.

(4) Psychological Testing and Developmental Testing

We received a request to add Psychological Testing and Developmental Testing (CPT codes 96112, 96113, 96130, 96136, and 96137) to the Medicare Telehealth Services List on a permanent basis. These services are currently on the Medicare Telehealth Services List and are assigned provisional status. In the March 31, 2020 interim final rule with comment period (IFC–1) (85 FR 19239), we originally added CPT codes 96130, 96136, and 96137 to the Medicare Telehealth Services List for the duration of the PHE for COVID–19, and in the CY 2021 PFS final rule (85 FR 85003), we stated we were retaining them on the list on a category 3 basis. In the CY 2023 PFS final rule (87 FR 69460), we added CPT codes 96112 and 96113 on a temporary basis.

As explained previously, we are not proposing to revise the status of codes from provisional to permanent in this proposed rule because we intend to conduct a comprehensive review. Therefore, we are not proposing to either remove these services from or to assign them permanent status on the Medicare Telehealth Services List.

(5) Therapy/Audiology/Speech Language Pathology

We received multiple requests to add the Therapy services described by CPT codes 97110, 97112, 97116, 97161 through 97164, 97530 and 97535, 97165 through 97168, and Audiology and Speech Language Pathology services CPT codes 92507, 92508, 92521 through 92524, 92526, 92607 through 92610, 96105 92626, 92627, 96125, 97129, 97130, 92607 through 92609 92550 through 92557, 92563, 92565 92567, 92568, 92570, 92587, 92588, 92601 through 92604, 92625 through 92627, and 92651 and 92652 to the Medicare Telehealth Services List on a permanent basis stating that continuing Telehealth flexibilities for these services could lead to reduced health care expenditures, increased patient access, and improved management of chronic disease and quality of life. These services are currently available on the Medicare Telehealth Services List and are assigned provisional status, and we refer readers to section II.D.1. for further discussion of these services. In the CY 2023 PFS final rule (87 FR 69451), we originally added CPT codes 90901, 97150, 97530, 97537, 97542, 97763, and 98960–98962 to the Medicare Telehealth Services List on a Category 3 basis. As explained previously, we are not proposing to revise the status of codes from provisional to permanent in this proposed rule because we intend to conduct a comprehensive review. Therefore, we are not proposing to assign them permanent status on the Medicare Telehealth Services List.

(6) Care Management

We received a request to permanently add General Behavioral Health Integration (CPT code 99484) and Principal Care Management (CPT codes 99424–99427) to the Medicare Telehealth Services List. These services are not on the Medicare Telehealth Services List, nor have they been previously added and removed. These services do not meet the criteria described by Step 2 of the 5-step process: determination of whether the service is subject to the provisions of section 1834(m) of the Act. As stated above, the scope of section 1834(m) of the Act is limited to services that would ordinarily be furnished with the furnishing practitioner and patient in the same location (88 78863), and for a service to be considered a telehealth service subject to and payable under section 1834(m) of the Act, the service must be so analogous to in-person care such that the telehealth service, as defined in § 410.78, is essentially a substitute for a face-to-face encounter. We do not consider these services to be Medicare telehealth services because they are not inherently face-to-face services, and the patient need not be present for the services to be furnished in its entirety. Therefore, we do not consider CPT codes 99484 and 99424–99427 to be telehealth services under section 1834(m) of the Act or our regulation at § 410.78. Therefore, we are not proposing to add this service to the Medicare Telehealth Services List.

(7) Posterior Tibial Nerve Stimulation for Voiding Dysfunction

We received a request to permanently add Posterior tibial neurostimulation (CPT code 64566) to the Medicare Telehealth Services List. This code is not on the Medicare Telehealth Services List, nor had it been previously added and removed. This service does not meet the criteria for addition described by Step 3 of the 5-step process, namely the review the elements of the service as described by the HCPCS code and determine whether each of them is capable of being furnished using an interactive telecommunications system as defined in § 410.78(a)(3). The requestor describes the services underlying CPT code 64566 as the continual or recurring treatments over a period of time consisting of the remote monitoring of device utilization and bladder diary for the generation of reports for review by the care provider. Based on our review, this description does not align with the elements of the service as described by CPT code 64566. CPT code 64566 describes a single treatment provided by a clinician who has direct contact with the patient and inserts an electrode into the skin overlying the posterior tibial nerve. Upon conclusion of the treatment, the clinician removes the electrode and examines and dresses the puncture wound. Providing these services would require in-person interaction. We are therefore not proposing to add the service to the Medicare Telehealth Services List because we do not believe the service elements can be met in full using two-way audio-video telecommunications technology.

(8) Radiation Treatment Management

We received requests to permanently add Radiation Treatment Management (CPT code 77427) to the Medicare Telehealth Services List. The code is currently on the Medicare Telehealth List with provisional status. In the March 31, 2020 IFC (85 FR 9240), we originally added CPT code 77427 on the Medicare Telehealth Services List for the duration of the PHE for Covid–19. A requester stated that data collected during the PHE demonstrates that the telehealth option is as safe as the in-person equivalent. We also received a request that we remove this code from the Medicare Telehealth Services List, citing the importance of in-person physical examination to ensure quality of care and stating that a telehealth modality presents patient safety concerns such as those related to the ability of the practitioner to address side effects of radiation therapy. Given the safety concerns raised by members of the practitioner community, we believe this service may not be safely and effectively furnished, and therefore believe that such concerns merit removing this item from the telehealth list. We are therefore proposing to remove this code from the Medicare Telehealth Services List, and we are

soliciting comment on these quality of care concerns.

(9) Home International Normalized Ratio (INR) Monitoring

We received a request to permanently add Home INR Monitoring (HCPCS code G0248) to the Medicare Telehealth Services List. This service is not on the Medicare Telehealth Services List, nor had it been previously added and removed. We are proposing to add HCPS code G0248 to the Medicare Telehealth Services List with provision status because our clinical analyses of these services indicate that they can be furnished in full using two-way, audio and video technology, and information provided by requesters indicates that there may be clinical benefit; however, there is not yet sufficient evidence available to consider the services for permanent status. This service as described by the HCPCS code describes face-to-face demonstration of use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results, and documentation of patient's ability to perform testing and report results, and we believe each of these service elements the elements is capable of being furnished using an interactive telecommunications system. Adding this service on a provisional basis will allow additional time for the development of evidence of clinical benefit when this service is furnished via telehealth for CMS to consider when evaluating this service for potential permanent addition to the Medicare Telehealth Services List.

(10) Caregiver Training

We received a request to permanently add Caregiver Training services, as described by HCPCS codes 97550 (*Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (eg, activities of daily living [ADLs], instrumental ADLs [iADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face to face; initial 30 minutes*) and CPT code 97551 *(Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (eg, activities of daily living [ADLs], instrumental ADLs [iADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face to face; each additional 15 minutes (List separately in addition to code for primary service))* to the Medicare Telehealth Services List. These codes do not currently appear on the Medicare Telehealth Services List nor had they previously been added or removed. We are proposing to add these services to the Medicare Telehealth List with provisional status for CY 2025, in addition to the other currently payable caregiver training service codes (CPT codes 97550, 97551, 97552, 96202, 96203). These codes are new services that were added to the PFS beginning in 2024. Given the limited utilization of those codes added for 2024, there are not peer-reviewed studies supporting these codes' ability to be furnished remotely. Adding these services on a provisional basis will allow additional time for the development of evidence of clinical benefit when these services are furnished via telehealth for CMS to consider when evaluating these services for potential permanent addition to the Medicare Telehealth Services List. Contingent upon finalizing the service code descriptions that we propose in section II.E. of this proposed rule, we also propose that HCPCS code GCTD1–3 and GCTB1–2 be added to the Medicare Telehealth Services list for CY 2025 on a provisional basis. We believe that these codes are similar to other services already available on the Medicare Telehealth Services List, including education and training for patient self-management (CPT codes 98960–98962), self-care/home management training (CPT codes 97535), and caregiver-focused health risk assessment (CPT code 96161). Further, it appears that all elements of these services may be furnished when using two-way interactive communications technology. Adding these services on a provisional basis will allow additional time for the development of evidence of clinical benefit when this service is furnished via telehealth for CMS to consider when evaluating these services for potential permanent addition to the Medicare Telehealth Services List.

c. Other Services Proposed for Addition to the Medicare Telehealth Services List

(1) Preexposure Prophylaxis (PrEP) of Human Immunodeficiency Virus (HIV)

As discussed in Section II.E. of this proposed rule, we are proposing national rates for HCPCS codes G0011 (Individual counseling for pre-exposure prophylaxis (PrEP) by physician or QHP to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence, 15–30 minutes) and G0013 (Individual counseling for pre-exposure prophylaxis (PrEP) by clinical staff to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence) pending the future finalization of the NCD for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection. We believe these services are similar to services currently on the Medicare Telehealth Services list, specifically HCPCS codes G0445 (High intensity behavioral counseling to prevent sexually transmitted infection; face-to-face, individual, includes: education, skills training and guidance on how to change sexual behavior; performed semi-annually, 30 minutes) and CPT code 99211 (Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional) as these codes are the codes from which HCPCS codes G0011 and G0013 were unbundled, respectively. As similarity to services currently on the Medicare telehealth list is one of our criteria for permanent addition, we are proposing to add HCPCS codes G0011 and G0013 to the Medicare Telehealth Services List with a permanent status.

The services that we are proposing to add to the Medicare Telehealth Services List are listed in Table 8.

BILLING CODE P

TABLE 8: Services Proposed for Addition to the Medicare Telehealth Services List for CY 2025

Category	HCPCS	Long Description	Proposed Status
PrEP for HIV	G0011	Individual counseling for pre-exposure prophylaxis (PrEP) by physician or QHP to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence, 15-30 minutes	Permanent
	G0013	Individual counseling for pre-exposure prophylaxis (PrEP) by clinical staff to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence	Permanent
Home INR Monitoring	G0248	Demonstration, prior to initiation of home inr monitoring, for patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets medicare coverage criteria, under the direction of a physician; includes: face-to-face demonstration of use and care of the inr monitor, obtaining at least one blood sample, provision of instructions for reporting home inr test results, and documentation of patient's ability to perform testing and report results	Provisional
Caregiver Training	97550	Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (eg, activities of daily living [adls], instrumental adls [iadls], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face to face; initial 30 minutes	Provisional
	97551	Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (eg, activities of daily living [adls], instrumental adls [iadls], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face to face; each additional 15 minutes (list separately in addition to code for primary service)	Provisional
	97552	Group caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (eg, activities	Provisional

Category	HCPCS	Long Description	Proposed Status
		of daily living [adls], instrumental adls [iadls], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face to face with multiple sets of caregivers	

Category	HCPCS	Long Description	Proposed Status
	96202	Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); initial 60 minutes	Provisional
	96203	Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); each additional 15 minutes (List separately in addition to code for primary service)	Provisional
	GCTD1	Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (without the patient present), face-to-face; initial 30 minutes	Provisional
	GCTD2	Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service) (Use GCTD2 in conjunction with GCTD1)	Provisional
	GCTD3	Group caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (without the patient present), face-to-face with multiple sets of caregivers	Provisional
	GCTB1	Caregiver training in behavior management/modification for caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; initial 30 minutes	Provisional

Category	HCPCS	Long Description	Proposed Status
	GCTB2	Caregiver training in behavior management/modification for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service) (Use GCTB2 in conjunction with GCTB1)	Provisional

BILLING CODE C

d. Frequency Limitations on Medicare Telehealth Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations

When adding some services to the Medicare Telehealth Services List in the past, we have included certain frequency restrictions on how often practitioners may furnish the service via Medicare telehealth. These include a limitation of one subsequent hospital care service furnished through telehealth every 3 days, added in the CY 2011 PFS final rule (75 FR 73317 through 73318), one subsequent nursing facility visit furnished through telehealth every 14 days, added in the CY 2011 PFS final rule (75 FR73318), and one critical care consultation service furnished through telehealth per day, added in the CY 2017 final rule (81 FR 80198). In establishing these limits, we cited concerns regarding the potential acuity and complexity of these patients.

We temporarily removed these frequency restrictions during the PHE for COVID–19. In the March 31, 2020 COVID–19 interim final rule with comment period (IFC) (85 FR 19241), we stated that we did not believe the frequency limitations for certain subsequent inpatient visits, subsequent NF visits, and critical care consultations furnished via Medicare telehealth were appropriate or necessary for the duration of the PHE because this would have been a patient population who would have otherwise not had access to clinically appropriate in-person treatment. Although the frequency limitations resumed effect on May 12, 2023 (upon expiration of the PHE), through enforcement discretion during the remainder of CY 2023 and notice-and-comment rulemaking for CY 2024, Medicare telehealth frequency limitations have been suspended for CY 2024 (88 FR 78876 through 78878) for the following codes relating to Subsequent Inpatient Visits, Subsequent Nursing Facility Visits, and Critical Care Consultation Services:

1. Subsequent Inpatient Visit CPT Codes

- 99231 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. when using total time on the date of the encounter for code selection, 25 minutes must be met or exceeded.*);
- 99232 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. when using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded.*); *and*
- 99233 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. when using total time on the date of the encounter for code selection, 50 minutes must be met or exceeded.*)

2. Subsequent Nursing Facility Visit CPT Codes

- 99307 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. when using total time on the date of the encounter for code selection, 10 minutes must be met or exceeded.*);
- 99308 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making. when using total time on the date of the encounter for code selection, 15 minutes must be met or exceeded.*);
- 99309 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. when using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.*); and
- 99310 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. when using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.*)

3. Critical Care Consultation Services: HCPCS Codes

- G0508 (*Telehealth consultation, critical care, initial, physicians typically spend 60 minutes communicating with the patient and providers via telehealth.*); and
- G0509 (*Telehealth consultation, critical care, subsequent, physicians typically spend 50 minutes communicating with the patient and providers via telehealth.*)

We are proposing to remove the frequency limitations for these codes for CY 2025.

In the CY 2024 PFS final rule (88 FR 78877), we solicited comments from interested parties on how practitioners have been ensuring that Medicare beneficiaries receive subsequent inpatient and nursing facility visits, as well as critical care consultation services since the expiration of the PHE. As discussed in that final rule, many commenters supported permanently removing these frequency limitations, stating that they are arbitrary and re-imposing the limitations would result in decreased access to care; that practitioners should be allowed to use

their clinical judgment to determine the type of visit, how many visits, and the type of treatment that is the best fit for the patient so long as the standard of care is met; and that lifting these limitations during the PHE has been instructive and demonstrates the value of continuing such flexibilities. Many commenters urged us to permanently remove them. That said, some commenters did not support removing these frequency limitations citing patient acuity and safety, some commenters cited the importance of in-person care for patients in acute care settings. Some commenters stated that telehealth patient assessments and evaluations are never the same as in-person, hands on visits and should not be considered a viable replacement with no limitations for in-person care. We are continuing to consider what changes we should be making to how telehealth services are reimbursed under Medicare in light of the way practice patterns may have changed following the PHE for COVID–19. Taking into account the information received from commenters in the CY 2024 PFS final rule, we believe it is reasonable to continue to pause certain pre-pandemic restrictions, such as the frequency limitations for the abovementioned codes for CY 2025. Removing such restrictions for CY 2025 will allow us to gather an additional year of data to determine how practice patterns are evolving and what changes, if any, to frequency limitations should be made. We do not believe pausing such frequency limitations for another year presents a level of safety risk requiring us to immediately reinstate the limitations. Our analysis of claims data indicates that the volume of services that would be affected by implementing these limitations is relatively low; in other words, these services are not being furnished via telehealth with such frequency that frequency limits are being met or exceeded very often or for many beneficiaries (claims data from 2020—2023 suggest that less than five percent received one or more of these services as a telehealth service). Therefore, while claims data does not suggest that lifting these limitations during the PHE has led to an increase in utilization, we continue to be interested in information from interested parties on our concerns regarding the potential acuity and complexity of these patients and how such acuity and complexity should complexity should influence our implementation of frequency limitations.

e. Audio-Only Communication Technology To Meet the Definition of ''Telecommunications System''

Through our regulation at § 410.78(a)(3), we define ''interactive telecommunications system'' as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. Through emergency regulations and waiver authority under section 1135(b)(8) of the Act, in response to the PHE for COVID–19, we allowed the use of audio-only communications technology to furnish services described by the codes for audio-only telephone evaluation and management services and behavioral health counseling and educational services. Section 4113 of the CAA, 2023, extended the availability of telehealth services that can be furnished using audio-only technology and provided for the extension of other PHE-related flexibilities including removal of the geographic and location limitations under section 1834(m) of the Act through December 31, 2024.

In the CY 2022 PFS final rule (86 FR 65060), in part to recognize the changes made by section 123 of the CAA, 2021 that removed the geographic restrictions for Medicare telehealth services for the diagnosis, evaluation, or treatment of a mental health disorder and the addition of the patient's home as a permissible originating site for these services, we revisited our regulatory definition of ''interactive telecommunications system'' beyond the circumstances of the PHE. Specifically, we finalized a policy to allow for audio-only services under certain circumstances and revised the regulation at § 410.78(a)(3) to permit the use of audio-only equipment for telehealth services furnished to established patients in their homes for purposes of diagnosis, evaluation, or treatment of a mental health disorder (including substance use disorders) if the distant site physician or practitioner is technically capable of using an interactive telecommunications system as defined previously, but the patient is not capable of, or does not consent to, the use of video technology. We also established this policy in part because mental health services are different from most other services on the Medicare telehealth services list in that many of the services primarily involve verbal conversation where visualization between the patient and furnishing physician or practitioner may be less critical to the provision of the service.

However, with the successive statutory extensions of the telehealth flexibilities implemented in response to the PHE for COVID–19, most recently by the CAA, 2023, and our adoption of other extensions where we have had authority to do so, we have come to believe that it would be appropriate to allow interactive audio-only telecommunications technology when any telehealth service is furnished to a beneficiary in their home (when the patient's home is a permissible originating site) and when the distant site physician or practitioner is technically capable of using an interactive telecommunications system as defined previously, but the patient is not capable of, or does not consent to, the use of video technology. While practitioners should always use their clinical judgment as to whether the use of interactive audio-only technology is sufficient to furnish a Medicare telehealth service, we recognize that there is variable broadband access in patients' homes, and that even when technologically feasible, patients simply may not always wish to engage with their practitioner in their home using interactive audio and video. Under current statute, with the expiration of the PHE-related telehealth flexibilities on December 31, 2024, the patient's home is a permissible originating site only for services for the diagnosis, evaluation, or treatment of a mental health or substance use disorder, and for the monthly ESRD-related clinical assessments described in section 1881(b)(3)(B) of the Act.

We are proposing to revise the regulation at § 410.78(a)(3) to state that an interactive telecommunications system may also include two-way, real-time audio-only communication technology for any telehealth service furnished to a beneficiary in their home if the distant site physician or practitioner is technically capable of using an interactive telecommunications system as defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication, but the patient is not capable of, or does not consent to, the use of video technology. Additionally, a modifier designated by CMS must be appended to the claim for services described in this paragraph to verify that these conditions have been met. These are CPT modifier ''93'' and, for RHCs and FQHCs, Medicare modifier ''FQ'' (Medicare telehealth service was furnished using audio-only communication technology).

Practitioners have the option to use the ''FQ'' or the ''93'' modifiers or both where appropriate and true, since they are identical in meaning.

f. Distant Site Requirements

In the CY 2024 PFS final rule (88 FR 78873 through 78874) we discussed that many commenters expressed concerns regarding the expiring flexibility for telehealth practitioners to bill from their currently enrolled location instead of their home address when providing telehealth services from their home. CMS issued an FAQ, available at *https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf*, which extended the flexibility for telehealth practitioners to bill from their currently enrolled location instead of their home address when providing telehealth services from their home through December 31, 2023. Interested parties suggested that the expiration of this flexibility poses a potential and imminent threat to the safety and privacy of health professionals who work from home and furnish telehealth services. Commenters cited recent examples of workplace violence in health care facilities, where direct harm to nurses and other medical staff occurred. In addition to safety and privacy concerns, interested parties explained that a significant number of practitioners would need to change their billing practices or add their home address to the Medicare enrollment file, coordinating with the appropriate Medicare Administrative Contractor in their jurisdiction, and this would present administrative burden. To address these concerns, commenters requested that CMS take steps to protect telehealth practitioners by adjusting enrollment requirements so that individual practitioners do not have to list their home addresses on enrollment forms.

In response, CMS finalized, through CY 2024, that we would continue to permit a distant site practitioner to use their currently enrolled practice location instead of their home address when providing telehealth services from their home.

We have continued to hear from interested parties who have stressed the importance of continuing this flexibility for the safety and privacy of health care professionals. Given the shift in practice patterns toward models of care that include the practitioner's home as the distant site, we believe it would be appropriate to continue this flexibility as CMS considers various proposals that may better protect the safety and privacy of practitioners. We are therefore proposing that through CY 2025 we will continue to permit the distant site practitioner to use their currently enrolled practice location instead of their home address when providing telehealth services from their home.

2. Other Non-Face-to-Face Services Involving Communications Technology Under the PFS

a. Direct Supervision Via Use of Two-Way Audio/Video Communications Technology

Under Medicare Part B, certain types of services, including diagnostic tests described under § 410.32 and services incident to a physician's (or other practitioner's) professional service described under § 410.26 (incident-to services), are required to be furnished under specific minimum levels of supervision by a physician or other practitioner. We define three levels of supervision in our regulation at § 410.32(b)(3): General Supervision, Direct Supervision, and Personal Supervision. Notwithstanding the temporary measures implemented in response to the PHE for COVID–19, direct supervision requires the physician (or other supervising practitioner) to be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the service. It does not mean that the physician (or other supervising practitioner) must be present in the room when the service is performed. Again, notwithstanding the temporary measures implemented in response to the PHE for COVID–19, we have established this ''immediate availability'' requirement to mean in-person, physical, not virtual, availability (please see the April 6, 2020 IFC (85 FR 19245) and the CY 2022 PFS final rule (86 FR 65062)).

Direct supervision is required for various types of services, including most incident-to services under § 410.26, many diagnostic tests under § 410.32, pulmonary rehabilitation services under § 410.47, cardiac rehabilitation and intensive cardiac rehabilitation services under § 410.49, and certain hospital outpatient services as provided under § 410.27(a)(1)(iv). In the March 31, 2020 COVID–19 IFC, we amended the definition of ''direct supervision'' for the duration of the PHE for COVID–19 (85 FR 19245 through 19246) at § 410.32(b)(3)(ii) to state that the necessary presence of the physician (or other practitioner) for direct supervision includes virtual presence through audio/video real-time communications technology. Instead of requiring the supervising physician's (or other practitioner's) physical presence, the amendment permitted a supervising physician (or other practitioner) to be considered ''immediately available'' through virtual presence using two-way, real-time audio/visual technology for diagnostic tests, incident-to services, pulmonary rehabilitation services, and cardiac and intensive cardiac rehabilitation services. We made similar amendments at § 410.27(a)(1)(iv) to specify that direct supervision for certain hospital outpatient services may include virtual presence through audio/video real-time communications. The CY 2021 PFS final rule (85 FR 84538 through 84540) and the CY 2024 PFS final rule (88 FR 78878) subsequently extended these policies through December 31, 2024. As stated in the CY 2024 PFS final rule, we extended this definition of direct supervision through December 31, 2024, in order to align the timeframe of the policy with other PHE-related telehealth policies that were extended most recently under the provisions of the CAA, 2023.

We note that in the CY 2021 PFS final rule (85 FR 84539) we clarified that, to the extent our policy allows direct supervision through virtual presence using audio/video real-time communications technology, the requirement could be met by the supervising physician (or other practitioner) being immediately available to engage via audio/video technology (excluding audio-only), and would not require real-time presence or observation of the service via interactive audio and video technology throughout the performance of the service. We noted that this was the case during the PHE and would continue to be the case following the PHE. While flexibility to provide direct supervision through audio/video real-time communications technology was adopted to be responsive to critical needs during the PHE for COVID–19 to ensure beneficiary access to care, reduce exposure risk and to increase the capacity of practitioners and physicians to respond to COVID–19, we expressed concern that direct supervision through virtual presence may not be sufficient to support PFS payment on a permanent basis, beyond the PHE for COVID–19, due to issues of patient safety. For instance, in complex, high-risk, surgical, interventional, or endoscopic procedures, or anesthesia procedures, a patient's clinical status can quickly change; in-person supervision would be necessary for such services to allow for rapid on-site decision-making in the event of an

adverse clinical situation. In addition to soliciting comment in the CY 2021 PFS proposed rule on whether there should be any additional ''guardrails'' or limitations to ensure patient safety/clinical appropriateness, beyond typical clinical standards, as well as restrictions to prevent fraud or inappropriate use, we solicited comment in the CY 2024 PFS proposed rule on whether we should consider extending the definition of direct supervision to permit virtual presence beyond December 31, 2024. Specifically, we stated that we were interested in input from interested parties on potential patient safety or quality concerns when direct supervision occurs virtually; for instance, if direct supervision of certain types of services with virtual presence of the supervising practitioner is more or less likely to present patient safety concerns, or if this flexibility would be more appropriate for certain types of services, or when certain types of auxiliary personnel are performing the supervised service. We were also interested in potential program integrity concerns that interested parties may have regarding this policy, such as overutilization or fraud and abuse.

(1) Proposal To Extend Definition of ''Direct Supervision'' To Include Audio-Video Communications Technology Through 2025

As discussed in the CY 2024 PFS final rule (88 FR 78878), in the absence of evidence that patient safety is compromised by virtual direct supervision, we are concerned about an abrupt transition to our pre-PHE policy that defines direct supervision to require the physical presence of the supervising practitioner. We noted that an immediate reversion to the pre-PHE definition of direct supervision would prohibit virtual direct supervision, which may present a barrier to access to many services, such as incident-to services, and that physicians and/or other supervising practitioners, in certain instances, would need time to reorganize their practice patterns established during the PHE to reimplement the pre-PHE approach to direct supervision without the use of audio/video technology. We acknowledge the utilization of this flexibility and recognize that many practitioners have stressed the importance of maintaining it, however we seek additional information regarding potential patient safety and quality of care concerns. This flexibility has been available and widely utilized since the beginning of the PHE, and we recognize that may enhance patient access. However, given the importance of certain services being furnished under direct supervision in ensuring quality of care and patient safety, and in particular the ability of the supervising practitioner to intervene if complications arise, we believe an incremental approach is warranted, particularly in instances where unexpected or adverse events may arise for procedures which may be riskier or more intense. In light of these potential safety and quality of care implications, and exercising an abundance of caution, we are extending this flexibility for all services on a temporary basis only. We are therefore proposing to continue to define direct supervision to permit the presence and ''immediate availability'' of the supervising practitioner through real-time audio and visual interactive telecommunications through December 31, 2025.

(2) Proposal To Permanently Define ''Direct Supervision'' To Include Audio-Video Communications Technology for a Subset of Services

In the CY 2024 PFS proposed rule, we solicited comment on extending or permanently establishing the virtual presence flexibility for certain services valued under the PFS given that these services typically are performed in their entirety by auxiliary personnel as defined at § 410.26(a)(1). We stated such services would include incident-to services wholly furnished by auxiliary personnel, Level I office or other outpatient E/M visits for established patients. We also mentioned Level I Emergency Department (ED) visits in this list, but have since concluded that ED services would not be wholly furnished by auxiliary personnel and, for that reason, have excluded them from the discussion in this proposed rule. Based on our review, these specific services present less of a patient safety concern than services for which there may be a need for immediate intervention of the supervising practitioner; as noted in the CY 2024 PFS proposed rule, allowing virtual presence for direct supervision of these services could balance patient safety concerns with the interest of supporting access and preserving workforce capacity for medical professionals while considering potential quality and program integrity concerns. After reviewing the various comments in response to this solicitation, additional feedback provided by interested parties, and conducting our own independent review, we believe these services are low risk by their nature, do not often demand in-person supervision, are typically furnished entirely by the supervised personnel, and allowing virtual presence for direct supervision of these services would balance patient safety concerns with the interest of supporting access and preserving workforce capacity.

We are proposing to adopt a definition of direct supervision that allows ''immediate availability'' of the supervising practitioner using audio/video real-time communications technology (excluding audio-only), but only for the following subset of incident-to services described under § 410.26: (1) services furnished incident to a physician or other practitioner's service when provided by auxiliary personnel employed by the billing practitioner and working under their direct supervision, and for which the underlying HCPCS code has been assigned a PC/TC indicator of '5';[10] and (2) services described by CPT code 99211 (*Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional*). As provided in the code descriptor for CPT code 99211, an office or other outpatient visit for the evaluation and management of an established patient may not require the presence of a physician or other practitioner and may be furnished incident to a physicians' service by a nonphysician employee of the physician under direct supervision. The service described by CPT code 99211 and the services that are identified with a PC/TC indicator of '5' as listed in the PFS Relative Value Files are services that are nearly always performed in entirety by auxiliary personnel. The vignette for CPT code 99211 describes the provision of supervision and guidance to the clinical staff as necessary. The code descriptor for this service specifies an E/M service that may not require the presence of a physician or other professional; and the current valuation, which is relatively low compared to other office and outpatient E/M services, suggests that this service would primarily be provided by auxiliary personnel.

We are proposing an incremental approach whereby we will adopt without any time limitation the definition of direct supervision

[10] For a full list of all PFS payment status indicators and descriptions, see the Medicare Claims Processing Manual (IOM Pub. 100–04, chapter 23, sections 30.2.2). For a full list of all PFS payment status indicators and descriptions, see the Medicare Claims Processing Manual (IOM Pub. 100–04, chapter 23, sections 30.2.2 and 50.6). Specific indicators by service are listed in the PFS Relative Value files at *https://www.cms.gov/medicare/payment/fee-schedules/physician/pfs-relative-value-files*).

permitting virtual presence for services that are inherently lower risk: that is, services that do not ordinarily require the presence of the billing practitioner, do not require direction by the supervising practitioner to the same degree as other services furnished under direct supervision, and are not services typically performed directly by the supervising practitioner.

For all other services required to be furnished under the direct supervision of the supervising physician or other practitioner, we are proposing, as described above, to continue to define ''immediate availability'' to include real-time audio and visual interactive telecommunications technology only through December 31, 2025.

We are proposing to revise the regulations at § 410.32(b)(3)(ii) to state that through December 31, 2025, the presence of the physician (or other practitioner) would include virtual presence through audio/video real-time communications technology (excluding audio-only).

We are proposing to revise the regulation at § 410.26(a)(2) to state that for the following services furnished after December 31, 2025, the presence of the physician (or other practitioner) required for direct supervision shall continue to include virtual presence through audio/video real-time communications technology (excluding audio-only): services furnished incident to a physician's service when they are provided by auxiliary personnel employed by the physician and working under his or her direct supervision and for which the underlying HCPCS code has been assigned a PC/TC indicator of '5'; and office and other outpatient visits for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional.

(3) Teaching Physician Billing for Services Involving Residents With Virtual Presence

In the CY 2021 PFS final rule (85 FR 84577 through 84584), we established a policy that, after the end of the PHE for COVID–19, teaching physicians may meet the requirements to be present for the key or critical portions of services when furnished involving residents through audio/video real-time communications technology (virtual presence), but only for services furnished in residency training sites located outside of an Office of Management and Budget (OMB)-defined metropolitan statistical area (MSA). We made this location distinction consistent with our longstanding interest in increasing beneficiary access to Medicare-covered services in rural areas. We noted the ability to expand training opportunities for residents in rural settings. For all other locations, we expressed concerns that continuing to permit teaching physicians to bill for services furnished involving residents when they are virtually present, outside the conditions of the PHE for COVID–19, may not allow the teaching physician to have personal oversight and involvement over the management of the portion of the case for which the payment is sought, under section 1842(b)(7)(A)(i)(I) of the Act. In addition, we stated concerns about patient populations that may require a teaching physician's experience and skill to recognize specialized needs or testing and whether it is possible for the teaching physician to meet these clinical needs while having a virtual presence for the key portion of the service. We refer readers to the CY 2021 PFS final rule (85 FR 84577 through 84584) for a more detailed description of our specific concerns. At the end of the PHE for COVID–19, and as finalized in the CY 2021 PFS final rule, we intended for the teaching physician to have a physical presence during the key portion of the service personally provided by residents in order to be paid for the service under the PFS, in locations that were within a MSA. This policy applied to all services, regardless of whether the patient was co-located with the resident or only present virtually (for example, the service was furnished as a 3-way telehealth visit, with the teaching physician, resident, and patient in different locations). However, interested parties expressed concerns regarding the requirement that the teaching physician be physically present with the resident when a service is furnished virtually (as a Medicare telehealth service) within an MSA. Some interested parties stated that during the PHE for COVID–19, when residents provided telehealth services, and the teaching physician was virtually present, the same safe and high-quality oversight was provided as when the teaching physician and resident were physically co-located. In addition, these interested parties stated that during telehealth visits, the teaching physician was virtually present during the key and critical portions of the telehealth service, available immediately in real-time, and had access to the electronic health record. After review of the public comments, we finalized a policy that allowed the teaching physician to have a virtual presence in all teaching settings, only in clinical instances when the service was furnished virtually (for example, a 3-way telehealth visit, with all parties in separate locations). This permitted teaching physicians to have a virtual presence during the key portion of the Medicare telehealth service for which payment was sought, through audio/video real-time communications technology, in all residency training locations through December 31, 2024.

As stated in the CY 2024 PFS final rule (88 FR 78880), we are concerned that an abrupt transition to our pre-PHE policy may present a barrier to access to many services. We also understand that teaching physicians have gained clinical experience providing services involving residents with virtual presence during the PHE for COVID–19 and could help us to identify circumstances where the teaching physician can routinely provide sufficient personal and identifiable services to the patient through their virtual presence during the key portion of the Medicare telehealth service. We sought comment and information to help us consider other clinical treatment situations where it may be appropriate to continue to permit the virtual presence of the teaching physician, while continuing to support patient safety, meeting the clinical needs for all patients, and ensuring burden reduction without creating risks to patient care or increasing opportunities for fraud. As summarized in the CY 2024 PFS final rule (88 FR 78881 through 78882), commenters encouraged us to establish this policy permanently and include in-person services to promote access to care, stated that teaching physicians should be allowed to determine when their virtual presence would be clinically appropriate, based on their assessment of the patient's needs and the competency level of the resident. While we continue to consider clinical scenarios where it may be appropriate to permit the virtual presence of the teaching physician, we are proposing to continue our current policy to allow teaching physicians to have a virtual presence for purposes of billing for services furnished involving residents in all teaching settings, but only when the service is furnished virtually (for example, a 3-way telehealth visit, with the patient, resident, and teaching physician in separate locations). This would permit teaching physicians to have a virtual presence during the key portion of the Medicare telehealth service for which payment is sought in any residency training location through December 31, 2025. The teaching physician's virtual presence would continue to require real-time observation (not mere availability) and

excludes audio-only technology. The documentation in the medical record must continue to demonstrate whether the teaching physician was physically present or present through audio/video real-time communications technology at the time of the Medicare telehealth service, which includes documenting the specific portion of the service for which the teaching physician was present through audio/video real-time communications technology.

(a) Request for Information for Teaching Physician Services Furnished Under the Primary Care Exception

The so-called primary care exception set forth at § 415.174 permits the teaching physician to bill for certain lower and mid-level complexity physicians' services furnished by residents in certain types of residency training settings even when the teaching physician is not present with the resident during the services as long as certain conditions are met, including that the services are furnished by residents with more than 6 months of training in the approved residency program; and that the teaching physician directs the care of no more than four residents at a time, remains immediately available and has no other responsibilities while directing the care, assumes management responsibility for beneficiaries seen by the residents, ensures that the services furnished are appropriate, and reviews certain elements of the services with each resident during or immediately after each visit. For a more detailed description of the list of services currently allowed under the primary care exception policy, we refer readers to the CY 2021 PFS final rule (85 FR 84585 through 84590).

We have received feedback from interested parties requesting that we permanently expand the list of services that can be furnished under the primary care exception to include all levels of E/M services and additional preventive services. These interested parties have stated that the fact that high-value primary care and preventive services are not included in the scope of the primary care exception discourages their integration in residency training in these primary care settings, which has a negative impact on physician training, patient access, and longer-term outcomes. Additionally, these interested parties have suggested that including all levels of E/M services under the primary care exception could support primary care workforce development and improve patient continuity of care without compromising patient safety; furthermore, including additional preventive services within the primary care exception would increase the utilization of high-value services.

We believe the primary care exception was intended to broaden opportunities for teaching physicians to involve residents in furnishing services under circumstances that preserve the direction of the care by the teaching physician and promote safe, high-quality patient care. As such, we are requesting information to help us consider whether and how best to expand the array of services included under the primary care exception in future rulemaking. We are interested in hearing more about the types of services that could be allowed under the primary care exception, specifically preventive services, and whether the currently required six months of training in an approved program is sufficient for residents to furnish these types of services without the presence of a teaching physician. We are seeking comment to help us consider whether adding certain preventive services or higher level E/M services to the primary care exception would hinder the teaching physician from maintaining sufficient personal involvement in the care to warrant PFS payment for the services being furnished by up to four residents at any given time. Similarly, we are requesting information on whether the inclusion in the primary care exception of specific higher-level or preventive services would impede the teaching physician's ability to remain immediately available for up to four residents at any given time, while directing and managing the care furnished by these residents.

3. Telehealth Originating Site Facility Fee Payment Amount Update

Section 1834(m)(2)(B) of the Act established the Medicare telehealth originating site facility fee for telehealth services furnished from October 1, 2001, through December 31, 2002 at $20.00, and specifies that, for telehealth services furnished on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act. The proposed MEI increase for CY 2025 is 3.6 percent and is based on the expected historical percentage increase of the 2017-based MEI. For the final rule, we propose to update the MEI increase for CY 2025 based on historical data through the second quarter of 2024. Therefore, for CY 2025, the proposed payment amount for HCPCS code Q3014 (*Telehealth originating site facility fee*) is $31.04. Table 9 shows the Medicare telehealth originating site facility fee and the corresponding MEI percentage increase for each applicable time period.

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TABLE 9: The Medicare Telehealth Originating Site Facility Fee

Time Period	MEI (%)	Facility Fee for Q3014
Oct. 1, 2001 to Dec. 31, 2002	NA	$ 20.00
2003	3.0	$ 20.60
2004	2.9	$ 21.20
2005	3.1	$ 21.86
2006	2.8	$ 22.47
2007	2.1	$ 22.94
2008	1.8	$ 23.35
2009	1.6	$ 23.72
2010	1.2	$ 24.00
2011	0.4	$ 24.10
2012	0.6	$ 24.24
2013	0.8	$ 24.43
2014	0.8	$ 24.63
2015	0.8	$ 24.83
2016	1.1	$ 25.10
2017	1.2	$ 25.40
2018	1.4	$ 25.76
2019	1.5	$ 26.15
2020	1.9	$ 26.65
2021	1.4	$ 27.02
2022	2.1	$ 27.59
2023	3.8	$ 28.64
2024	4.6	$ 29.96
2025*	3.6	$ 31.04

*Reflects the most recent estimate of the CY 2025 MEI percentage increase and will be updated in the final rule based on historical data through the second quarter of 2024.

BILLING CODE C

4. Payment for Outpatient Therapy Services, Diabetes Self-Management Training, and Medical Nutrition Therapy When Furnished by Institutional Staff to Beneficiaries in Their Homes Through Communication Technology

For information related to outpatient physical therapy, occupational therapy, speech-language pathology, diabetes self-management training (DSMT) and medical nutritional therapy (MNT) services furnished by institutional staff in hospitals and other institutional settings to beneficiaries in their homes through communication technology, please refer to section X.A. in the CY 2025 Hospital Outpatient Prospective Payment System (OPPS) proposed rule (FR Doc. 2024–15087), on public inspection July 10, 2024, and publishing in the **Federal Register** of July 22, 2024.

E. Valuation of Specific Codes

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since the inception of the PFS, it has also been a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. Initially, this was accomplished primarily through the 5-year review process, which resulted in revised work RVUs for CY 1997, CY 2002, CY 2007, and CY 2012, and revised PE RVUs in CY 2001, CY 2006, and CY 2011, and revised MP RVUs in CY 2010, CY 2015, and CY 2020. Under the 5-year review process, revisions in RVUs were proposed and finalized via rulemaking. In addition to the 5-year reviews, beginning with CY 2009, CMS and the RUC identified a number of potentially misvalued codes each year using various identification screens, as outlined in section II.C. of this proposed rule, Potentially Misvalued Services under the PFS. Historically, when we received RUC recommendations, our process had been to establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there were coding changes in the final rule with comment period for a year. Then, during the 60-day period following the publication of the final rule with comment period, we accepted public comment about those valuations. For services furnished during the calendar year following the publication of interim final rates, we paid for services based upon the interim final values established in the final rule. In the final rule with comment period for the subsequent year, we considered and responded to public comments received on the interim final values, and typically made any appropriate adjustments and finalized those values.

In the CY 2015 PFS final rule with comment period (79 FR 67547), we finalized a new process for establishing values for new, revised and potentially misvalued codes. Under the new process, we include proposed values for these services in the proposed rule, rather than establishing them as interim final in the final rule with comment period. Beginning with the CY 2017 PFS proposed rule (81 FR 46162), the new process was applicable to all codes, except for new codes that describe truly new services. For CY 2017, we proposed new values in the CY 2017 PFS proposed rule for the vast majority of

new, revised, and potentially misvalued codes for which we received complete RUC recommendations by February 10, 2016. To complete the transition to this new process, for codes for which we established interim final values in the CY 2016 PFS final rule with comment period (81 FR 80170), we reviewed the comments received during the 60-day public comment period following release of the CY 2016 PFS final rule with comment period (80 FR 70886), and re-proposed values for those codes in the CY 2017 PFS proposed rule. We considered public comments received during the 60-day public comment period for the proposed rule before establishing final values in the CY 2017 PFS final rule. As part of our established process, we will adopt interim final values only in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive recommendations in time to propose values.

As part of our obligation to establish RVUs for the PFS, we thoroughly review and consider available information including recommendations and supporting information from the RUC, the Health Care Professionals Advisory Committee (HCPAC), public commenters, medical literature, Medicare claims data, comparative databases, comparison with other codes within the PFS, as well as consultation with other physicians and healthcare professionals within CMS and the Federal Government as part of our process for establishing valuations. Where we concur that the RUC's recommendations, or recommendations from other commenters, are reasonable and appropriate and are consistent with the time and intensity paradigm of physician work, we proposed those values as recommended. Additionally, we continually engage with interested parties, including the RUC, with regard to our approach for accurately valuing codes, and as we prioritize our obligation to value new, revised, and potentially misvalued codes. We continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process.

2. Methodology for Establishing Work RVUs

For each code identified in this section, we conduct a review that includes the current work RVU (if any), RUC-recommended work RVU, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal RUC process.

Components that we use in the building block approach may include preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could include the CPT codes that make up the bundled code and the inputs associated with those codes. We use the building block methodology to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code. Magnitude estimation refers to a methodology for valuing work that determines the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS without explicitly valuing the components of that work. In addition to these methodologies, we frequently utilize an incremental methodology in which we value a code based upon its incremental difference between another code and another family of codes. Section 1848(c)(1)(A) of the Act specifically defines the work component as the resources that reflect time and intensity in furnishing the service. Also, the published literature on valuing work has recognized the key role of time in overall work. For particular codes, we refine the work RVUs in direct proportion to the changes in the best information regarding the time resources involved in furnishing particular services, either considering the total time or the intraservice time.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently, there are preservice time packages for services typically furnished in the facility setting (for example, preservice time packages reflecting the different combinations of straightforward or difficult procedure, and straightforward or difficult patient). Currently, there are three preservice time packages for services typically furnished in the nonfacility setting.

We developed several standard building block methodologies to value services appropriately when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an E/M service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. Our longstanding adjustments have reflected a broad assumption that at least one-third of the work time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit.

Accordingly, in cases where we believe that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjust the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service multiplied by the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU.

Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes $\times$ 0.0224 IWPUT) if we do not believe the overlap in time had already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, now addresses the overlap in time and work when a service is typically furnished on the same day as an E/M service.

The following paragraphs discuss our approach to reviewing RUC recommendations and developing

proposed values for specific codes. When they exist, we also include a summary of interested party reactions to our approach. We noted that many commenters and interested parties have expressed concerns over the years with our ongoing adjustment of work RVUs based on changes in the best information we had regarding the time resources involved in furnishing individual services. We have been particularly concerned with the RUC's and various specialty societies' objections to our approach given the significance of their recommendations to our process for valuing services and since much of the information we used to make the adjustments is derived from their survey process. We note that we are obligated under the statute to consider both time and intensity in establishing work RVUs for PFS services. As explained in the CY 2016 PFS final rule with comment period (80 FR 70933), we recognize that adjusting work RVUs for changes in time is not always a straightforward process, so we have applied various methodologies to identify several potential work values for individual codes.

We have observed that for many codes reviewed by the RUC, recommended work RVUs have appeared to be incongruous with recommended assumptions regarding the resource costs in time. This has been the case for a significant portion of codes for which we recently established or proposed work RVUs that are based on refinements to the RUC-recommended values. When we have adjusted work RVUs to account for significant changes in time, we have started by looking at the change in the time in the context of the RUC-recommended work RVU. When the recommended work RVUs do not appear to account for significant changes in time, we have employed the different approaches to identify potential values that reconcile the recommended work RVUs with the recommended time values. Many of these methodologies, such as survey data, building block, crosswalks to key reference or similar codes, and magnitude estimation have long been used in developing work RVUs under the PFS. In addition to these, we sometimes use the relationship between the old time values and the new time values for particular services to identify alternative work RVUs based on changes in time components.

In so doing, rather than ignoring the RUC-recommended value, we have used the recommended values as a starting reference and then applied one of these several methodologies to account for the reductions in time that we believe were not otherwise reflected in the RUC-recommended value. If we believe that such changes in time are already accounted for in the RUC's recommendation, then we do not make such adjustments. Likewise, we do not arbitrarily apply time ratios to current work RVUs to calculate proposed work RVUs. We use the ratios to identify potential work RVUs and consider these work RVUs as potential options relative to the values developed through other options.

We do not imply that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs. Instead, we believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. If the RUC's recommendation has appeared to disregard or dismiss the changes in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we have generally used one of the aforementioned methodologies to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure.

Several interested parties, including the RUC, have expressed general objections to our use of these methodologies and suggested that our actions in adjusting the recommended work RVUs are inappropriate; other interested parties have also expressed general concerns with CMS refinements to RUC-recommended values in general. In the CY 2017 PFS final rule (81 FR 80272 through 80277), we responded in detail to several comments that we received regarding this issue. In the CY 2017 PFS proposed rule (81 FR 46162), we requested comments regarding potential alternatives to making adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services; however, we did not receive any specific potential alternatives. As described earlier in this section, crosswalks to key reference or similar codes are one of the many methodological approaches we have employed to identify potential values that reconcile the RUC-recommend work RVUs with the recommended time values when the RUC-recommended work RVUs did not appear to account for significant changes in time.

In response to comments, in the CY 2019 PFS final rule (83 FR 59515), we clarified that terms ''reference services'', ''key reference services'', and ''crosswalks'' as described by the commenters are part of the RUC's process for code valuation. These are not terms that we created, and we do not agree that we necessarily must employ them in the identical fashion for the purposes of discussing our valuation of individual services that come up for review. However, in the interest of minimizing confusion and providing clear language to facilitate feedback from interested parties, we stated that we would seek to limit the use of the term, ''crosswalk,'' to those cases where we are making a comparison to a CPT code with the identical work RVU. (83 FR 59515) We note that we also occasionally make use of a ''bracket'' for code valuation. A ''bracket'' refers to when a work RVU falls between the values of two CPT codes, one at a higher work RVU and one at a lower work RVU.

We look forward to continuing to engage with interested parties and commenters, including the RUC, as we prioritize our obligation to value new, revised, and potentially misvalued codes; and we will continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process. We refer readers to the detailed discussion in this section of the valuation considered for specific codes. Table 13 contains a list of codes and descriptors for which we are proposing work RVUs for CY 2025; this includes all codes for which we received RUC recommendations by February 10, 2024. The proposed work RVUs, work time and other payment information for all CY 2025 payable codes are available on the CMS website under downloads for the CY 2025 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*).

3. Methodology for the Direct PE Inputs To Develop PE RVUs

a. Background

On an annual basis, the RUC provides us with recommendations regarding PE inputs for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code-by-code basis. Like our review of recommended work RVUs, our review of recommended direct PE inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and

comparative databases, as well as a comparison with other codes within the PFS, and consultation with physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. When we determine that the RUC's recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service, are consistent with the principles of relativity, and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the recommended PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or nonfacility direct PE inputs and refine the inputs accordingly.

Our review and refinement of the RUC-recommended direct PE inputs includes many refinements that are common across codes, as well as refinements that are specific to particular services. Table 14 details our refinements of the RUC's direct PE recommendations at the code-specific level. In section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units (PE RVUs), we address certain refinements that will be common across codes. Refinements to particular codes are addressed in the portions of that section that are dedicated to particular codes. We note that for each refinement, we indicate the impact on direct costs for that service. We note that, on average, in any case where the impact on the direct cost for a particular refinement is $0.35 or less, the refinement has no impact on the PE RVUs. This calculation considers both the impact on the direct portion of the PE RVU, as well as the impact on the indirect allocator for the average service. In this proposed rule, we also note that many of the refinements listed in Table 14 result in changes under the $0.35 threshold and would be unlikely to result in a change to the RVUs.

We note that the direct PE inputs for CY 2025 are displayed in the CY 2025 direct PE input files, available on the CMS website under the downloads for the CY 2025 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* The inputs displayed there have been used in developing the CY 2025 PE RVUs as displayed in Addendum B (see *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates*).

b. Common Refinements

(1) Changes in Work Time

Some direct PE inputs are directly affected by revisions in work time. Specifically, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs. The direct PE input recommendations generally correspond to the work time values associated with services. We believe that inadvertent discrepancies between work time values and direct PE inputs should be refined or adjusted in the establishment of proposed direct PE inputs to resolve the discrepancies.

(2) Equipment Time

Prior to CY 2010, the RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the RUC provide equipment times along with the other direct PE recommendations, and we provided the RUC with general guidelines regarding appropriate equipment time inputs. We appreciate the RUC's willingness to provide us with these additional inputs as part of its PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We clarified this principle over several years of rulemaking, indicating that we consider equipment time as the time within the intraservice period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For those services for which we allocate cleaning time to portable equipment items, because the portable equipment does not need to be cleaned in the room where the service is furnished, we do not include that cleaning time for the remaining equipment items, as those items and the room are both available for use for other patients during that time. In addition, when a piece of equipment is typically used during follow-up postoperative visits included in the global period for a service, the equipment time will also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of the clinical staff may be occupied with a preservice or postservice task related to the procedure. We also noted that we believe these same assumptions will apply to inexpensive equipment items that are used in conjunction with and located in a room with non-portable highly technical equipment items since any items in the room in question will be available if the room is not being occupied by a particular patient. For additional information, we referred readers to our discussion of these issues in the CY 2012 PFS final rule with comment period (76 FR 73182) and the CY 2015 PFS final rule with comment period (79 FR 67639).

(3) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, intraservice, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the RUC-recommended direct PE inputs, commonly called the ''PE worksheets.'' For most of these described tasks, there is a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. The RUC sometimes recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, we review the deviations from the standards and any rationale provided for the deviations. When we do not accept the RUC-recommended exceptions, we refine the proposed direct PE inputs to conform to the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the preservice clinical labor tasks to avoid duplicative inputs and to reflect the resource costs of furnishing the typical service.

We refer readers to section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units (PE RVUs), for more information regarding the collaborative work of CMS and the RUC in improvements in standardizing clinical labor tasks.

(4) Recommended Items That Are Not Direct PE Inputs

In some cases, the PE worksheets included with the RUC's

recommendations include items that are not clinical labor, disposable supplies, or medical equipment or that cannot be allocated to individual services or patients. We addressed these kinds of recommendations in previous rulemaking (78 FR 74242), and we do not use items included in these recommendations as direct PE inputs in the calculation of PE RVUs.

(5) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. However, some recommendations include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended that a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide us copies of sales invoices. For CY 2025 we received invoices for several new supply and equipment items. Tables 17 and 18 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units, we encourage interested parties to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encourage interested parties to submit invoices or other information to improve the accuracy of pricing for these items in the direct PE database by February 10th of the following year for consideration in future rulemaking, similar to our process for consideration of RUC recommendations.

We remind interested parties that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. Tables 17 and 18 also include the number of invoices received and the number of nonfacility allowed services for procedures that use these equipment items. We provide the nonfacility allowed services so that interested parties will note the impact the particular price might have on PE relativity, as well as to identify items that are used frequently, since we believe that interested parties are more likely to have better pricing information for items used more frequently. A single invoice may not be reflective of typical costs, and we encourage interested parties to provide additional invoices so that we might identify and use accurate prices in the development of PE RVUs.

In some cases, we do not use the price listed on the invoice that accompanies the recommendation because we identify publicly available alternative prices or information that suggests a different price is more accurate. In these cases, we include this in the discussion of these codes. In other cases, we cannot adequately price a newly recommended item due to inadequate information. Sometimes, no supporting information regarding the price of the item has been included in the recommendation. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, vendor price quotes instead of paid invoices). In cases where the information provided on the item allows us to identify clinically appropriate proxy items, we might use existing items as proxies for the newly recommended items. In other cases, we include the item in the direct PE input database without any associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the final PE RVU for particular services, it facilitates our ability to incorporate a price once we obtain information and are able to do so.

(6) Service Period Clinical Labor Time in the Facility Setting

Generally speaking, our direct PE inputs do not include clinical labor minutes assigned to the service period because the cost of clinical labor during the service period for a procedure in the facility setting is not considered a resource cost to the practitioner since Medicare makes separate payment to the facility for these costs. We address code-specific refinements to clinical labor in the individual code sections.

(7) Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

We note that the list of services for the upcoming calendar year that are subject to the MPPR on diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services, and therapy services; and the list of procedures that meet the definition of imaging under section 1848(b)(4)(B) of the Act, and therefore, are subject to the OPPS cap; are displayed in the public use files for the PFS proposed and final rules for each year. The public use files for CY 2025 are available on the CMS website under downloads for the CY 2025 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. For more information regarding the history of the MPPR policy, we refer readers to the CY 2014 PFS final rule with comment period (78 FR 74261 through 74263).

Effective January 1, 2007, section 5102(b)(1) of the Deficit Reduction Act of 2005 (Pub. L. 109–171) (DRA) amended section 1848(b)(4) of the Act to require that, for imaging services, if—(i) The TC (including the TC portion of a global fee) of the service established for a year under the fee schedule without application of the geographic adjustment factor, exceeds (ii) The Medicare OPD fee schedule amount established under the prospective payment system (PPS) for HOPD services under section 1833(t)(3)(D) of the Act for such service for such year, determined without regard to geographic adjustment under section 1833(t)(2)(D), the Secretary shall substitute the amount described in clause (ii), adjusted by the geographic adjustment factor under the PFS, for the fee schedule amount for such TC for such year. As required by section 1848(b)(4)(A) of the Act, for imaging services furnished on or after January 1, 2007, we cap the TC of the PFS payment amount for the year (prior to geographic adjustment) by the Outpatient Prospective Payment System (OPPS) payment amount for the service (prior to geographic adjustment). We then apply the PFS geographic adjustment to the capped payment amount. Section 1848(b)(4)(B) of the Act defines imaging services as ''imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging (MRI), computed tomography (CT), and fluoroscopy, but excluding diagnostic and screening mammography.'' For more information regarding the history of the cap on the TC of the PFS payment amount under the DRA (the ''OPPS cap''), we refer readers to the CY 2007 PFS final rule with comment period (71 FR 69659 through 69662).

For CY 2025, we identified new and revised codes to determine which services meet the definition of ''imaging services'' as defined at section 1848(b)(4)(B) of the Act for purposes of this cap. Beginning for CY 2025, we are proposing to include the following services on the list of codes to which the OPPS cap applies: CPT codes 0868T (*High-resolution gastric electrophysiology mapping with simultaneous patient-symptom profiling, with interpretation and*

report), 0876T (Duplex scan of hemodialysis fistula, computer-aided, limited (volume flow, diameter, and depth, including only body of fistula)), 74263 (Computed tomographic (ct) colonography, screening, including image postprocessing), 9X059 (*Computerized ophthalmic diagnostic imaging (eg, optical coherence tomography [OCT]), posterior segment, with interpretation and report, unilateral or bilateral; retina including OCT angiography*), 93X94 (*Vasoreactivity study performed with transcranial Doppler study of intracranial arteries, complete (List separately in addition to code for primary procedure)*), 93X95 (*Emboli detection without intravenous microbubble injection performed with transcranial Doppler study of intracranial arteries, complete (List separately in addition to code for primary procedure)*), and 93X96 (*Venous-arterial shunt detection with intravenous microbubble injection performed with transcranial Doppler study of intracranial arteries, complete (List separately in addition to code for primary procedure)*). We believe that these codes meet the definition of imaging services under section 1848(b)(4)(B) of the Act, and thus, should be subject to the OPPS cap.

In the CY 2024 PFS final rule (88 FR 78894), we noted that in response to the CY 2024 PFS proposed rule, commenters requested that CMS remove CPT code 92229 (*Imaging of retina for detection or monitoring of disease; point-of-care autonomous analysis and report, unilateral or bilateral*) from the OPPS cap list because it does not include an associated PC or physician interpretation and it is primarily utilized in the physician office setting. We are soliciting comment on the appropriateness of applying the OPPS cap to services such as this for which the interpretation component is not captured by work RVUs, and the service is not split into technical and professional components. We are more broadly evaluating how services involving assistive technologies are most accurately valued. We note that the OPPS rate for this service is currently higher than what would be paid in a physician office setting, and therefore the OPPS cap does not currently apply to CPT code 92229 as of 2024.

4. Valuation of Specific Codes for CY 2025

(1) Skin Cell Suspension Autograft (CPT codes 15XX1, 15XX2, 15XX3, 15XX4, 15XX5, 15XX6, 15XX7, and 15XX8)

In September 2023, the CPT Editorial Panel approved the creation of eight new CPT codes to describe skin cell suspension autograft (SCSA) procedures. The code set includes a 000-day global base code (CPT code 15XX1 (*Harvest of skin for skin cell suspension autograft; first 25 sq cm or less*)) and an add-on code (CPT code 15XX2 (*Harvest of skin for skin cell suspension autograft; each additional 25 sq cm or part thereof (List separately in addition to code for primary procedure)*)) describing the harvesting component of the procedure, an XXX global base code (CPT code 15XX3 (*Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin*) and an add-on code (CPT code 15XX4 (*Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; each additional 25 sq cm of harvested skin or part thereof (List separately in addition to code for primary procedure)*)) describing the preparation component of the procedure, and two 090-day global base codes and two add-on codes for the application component to distinguish between body areas: trunk, arms, and legs with CPT codes 15XX5 (*Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; first 480 sq cm or less*) and 15XX6 (*Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; each additional 480 sq cm or part thereof (List separately in addition to code for primary procedure)*); and face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, or multiple digits with CPT codes 15XX7 (*Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 480 sq cm or less*) and 15XX8 (*Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 480 sq cm or part thereof (List separately in addition to code for primary procedure)*).

We disagree with the RUC-recommended work RVUs of 3.00, 2.00, 2.51, 2.00, 10.97, 2.50, 12.50, and 3.00 for CPT codes 15XX1 through 15XX8, respectively, and are proposing contractor-pricing for these CPT codes due to concerns with the coding structure of the code family and the total physician time that results when these codes are billed multiple times on the same date of service for the typical patient.

We note that our concerns with these CPT codes are expansive. Firstly, we note that these CPT codes represent a segmentation of a single service that is performed sequentially on the same date of service. We are seeking comment on whether the segmentation of the harvest, preparation, and application is necessary when these are sequential service parts of one episode of care, and could be simplified by having just two codes that encompass all three service parts (harvest, preparation, and application), to differentiate the two different application areas. We also are soliciting comment on the base and add-on codes' incremental square centimeters, considering that the typical size treatment area described in the vignettes could result in the add-on codes being billed multiple times, particularly for the base application CPT code 15XX5 and add-on CPT code 15XX6. Based on the meeting notes from the September 2023 CPT Editorial Panel meeting, the specialty society initially structured their coding request to ''bundle'' the service components into fewer codes, but it is unclear to us why these codes were further segmented. We believe that the very large range of intraservice times from the 33 burn surgeons may have been exacerbated by the harvest, preparation, and application components of the service being segmented in this manner. Most notably, CPT code 15XX1, which describes the first 25 sq cm of harvest, base code, had an intraservice survey time range of 5 to 480 minutes, and CPT code 15XX7, which describes the first 480 sq cm of application to the face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, had an intraservice survey time range of 10 to 360 minutes.

We note that the survey median intraservice times for CPT codes 15XX1 through 15XX8 contradict numerous publicly available sources that describe much lower times for this service or specific service parts. Most notably, the manufacturer of the RECELL Autologous Cell Harvesting Device (RECELL® System) used in this service, indicates

that a suspension of Spray-On Skin™ Cells using a small sample of the patient's own skin for the treatment of thermal burn wounds and full-thickness skin defects is ''prepared and applied at the point of care in as little as 30 minutes.'' [11] Additionally, Temple University Hospital published a news article on December 20, 2019, just 11 months after the U.S. Food and Drug Administration (FDA) approval of the RECELL® System for the treatment of acute thermal second and third-degree burns in adult patients in January 2019, stating that the entire process of skin sample collection, enzyme solution preparation, and suspension spraying/application ''can take as little as 30 minutes'' and ''treat a wound up to 80 times the size of the donor skin sample.'' [12] Additionally, an article published in Europe PubMed Central states that the procedure takes approximately 30 minutes and is performed by a burn surgeon trained in how to use RECELL® System, and does not require specialized laboratory staff.[13] Additionally, a 2007 study aimed at comparing the results from the RECELL® System and the classic skin grafting for epidermal replacement in deep partial thickness burns showed a total procedure time of 59±4 minutes for the RECELL® System group.[14]

More granularly, the FDA's Instructions for Use of the RECELL® Autologous Cell Harvesting Device state that ''if a skin sample is harvested and processed according to these instructions, it should require between 15 and 30 minutes of contact with the Enzyme''.[15] Additionally, the National Institute for Health and Care Excellence (NICE) produced guidance on using the RECELL® System based on the consideration of evidence submitted and the views of expert advisers, and stated that the harvested skin is added to the proprietary enzyme solution in a processing unit and heated for 15 to 30 minutes to disaggregate the cells. The skin is then removed and scraped with a scalpel to develop a plume of cells. These cells are added to a buffer solution, aspirated and filtered to create a cell suspension that contains keratinocytes, melanocytes, fibroblasts and Langerhans cells.[16] This correlates to the preparation component of the service described by CPT codes 15XX3 and 15XX4, for which the RUC recommended the survey median time of 33 and 28 minutes, respectively.

We believe that the publicly available sources that make representations about the total service and preparation times contradict the RUC-recommended median times based on the survey of 33 burn surgeons. Moreover, when we considered how the add-on CPT codes 15XX2, 15XX4, 15XX6, and 15XX8 would be billed based on the typical patient described in the vignettes, we believe the survey times are inflated compared to the publicly available sources, likely due to how the survey respondents considered the service given the segmentation of the code set. For example, the vignette for CPT code 15XX5 describing the application to the trunk, arms, and legs says ''A 35-year-old male sustained partial-thickness thermal burns on his trunk and arms measuring 3,600 sq cm. A skin cell suspension autograft is applied to 480 sq cm of the wound bed.'' Of the 33 burn surgeons surveyed, 96 percent found this vignette to be typical. Given the typical sq cm application area of 3,600 sq cm and the expansion ratio of harvested and prepared skin to treatment skin for application of 1:80, the typical episode of care would constitute 1 unit of both CPT codes 15XX1 and 15XX2 for harvesting, 1 unit of both CPT codes 15XX3 and 15XX4 for preparation, 1 unit of CPT code 15XX5 for the first 480 sq cm of application, and 7 units of CPT code 15XX6 for the remaining 3,120 sq cm of application area. When the RUC-recommended intraservice and total times (not including the post-operative visit time for CPT code 15XX5) for all the units billed on the same date of service as sequential service parts are summed, the intraservice time totals to 399 minutes and total time (not including the post-operative visit time included in the global period for CPT code 15XX5) totals to 529 minutes. The intraservice time total alone is nearly 6 and 2/3 hours.

We note the RUC recommended that CPT codes 15XX1 through 15XX8 be placed on the New Technology list to be re-reviewed by the RUC for both work and PE for the September 2026 or January 2027 RUC meeting when 2025 Medicare utilization data is available, and at that time, the RUC would consider if other specialties were performing the service and if the service was performed in the non-facility setting. We look forward to re-reviewing these CPT codes when recommendations are re-submitted with more robust and inclusive survey data. In the meantime, we encourage the reconsideration of the family's coding structure by the CPT Editorial Panel given the challenging aspects of this service, including the fact that the current coding structure represents a severely segmented single episode of care with troublesome billing patterns for the typical patient, particularly for the add-on CPT code 15XX6 describing the additional 480 sq cm increments of application on the trunk, arms, and legs. This code is particularly concerning because the coding structure of the family requires 7 units of add-on CPT code 15XX6 to be billed for the typical patient. Similarly, the typical patient described in the vignettes for this family of codes would require 3 units of add-on CPT code 15XX8 due to the coding structure.

We are also seeking feedback on the recommended global period for CPT code 15XX3. The RUC recommended an XXX global period, which indicates that the global concept does not apply, but we believe a 000-day global period, indicating an endoscopic or minor procedure with related preoperative and postoperative relative values on the day of the procedure only in the fee schedule payment amount, may be more appropriate given the nature of the service (which is intertwined with the other codes in the series) and that the entire service cannot be completed without 15XX3. This would allow the entire service to run within a surgical global period.

We note that we believe contractor-pricing is appropriate for CPT codes 15XX1 through 15XX8 until reconsideration of the coding structure and re-survey is complete, given the concerning aspects of the CPT codes. We note that this service is currently billed for using contractor-priced CPT code 17999 (*Unlisted procedure, skin, mucous membrane and subcutaneous*

[11] *https://avitamedical.com/.*

[12] Temple Burn Center Using Spray-On SkinTM Cells Technology to Offer Patients a New, Less Invasive Option for the Treatment of Severe Burns. (2019, December 20). *https://medicine.temple.edu/news/temple-burn-center-using-spray-skin-cells-technology-offer-patients-new-less-invasive-option.*

[13] Cooper-Jones B, Visintini S. A Noncultured Autologous Skin Cell Spray Graft for the Treatment of Burns. In: CADTH Issues in Emerging Health Technologies. Canadian Agency for Drugs and Technologies in Health, Ottawa (ON); 2016. PMID: 30855772.

[14] G. Gravante, M.C. Di Fede, A. Araco, M. Grimaldi, B. De Angelis, A. Arpino, V. Cervelli, A. Montone, A randomized trial comparing ReCell® system of epidermal cells delivery versus classic skin grafts for the treatment of deep partial thickness burns, Burns, Volume 33, Issue 8, 2007, Pages 966–972, ISSN 0305–4179, *https://doi.org/10.1016/j.burns.2007.04.011.*

[15] *https://www.fda.gov/media/169630/download.*

[16] National Institute for Health and Care Excellence. The ReCell Spray-On Skin system for treating skin loss, scarring and depigmentation after burn injury. Medical technologies guidance [MTG21] [internet]. 2014. [Accessed 16 Nov 2017*]. https://www.nice.org.uk/guidance/mtg21/documents/the-recell-sprayon-skin-system-for-treating-skin-loss-scarring-and-depigmentation-after-burn-injury-medical-technology-consultation-document.*

tissue) and the eight new codes are expected to be a very low utilization.

(2) Hand, Wrist, & Forearm Repair & Recon (CPT Codes 25310, 25447, 2X005, and 26480)

In September 2022, the RUC referred CPT codes 26480 and 25447 to the CPT Editorial Panel for a code bundling solution. In May 2023, the CPT Editorial Panel approved a new bundled code (CPT code 2X005) to report intercarpal or carpometacarpal joint suspension arthroplasty, including transfer or transplant of tendon, with interposition when performed while CPT code 25447 was revised to clarify that the code only included interposition of a tendon and not suspension. This family of codes was surveyed for the September 2023 RUC meeting.

We disagree with the RUC-recommended work RVU of 9.50 for CPT code 25310 (*Tendon transplantation or transfer, flexor or extensor, forearm and/or wrist, single; each tendon*) and we are instead proposing a work RVU of 9.00 based on the survey 25th percentile result. In reviewing CPT code 25310, we noted that the recommended intraservice time was unchanged at 60 minutes in the new survey; however, the RUC-recommended work RVU is increasing from the current 8.08 to 9.50. Although we do not imply that changes in work time as reflected in survey values must equate to a one-to-one or linear change in the valuation of work RVUs, we believe that since the two components of work are time and intensity, increases in the recommended work RVU should typically be reflected in increases in the surveyed work time. We recognize that the total time for CPT code 25310 is increasing from 235 minutes to 263 minutes (an increase of 12 percent) due to changes in the code's post-operative office visits which will now take place at a higher level. However, this again does not match the increase in the recommended work RVU, which is increasing from 8.08 to 9.50 (approximately 18 percent). We believe that it would be more accurate to propose the survey 25th percentile work RVU of 9.00 for CPT code 25310 which matches this increase in the total work time. We also note that the intensity of CPT code 25310 is decreasing, not increasing, as recommended by the RUC which further suggests that a work RVU of 9.50 would not be appropriate for this code given the surveyed work times.

We disagree with the RUC-recommended work RVU of 11.14 for CPT code 25447 (*Arthroplasty, intercarpal or carpometacarpal joints; interposition (eg, tendon)*) and we are instead proposing a work RVU of 10.50 based on the survey 25th percentile result. In reviewing CPT code 25447, we noted that the recommended intraservice time was decreasing from 100 minutes to 75 minutes in the new survey; however, the RUC recommended maintaining the current work RVU of 11.14. Although we do not imply that changes in work time as reflected in survey values must equate to a one-to-one or linear change in the valuation of work RVUs, we believe that since the two components of work are time and intensity, decreases in the surveyed work time should typically be reflected in decreases to the work RVU. We recognize that the total time for CPT code 25447 is slightly increasing from 278 minutes to 281 minutes (an increase of about 1 percent) due to changes in the code's post-operative office visits which will now take place at a higher level. However, we believe that the sizable decrease in surveyed intraservice work time (a reduction of approximately 33 percent) better supports proposing the survey 25th percentile work RVU of 10.50 instead of maintaining the current work RVU of 11.14. We also disagree with the RUC that the intensity of CPT code 25447 is unchanged due to increases in the post-operative work; we believe that the sizable decrease in surveyed intraservice work time indicates a modest decrease in intensity. We note again that the intensity of CPT code 25310 is decreasing, not increasing, as recommended by the RUC which suggests that a similar pattern is likely taking place with clinically similar procedures elsewhere in the same code family.

We disagree with the RUC-recommended work RVU of 13.90 for CPT code 2X005 (*Arthroplasty, intercarpal or carpometacarpal joints; suspension, including transfer or transplant of tendon, with interposition, when performed*) and we are instead proposing a work RVU of 11.85 based on the survey 25th percentile result. We note that the RUC typically values new codes such as CPT code 2X005 using this survey 25th percentile work RVU as opposed to the survey median work RVU that it recommended. The RUC's recommendations stated that CPT code 2X005 should be valued higher than CPT code 25447 due to having higher intensity, a relationship which is preserved at our proposed work RVUs of 11.85 and 10.50 respectively. The RUC also stated in its recommendations that CPT code 2X005 should be valued higher than reference CPT code 29828 (*Arthroscopy, shoulder, surgical; biceps tenodesis*) because it has more intraservice time and total work time. However, the RUC also stated elsewhere in its recommendations that the arthroscopy described by CPT code 29828 is more intense than the arthroplasty procedures described by this family of codes, which we believe supports CPT code 29828 having a higher work RVU despite its lower work times. Based on this information, we believe that proposing the survey 25th percentile work RVU of 11.85 is the most accurate valuation for CPT code 2X005.

We disagree with the RUC-recommended work RVU of 9.50 for CPT code 26480 (*Transfer or transplant of tendon, carpometacarpal area or dorsum of hand; without free graft, each tendon*) and we are instead proposing a work RVU of 9.00 based on the survey 25th percentile result. In reviewing CPT code 26480, we noted that the recommended intraservice time was unchanged at 60 minutes in the new survey; however, the RUC-recommended work RVU is increasing from the current 6.90 to 9.50. Although we do not imply that changes in work time as reflected in survey values must equate to a one-to-one or linear change in the valuation of work RVUs, we believe that since the two components of work are time and intensity, increases in the recommended work RVU should typically be reflected in increases in the surveyed work time. We recognize that the total time for CPT code 26480 is increasing from 227 minutes to 263 minutes (an increase of 16 percent) due to changes in the code's post-operative office visits which will now take place at a higher level. However, this again does not match the increase in the recommended work RVU, which is increasing from 6.90 to 9.50 (approximately 38 percent). We believe that it would be more accurate to propose the survey 25th percentile work RVU of 9.00 for CPT code 26480 which more closely matches this increase in the total work time. We also note that CPT codes 25310 and 26480 were surveyed as having identical work times and identical survey 25th percentile and survey median work RVUs. We concur with the RUC that these two codes should be valued at the same work RVU, however we continue to believe that the survey 25th percentile work RVU of 9.00 is a more accurate choice in both cases. We are proposing the RUC-recommended direct PE inputs for all four codes in the family without refinement.

(3) CAR–T Therapy Services (CPT Codes 3X018, 3X019, 3X020, and 3X021)

In September 2023, the CPT Editorial Panel deleted four category III codes (0537T–0540T) and approved the addition of four new codes (3X018–3X021) that describe only steps of the complex CAR–T Therapy process performed and supervised by physicians. The RUC recommended four different work RVUs for codes 3X018, 3X019, 3X020, and 3X021 and only recommended direct PE values for code 3X021.

For CPT code 3X018 (Chimeric antigen receptor T-cell (CAR–T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR–T cells, per day) the RUC recommended a work RVU of 1.94. For CPT code 3X019 (*Chimeric antigen receptor T-cell (CAR–T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)*) the RUC recommended a work RVU of 0.79. For CPT code 3X021 (*Chimeric antigen receptor T-cell (CAR–T) therapy; CAR–T cell administration, autologous*) the RUC recommended a work RVU of 3.00. For CPT code 3X020 (*Chimeric antigen receptor T-cell (CAR–T) therapy; receipt and preparation of CAR–T cells for administration*) the RUC recommended a work RVU of 0.80 and for CPT code 3X020, we are proposing the RUC-recommended work RVU of 0.80. We are proposing the RUC-recommended work RVUs for CPT codes 3X018, 3X019, and 3X021 respectively.

As mentioned previously, the RUC recommended direct PE values for only one code, CPT code 3X021, and the RUC recommended that the non-facility PE RVU for CPT codes 3X018–3X020 should be contractor-priced. However, contractor pricing can only be applied at the whole code level, not to a single component of the valuation. Therefore, for CPT codes 3X018–3X020 we are treating these codes as having no recommended direct PE values and are seeking comment on direct PE values for these codes. We are proposing the RUC-recommended direct PE inputs for CPT code 3X021.

(4) Therapeutic Apheresis and Photopheresis (CPT Codes 36514, 36516, and 36522)

In the CY 2024 PFS final rule, we finalized CPT codes 36514 (*Therapeutic apheresis; for plasma pheresis*), 36516 (*Therapeutic apheresis; with extracorporeal immunoadsorption, selective adsorption or selective filtration and plasma reinfusion*), and 36522 (*Photopheresis, extracorporeal*) as potentially misvalued, as we believed there may have been a possible disparity with the clinical labor type (88 FR 78848). As a result, the PE clinical labor type was reviewed for these three codes at the January 2024 RUC meeting, with no work review. The PE Subcommittee and the RUC agreed that clinical staff code L042A (RN/LPN) did not appropriately represent the work of an Apheresis Nurse Specialist. There is not a clinical staff code for an Apheresis Nurse Specialist; however, the RUC agreed with the specialty societies' recommendation that the training and experience of an oncology nurse (clinical staff code L056A, RN/OCN) would more accurately reflect the work of an apheresis nurse for these CPT codes. The RUC submitted new PE recommendations for these three codes based on the use of the L056A clinical labor type.

We are proposing the RUC-recommended direct PE inputs for CPT codes 36514, 36516, and 36522 without refinement. The RUC did not make recommendations and we are not proposing any changes to the work RVU for CPT codes 36514, 36516, and 36522.

(5) Intra-Abdominal Tumor Excision or Destruction (CPT Codes 4X015, 4X016, 4X017, 4X018, and 4X019)

In May 2023, the CPT Editorial Panel created five new codes to describe the sum of the maximum length of intra-abdominal (that is, peritoneal, mesenteric, retroperitoneal), primary or secondary tumor(s) or cyst(s) excised or destroyed: CPT code 4X015 (*Excision or destruction, open, intra-abdominal (i.e., peritoneal, mesenteric, retroperitoneal), primary or secondary tumor(s) or cyst(s), sum of the maximum length of tumor(s) or cyst(s); 5 cm or less*), CPT code 4X016 (*Excision or destruction, open, intra-abdominal (i.e., peritoneal, mesenteric, retroperitoneal), primary or secondary tumor(s) or cyst(s), sum of the maximum length of tumor(s) or cyst(s); 5.1 to 10 cm*), CPT code 4X017 (*Excision or destruction, open, intra-abdominal (i.e., peritoneal, mesenteric, retroperitoneal), primary or secondary tumor(s) or cyst(s), sum of the maximum length of tumor(s) or cyst(s); 10.1 to 20 cm*), CPT code 4X018 (*Excision or destruction, open, intra-abdominal (i.e., peritoneal, mesenteric, retroperitoneal), primary or secondary tumor(s) or cyst(s), sum of the maximum length of tumor(s) or cyst(s); 20.1 to 30 cm*), and CPT code 4X019 (*Excision or destruction, open, intra-abdominal (i.e., peritoneal, mesenteric, retroperitoneal), primary or secondary tumor(s) or cyst(s), sum of the maximum length of tumor(s) or cyst(s); greater than 30 cm*). These new CPT codes will replace existing CPT codes 49203 (*Excision or destruction, open, intra-abdominal tumors, cysts or endometriomas, 1 or more peritoneal, mesenteric, or retroperitoneal primary or secondary tumors; largest tumor 5 cm diameter or less*), 49204 (*Excision or destruction, open, intra-abdominal tumors, cysts or endometriomas, 1 or more peritoneal, mesenteric, or retroperitoneal primary or secondary tumors; largest tumor 5.1–10.0 cm diameter*), and 49205 (*Excision or destruction, open, intra-abdominal tumors, cysts or endometriomas, 1 or more peritoneal, mesenteric, or retroperitoneal primary or secondary tumors; largest tumor greater than 10.0 cm diameter*) that described tumor excision or destruction based on the size of the single largest tumor, cyst, or endometrioma removed, no matter the number of tumors. For CY 2025, the RUC recommended a work RVU of 22.00 for CPT code 4X015, a work RVU of 28.65 for CPT code 4X016, a work RVU of 34.00 for CPT code 4X017, a work RVU of 45.00 for CPT code 4X018, and a work RVU of 55.00 for CPT code 4X019.

We are proposing the RUC-recommended work RVUs of 22.00 for CPT code 4X015, 28.65 for CPT code 4X016, and 34.00 for CPT code 4X017.

We disagree with the RUC-recommended work RVU of 45.00 for CPT code 4X018 and we are proposing a work RVU of 40.00 based on the survey 25th percentile. Compared to the predecessor CPT code 49205, the intra-service time ratio for CPT code 4X018 suggests a work RVU of 41.51 and the total time ratio suggests a work RVU of 38.02. These changes in surveyed work time as compared with predecessor CPT code 49205 suggest that the recommended work RVU of 45.00 is inappropriately high. We also note that the RUC recommended the survey 25th percentile work RVU for CPT codes 4X015, 4X016, and 4X017. Therefore, we believe that proposing a work RVU of 40.00 for CPT code 4X018 keeps the valuation consistent with the other CPT codes in this family. Our proposed work RVU of 40.00 for CPT code 4X018 is supported by the following reference CPT codes with similar intra-service time (310 minutes) and similar total time (814 minutes): reference CPT code 69970 (*Removal of tumor, temporal bone*) with a work RVU of 32.41 with 330 minutes intra-service time and 793 minutes of total time, and reference CPT code 33864 (*Ascending aorta graft, with cardiopulmonary bypass with valve suspension, with coronary reconstruction and valve-sparing aortic root remodeling (e.g., David Procedure,*

Yacoub Procedure)) with a work RVU of 60.80 with 300 minutes of intra-service time and 838 minutes of total time. We believe the proposed work RVU of 40.00 is a more appropriate value overall than 45.00 when compared to the range of codes with similar intra-service time and similar total time.

We disagree with the RUC-recommended work RVU of 55.00 for CPT code 4X019 and we are proposing a work RVU of 50.00 based on the survey 25th percentile. Compared to the predecessor CPT code 49205, the intra-service time ratio for CPT code 4X019 suggests a work RVU of 48.21 and the total time ratio suggests a work RVU of 48.86. These changes in surveyed work time as compared with predecessor CPT code 49205 suggest that the recommended work RVU of 55.00 is inappropriately high. We also note again that the RUC recommended the survey 25th percentile work RVU for CPT codes 4X015, 4X016, and 4X017. Therefore, we believe that proposing a work RVU of 50.00 for CPT code 4X019 keeps the valuation consistent with the other CPT codes in this family. Our proposed work RVU of 50.00 for CPT code 4X019 is supported by the following reference CPT codes with similar intra-service time (360 minutes) and similar total time (1,046 minutes): reference CPT code 61598 (*Transpetrosal approach to posterior cranial fossa, clivus or foramen magnum, including ligation of superior petrosal sinus and/or sigmoid sinus*) with a work RVU of 36.53 with 377.7 minutes intra-service time and 1,048.1 minutes of total time, and reference CPT code 47140 (*Donor hepatectomy (including cold preservation), from living donor; left lateral segment only (segments II and III)*) with a work RVU of 59.40 with 355 minutes of intra-service time and 1,073 minutes of total time. We believe the proposed RVU of 50.00 is a more appropriate value overall than 55.00 when compared to the range of codes with similar intra-service time and similar total time.

We also note that the RUC's recommendations for the first three codes in the family (CPT codes 4X015–4X017) maintained the same amount of intensity as their respective predecessor codes, and in fact slightly decreased in intensity in the case of CPT codes 4X015 and 4X016. However, the RUC recommended a notable increase in intensity for CPT codes 4X018 and 4X019 over predecessor code 49205 due to its selection of the survey median work RVU in both cases. We do not believe that this increase in intensity for CPT codes 4X018 and 4X019 is warranted due to their clinical similarities to the previous coding in the family, especially given that CPT code 49205 had the lowest intensity in the family. We believe that this intensity argument further supports our choice to propose the survey 25th percentile work RVU for these two codes, matching the RUC recommendations for CPT code 4X015–4X017.

We are proposing the RUC-recommended direct PE inputs for CPT codes 4X015, 4X016, 4X017, 4X018, and 4X019 without refinement.

(6) Bladder Neck and Prostate Procedures (CPT Codes 5XX05 and 5XX06)

In September 2023, the CPT Editorial Panel created two Category I CPT codes to describe the insertion or removal of a temporary device to remodel the bladder neck and prostate using pressure to create necrosis and relieve lower urinary tract symptoms (LUTS) secondary to benign prostate hyperplasia (BPH). These two new 000-day global Category I codes were surveyed and reviewed for the January 2024 RUC meeting.

At the January 2024 RUC meeting, the specialty society indicated that CPT code 5XX05's survey 25th percentile work RVU of 3.91 was too high for this procedure compared to other services in the physician fee schedule with similar intra-service time. The specialty society recommended, and the RUC agreed that the recommended work RVU for CPT code 5XX05 should be crosswalked to CPT code 52284 (*Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed*). Because these procedures are similar in intensity and both require precise placement of an intraurethral device, we concur with the RUC and we are proposing the RUC recommended work RVU of 3.10 for CPT code 5XX05.

At the January 2024 RUC meeting, the specialty society indicated that CPT code 5XX06's survey 25th percentile work RVU of 2.00 was too high for this procedure compared to other services in the physician fee schedule with similar intra-service time. The specialty society recommended, and the RUC agreed, that CPT code 5XX06 should have a direct work RVU crosswalk to CPT code 27096 (*Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed*). We are proposing the RUC recommended work RVU of 1.48 for CPT code 5XX06.

We are also proposing the RUC-recommended direct PE inputs for CPT codes 5XX05 and 5XX06 without refinement. However, we note possible duplications in two of the supply items within CPT code 5XX05. Specifically, supply item SB027 (*gown, staff, impervious*) is already included in supply item SA042 (*pack, cleaning and disinfecting, endoscope*), and supply item SB024 (*gloves, sterile*) is included in supply items SA058 (pack, urology cystoscopy visit). We are seeking comments on whether a total of three SB027 impervious staff gowns and two SB024 pairs of sterile gloves would be typical and necessary when providing this procedure.

(7) MRI-Monitored Transurethral Ultrasound Ablation of Prostate (CPT Codes 5X006, 5X007, and 5X008)

At the April 2023 CPT Editorial Panel meeting, three new CPT codes were approved for MRI-monitored transurethral ultrasound ablation (TULSA). These codes were surveyed for the September 2023 RUC meeting and recommendations submitted to CMS for inclusion in the CY 2025 PFS proposed rule.

For CY 2025, we are proposing the RUC-recommended work RVUs for all three CPT codes. However, we note that interested parties may have concerns regarding the experience of the survey respondents and the intra-service times provided in the survey data. We welcome commenters to provide additional data that we could consider in the valuation of the work and direct PE inputs for these CPT codes. We are proposing a work RVU of 4.05 for CPT code 5X006 (*Insertion of transurethral ablation transducers for delivery of thermal ultrasound for prostate tissue ablation, including suprapubic tube placement during the same session and placement of an endorectal cooling device, when performed*), a work RVU of 9.80 for CPT code 5X007 (*Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation*), and a work RVU of 11.50 for CPT code 5X008 (*Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation; with insertion of transurethral ultrasound transducers for delivery of the thermal ultrasound, including suprapubic tube placement and placement of an endorectal cooling device, when performed*). We are also proposing the RUC-recommended direct PE inputs for CPT codes 5X006, 5X007, and 5X008 without refinement.

(8) Insertion of Cervical Dilator (CPT Code 59200)

In the CY 2024 PFS final rule, we finalized CPT Code 59200 (*Insertion of cervical dilator (e.g., laminaria, prostaglandin) (separate procedure)*) as potentially misvalued. The code is to be used to report the total duration of time spent on a patient history and physical, reviewing lab resulting, discussing risk and benefits of the procedure, obtaining consent, performing the procedure, and assessing the patient post-procedure. The RUC reviewed the work RVU and PE inputs for CPT code 59200 at their January 2024 meeting. We are proposing the RUC-recommended work RVU of 1.20 for CPT code 59200. We are also proposing the RUC-recommended direct PE inputs for CPT code 59200 without refinements.

(9) Guided High Intensity Focused Ultrasound (CPT Code 6XX00)

In September 2023, the CPT Editorial Panel created a new Category I code to describe magnetic resonance image guided high intensity focused ultrasound intracranial ablation for treatment of a severe central tremor that is recalcitrant to other medical treatments. This service is typically performed by a neurosurgeon without the involvement of a separate radiologist. This new code replaces the existing Category III code 0398T.

We are not proposing the RUC-recommended work RVU of 18.95 for CPT code 6XX00 and are instead proposing a work RVU of 16.60 based on a crosswalk to CPT code 61626 (*Transcatheter permanent occlusion or embolization (e.g., for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; non-central nervous system, head or neck (extracranial, brachiocephalic branch)*), which describes a similar tumor destruction service that has similar time and intensity values to this service, and we support this value by referencing CPT code 33889 (*Open subclavian to carotid artery transposition performed in conjunction with endovascular repair of descending thoracic aorta, by neck incision, unilateral*) and 33894 (*Endovascular stent repair of coarctation of the ascending, transverse, or descending thoracic or abdominal aorta, involving stent placement; across major side branches*). We do not believe that this service is significantly more intense than the key reference codes, CPT codes 61736 (*Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; single trajectory for 1 simple lesion*) and 61737 (*Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; multiple trajectories for multiple or complex lesion(s)*), as the RUC-recommended work value implies. Our proposed work RVU of 16.60 for CPT code 6XX00 largely matches the intensity of CPT code 61736 which we believe is a more accurate valuation for this service, as opposed to the RUC recommendation which would have significantly more intensity.

We are proposing the RUC-recommended direct PE inputs for CPT code 6XX00 without refinement.

(10) Percutaneous Radiofrequency Ablation of Thyroid (CPT Codes 6XX01 and 6XX02)

In January 2024, the RUC surveyed codes 6XX01 (*Ablation of 1 or more thyroid nodule(s), one lobe or the isthmus, percutaneous, including imaging guidance, radiofrequency*) and its respective add-on code 6XX02 (*Ablation of 1 or more thyroid nodule(s), additional lobe, percutaneous, with imaging guidance, radiofrequency (List separately in addition to code for primary service*) and recommended both work RVUs and PE values for this code family.

For CPT code 6XX01, the RUC recommended a work RVU of 5.75 and we are proposing the RUC-recommended work RVU of 5.75.

For add-on code CPT 6XX02, the RUC recommended a work RVU of 4.25 and we are proposing the RUC-recommended work RVU for this code. We are also proposing the RUC-recommended direct PE values for both codes 6XX01 and 6XX02.

(11) Fascial Plane Blocks (CPT Codes 6XX07, 6XX08, 6XX09, 6XX10, 6XX11, 6XX12, 64486, 64487, 64488, and 64489)

In September 2023, the CPT Editorial Panel created six new Category I CPT codes, CPT code 6XX07 (*Thoracic fascial plane block, unilateral; by injection(s), including imaging guidance, when performed*), 6XX08 (*Thoracic fascial plane block, unilateral; by continuous infusion(s), including imaging guidance, when performed*), 6XX09 (*Thoracic fascial plane block, bilateral; by injection(s), including imaging guidance, when performed*), 6XX10 (*Thoracic fascial plane block, bilateral; by continuous infusion(s), including imaging guidance, when performed*), 6XX11 (*Lower extremity fascial plane block, unilateral; by injection(s), including imaging guidance, when performed*), and 6XX12 (*Lower extremity fascial plane block, unilateral; by continuous infusion(s), including imaging guidance, when performed*) to report thoracic or lower extremity fascial plane blocks, typically used for post-operative pain management. Four existing CPT codes describing transversus abdominis plane (TAP) blocks, 64486 (*Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) unilateral; by injection(s) (includes imaging guidance, when performed)*), 64487 (*Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) unilateral; by continuous infusion(s) (includes imaging guidance, when performed)*), 64488 (*Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) bilateral; by injections (includes imaging guidance, when performed)*) 64489 (*Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) bilateral; by continuous infusions (includes imaging guidance, when performed)*), were included as part of this code family for RUC review in January 2024.

We are proposing the RUC-recommended work RVU for all ten codes in this family. We are proposing a work RVU of 1.50 for CPT code 6XX07, 1.74 for CPT code 6XX08, 1.67 for CPT code 6XX09, 1.83 for CPT code 6XX10, 1.34 for CPT code 6XX11, 1.67 for CPT code 6XX12, 1.20 for CPT code 64486, 1.39 for CPT code 64487, 1.40 for CPT code 64488, and 1.75 for CPT code 64489.

We are also proposing the RUC recommended direct PE inputs for CPT codes 6XX08, 6XX09, 6XX10, 6XX12, 64487, 64488, and 64489. We disagree with one of the RUC recommended direct PE inputs for CPT codes 6XX07, 6XX11, and 64486. The RUC stated they believe that there is a rounding error in the CA019 clinical labor time, ''Assist physician or other qualified healthcare professional—directly related to physician work time (67%)'', for these three codes. We disagree with the RUC that there are rounding errors in these codes and we are proposing to maintain the current 7 minutes of CA019 clinical labor time for CPT codes 6XX07, 6XX11, and 64486. We note that this matches the pattern of CA019 clinical labor time for the rest of the codes in the family, which remained the same or slightly decreased in each case. This refinement to the CA019 clinical labor time also means that we are proposing a decrease of 0.5 minutes to the equipment time for the stretcher (EF018) and 3-channel ECG

(EQ011) which decreases from 25.5 to 25 minutes for these three codes. We are proposing all of the other RUC-recommended direct PE inputs for CPT codes 6XX07, 6XX11, and 64486 without refinement.

(12) Skin Adhesives (CPT Codes 64590 and 64595 and HCPCS Codes G0168, G0516, G0517, and G0518)

In April 2022, the RUC approved the use of SG007 (*adhesive, skin (Dermabond)*) for CPT code 64590 (*insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver*) and 64595 (*revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array*). In April 2023, the PE Subcommittee reviewed the following six codes on the Medicare Physician Fee Schedule 64590, 64595, G0168, G0516, G0517, G0518 that utilize Dermabond (supply code S6007) in order to identify justification for its use versus the generic version and present its findings to the RUC for approval. The RUC reviewed all six codes for PE only and did not submit work recommendations.

For CPT codes 64590 and 64595 and HCPCS code G0168 (*Wound closure utilizing tissue adhesive(s) only*), the RUC recommends that CMS remove the supply input SG007 adhesive, skin (Dermabond) and add one unit of SH076 adhesive, cyanoacrylate (2ml uou). We are proposing the RUC-recommended direct PE inputs for CPT codes 64590 and 64595 and HCPCS code G0168. Similarly, for HCPCS codes G0516 (*Insertion of non-biodegradable drug delivery implants, 4 or more (services for subdermal rod implant*), G0517 (*Removal of non-biodegradable drug delivery implants, 4 or more (services for subdermal implants*), and G0518 (*Removal with reinsertion, non-biodegradable drug delivery implants, 4 or more (services for subdermal implants*), the RUC recommends that CMS remove the supply input SG007 adhesive, skin (Dermabond) and add one unit of SH076 adhesive, cyanoacrylate (2ml uou). We are proposing the RUC-recommended direct PE inputs for HCPCS codes G0516–G0518.

(13) Iris Procedures (CPT Codes 66680, 66682, and 6X004)

In April 2023, the CPT Editorial Panel deleted three related Category III CPT codes, CPT code 0616T (*Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens*), CPT code 0617T (*with removal of crystalline lens and insertion of intraocular lens*), and CPT code 0618T (with secondary intraocular lens placement or intraocular lens exchange). At the same time, CPT created a new Category I code 6X004 (*Implantation of iris prosthesis, including suture fixation and repair or removal of iris, when performed*) which describes insertion of an artificial iris into an eye with a partial or complete iris defect due to a congenital defect or surgical or non-surgical trauma. The new Category I CPT code 6X004 replaced the three Category III codes to simplify reporting. Concurrent with these updates, the RUC surveyed the two other 90-day global iris repair codes, CPT code 66680 (*Repair of iris, ciliary body (as for iridodialysis)*) and CPT code 66682 (*Suture of iris, ciliary body (separate procedure) with retrieval of suture through small incision (e.g., McCannel suture)*).

We disagree with the RUC-recommended work RVU of 10.25 for CPT code 66680. We are proposing a work RVU of 7.97 for CPT code 66680 based on a crosswalk to CPT code 67904 (*Repair of blepharoptosis; (tarso) levator resection or advancement, external approach*). When we reviewed CPT code 66680, we found that the RUC recommended work RVU does not maintain relativity with other 90-day global period codes with the same intraservice time of 45 minutes and similar total time around 182 minutes. The total time ratio between the current time of 159 minutes and the recommended time established by the RUC survey of 182 minutes equals 1.145 percent. This ratio, 1.145 percent, when applied to the current work RVU of 6.39 would suggest a work RVU of 7.31 which is far below the RUC's recommended work RVU of 10.25. Based on this total time ratio, we believe a more appropriate work valuation for CPT code 66680 is 7.97 based on a crosswalk to CPT code 67904.

We disagree with the RUC-recommended work RVU of 10.87 for CPT code 66682. We are proposing a work RVU of 8.74 based on the total time ratio between the current time of 169.5 minutes and the recommended time established by the RUC survey of 202 minutes. This ratio equals 1.192 percent, and 1.192 percent of the current work RVU of 7.33 suggests a work RVU of 8.74 for CPT code 66682. When we reviewed CPT code 66682, we found that the recommended work RVU was higher than nearly all of the other 90-day global codes with similar time values. The RUC's recommended work RVU does not maintain relativity with other 90-day global period codes with the same intraservice time value of 45 minutes and similar total time of 202. We found that work RVU crosswalks to CPT codes of similar intraservice and total time were too low, such as CPT code 45171 with a work RVU of 8.13. A more appropriate work RVU for CPT code 66682 is 8.74 based on the total time ratio.

The RUC recommended a work RVU of 12.80 for CPT 6X004, the RUC survey 25th percentile result, with an intraservice time of 60 minutes and a total time of 224 minutes. We disagree with the RUC-recommended work RVU of 12.80 for CPT code 6X004. Although we disagree with the RUC-recommended work RVU, we concur that the relative difference in work between CPT codes 66682 and 6X004 is equivalent to the recommended interval of 1.93 RVUs. Therefore, we are proposing a work RVU of 10.67 for CPT code 6X004, based on the recommended interval of 1.93 additional RVUs above our proposed work RVU of 8.74 for CPT code 66682. This proposed work RVU of 10.67 falls between the work RVU values of existing codes with similar intraservice and total time values. For example, CPT code 65850 (60 minutes of intraservice time and 233 minutes of total time) has a work RVU of 11.39 and CPT code 24164 with the same intraservice time and 228 minutes of total time has a work RVU of 10.00. We believe that the work valuation of these CPT codes, which bracket our proposed work RVU of 10.67, provide additional support for our proposed valuation.

We also disagree with the RUC's recommended work RVUs for the codes in this family because they suggest that there has been a tremendous increase in intensity as compared to how these services have historically been valued. CPT code 66680 is more than doubling in intensity at the RUC's recommended work RVU of 10.25, which we do not believe to be the case given that the code descriptor remains unchanged and the surveyed intraservice work time is unchanged at 45 minutes. This same pattern holds true for CPT code 66682, which would be increasing in intensity by more than 50% at the RUC's recommended work RVU of 10.87, and which similarly has no change in its code descriptor and a modest increase in its surveyed work time. We concur that the intensity of these services has likely gone up over time, which is why we are proposing modest intensity increases for both codes, however we continue to disagree that the very

substantial intensity increases recommended by the RUC would be accurate for this code family. We believe that our proposed work RVUs are more in line with how these services have historically been valued and better maintain relativity with the rest of the fee schedule.

We are proposing the direct PE inputs as recommended by the RUC for all three codes in the family without refinement.

(14) Magnetic Resonance Examination Safety Procedures (CPT Codes 7XX00, 7XX01, 7XX02, 7XX03, 7XX04, and 7XX05)

In September 2023, the CPT Editorial Panel created a new code family to describe magnetic resonance (MR) examination safety procedures and capture the physician work involving patients with implanted medical devices that require access to MR diagnostic procedures: CPT code 7XX00 (*MR safety implant and/or foreign body assessment by trained clinical staff, including identification and verification of implant components from appropriate sources (e.g., surgical reports, imaging reports, medical device databases, device vendors, review of prior imaging), analyzing current MR conditional status of individual components and systems, and consulting published professional guidance with written report; initial 15 minutes*), CPT code 7XX01 (*MR safety implant and/or foreign body assessment by trained clinical staff, including identification and verification of implant components from appropriate sources (e.g., surgical reports, imaging reports, medical device databases, device vendors, review of prior imaging), analyzing current MR conditional status of individual components and systems, and consulting published professional guidance with written report; each additional 30 minutes (List separately in addition to code for primary procedure)*), CPT code 7XX02 (*MR safety determination by a physician or other qualified health care professional responsible for the safety of the MR procedure, including review of implant MR conditions for indicated MR exam, analysis of risk versus clinical benefit of performing MR exam, and determination of MR equipment, accessory equipment, and expertise required to perform examination with written report*), CPT code 7XX03 (*MR safety medical physics examination customization, planning and performance monitoring by medical physicist or MR safety expert, with review and analysis by physician or qualified health care professional to prioritize and select views and imaging sequences, to tailor MR acquisition specific to restrictive requirements or artifacts associated with MR conditional implants or to mitigate risk of non-conditional implants or foreign bodies with written report*), CPT code 7XX04 (*MR safety implant electronics preparation under supervision of physician or other qualified health care professional, including MR-specific programming of pulse generator and/or transmitter to verify device integrity, protection of device internal circuitry from MR electromagnetic fields, and protection of patient from risks of unintended stimulation or heating while in the MR room with written report*), and CPT code 7XX05 (*MR safety implant positioning and/or immobilization under supervision of physician or qualified health care professional, including application of physical protections to secure implanted medical device from MR-induced translational or vibrational forces, magnetically induced functional changes, and/or prevention of radiofrequency burns from inadvertent tissue contact while in the MR room with written report*). For CY 2025, new CPT codes 7XX00 and 7XX01 are PE only services that represent the preparatory research and review completed by clinical staff (that is, MRI technologist and/or a medical physicist) that will be utilized by the physician or qualified health professional for the other four services (CPT codes 7XX02, 7XX03, 7XX04, and 7XX05) in this code family.

We are proposing the RUC-recommended work RVU of 0.60 for CPT code 7XX02, the work RVU of 0.76 for CPT code 7XX03, the work RVU of 0.75 for CPT code 7XX04, and the work RVU of 0.60 for CPT code 7XX05.

We are proposing the following refinements to the direct PE inputs. For CPT codes 7XX00, 7XX01, 7XX02, 7XX04, and 7XX05, we are proposing to refine the clinical labor for the CA034 activity (*Document procedure (nonPACS) (e.g., mandated reporting, registry logs, EEG file, etc.)*) performed by the MRI Technologist from 2 minutes to 1 minute. We note that the clinical labor for the CA032 activity (*Scan exam documents into PACS. Complete exam in RIS system to populate images into work queue.*) included in the direct PE inputs for reference CPT code 70543 (*Magnetic resonance (e.g., proton) imaging, orbit, face, and/or neck; without contrast material(s), followed by contrast material(s) and further sequences*) is a similar clinical labor activity and has 1 minute of time. We also note that the Medical Physicist has 1 minute of recommended clinical labor time for the CA034 activity for CPT code 7XX03. Therefore, we believe that the MRI Technologist should have the same time (1 minute) for the CA034 activity for the remaining codes in the family to maintain consistency across these services.

For CPT code 7XX01, we are proposing to refine the clinical labor for the CA021 activity (*Perform procedure/service—NOT directly related to physician work time*) from 27 minutes to 14 minutes. We believe this clinical labor time should be double the 7 minutes assigned to the CA021 activity for CPT code 7XX00. The description for CPT code 7XX00 is for the ''initial 15 minutes'' and CPT code 7XX01 is for ''each additional 30 minutes,'' that is, double the time of CPT code 7XX00. We believe that the clinical labor associated with the CA021 activity should match this pattern in which CPT code 7XX01 contains double the time of CPT code 7XX00. This proposed refinement to the CA021 clinical labor also results in a proposed decrease to the equipment time for the Technologist PACS workstation (ED050) from 45 minutes to 32 minutes.

For CPT code 7XX03, the RUC recommended 13 minutes of equipment time for the Professional PACS Workstation (ED053) listed as a Facility PE input. We believe this was an unintended technical error and we are proposing to remove this time from the direct PE inputs for CPT code 7XX03.

For CPT codes 7XX04 and 7XX05, we proposing to refine the clinical labor time for the CA024 activity (*Clean room/equipment by clinical staff*) from 2 minutes to 1 minute. According to the PE recommendations, only the new equipment code EQ412 (*Vitals monitoring system (MR Conditional)*) is being cleaned and not the entire room. We believe that 1 minute of clinical labor time would be typical for cleaning the EQ412 equipment. Our proposed clinical labor refinement also results in a proposed decrease to the equipment time for EL008 (*room, MR*) and EQ412 by 1 minute for these two codes.

For CPT code 7XX05, we are proposing to remove supply item SL082 (*impression material, dental putty (per bite block)*). We believe this was an error since the PE recommendations did not list SL082 as one of the included supplies for CPT code 7XX05 and it does not appear as a supply input for any of the other codes in the family.

(15) Screening Virtual Colonoscopy (CPT Code 74263)

As discussed in section III.K. of this proposed rule, we are proposing to exercise our authority at section

1861(pp)(1)(D) of the Act to update and expand coverage for colorectal cancer screening and adding coverage for the computed tomography colonography procedure. Accordingly, we are assigning an active payment status for CPT code 74263 (Computed tomographic (ct) colonography, screening, including image postprocessing). We note that, as proposed above, the OPPS cap would apply to this code, and payment for the TC of this service would be capped at the OPPS payment rate.

(16) Ultrasound Elastography (CPT Codes 76981, 76982, and 76983)

This code family was flagged for re-review at the April 2023 RUC meeting by the new technology/new services screen. Due to increased utilization of CPT code 76981 (*Ultrasound, elastography; parenchyma (e.g., organ)*), the entire code family was resurveyed for the September 2023 RUC meeting. We are proposing the RUC-recommended work RVUs of 0.59, 0.59, and 0.47 for CPT codes 76981, 76982 (*Ultrasound, elastography; first target lesion*), and 76983 (*Ultrasound, elastography; each additional target lesion (List separately in addition to code for primary procedure)*), respectively. We are proposing the RUC-recommended direct PE inputs for CPT codes 76981, 76982, and 76983 without refinement.

(17) CT Guidance Needle Placement (CPT Code 77012)

CPT code 77012 (*Computed tomography guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), radiological supervision and interpretation*) was reviewed at the September 2023 RUC meeting to account for deferred updates to the vignette to reflect the typical patient until updated utilization data was available to reflect coding changes that occurred in 2019. We are proposing the RUC-recommended work RVU of 1.50 for CPT code 77012.

We are proposing to refine the equipment time for the CT room (EL007) to maintain the current time of 9 minutes. CPT code 77012 is a radiological supervision and interpretation (RS&I) procedure and there has been a longstanding convention in the direct PE inputs, shared by 38 other codes, to assign an equipment time of 9 minutes for the equipment room in these procedures. We made the same refinement in the CY 2019 PFS final rule (83 FR 59553 through 59554) and continue to believe that it would not serve the interests of relativity to increase the equipment time for the CT room in CPT code 77012 without also addressing the equipment room time for the other radiological supervision and interpretation procedures. In response to the CY 2019 proposal, several commenters stated that they agreed with CMS that other RS&I codes use the 9 minutes for room time as a precedent, but that it is specific to angiographic rooms. We agreed with the commenters that at least some portion of the procedure is performed in the CT room, but we continue to believe that it would not serve the interests of relativity to increase the equipment time for the CT room in CPT code 77012 without also addressing the equipment room time for the other radiological supervision and interpretation procedures in a more comprehensive fashion. We also disagreed with the commenters that this policy is specific to angiography rooms, as CPT codes 75989 (*Radiological guidance (i.e., fluoroscopy, ultrasound, or computed tomography), for percutaneous drainage (e.g., abscess, specimen collection), with placement of catheter, radiological supervision and interpretation*) and 77012 both employ CT rooms and currently utilize the standardized 9 minutes of equipment time, and CPT code 76080 (*Radiologic examination, abscess, fistula or sinus tract study, radiological supervision and interpretation*) employs a radiographic-fluoroscopic room with the 9 minute standard equipment time. We continue to believe that 9 minutes for EL007 is appropriate for this RS&I code, therefore, we are proposing to maintain the current equipment room time of 9 minutes for EL007 until this group of procedures can be subject to a more comprehensive review. We are proposing all other RUC-recommended direct PE inputs for CPT code 77012.

(18) Telemedicine Evaluation and Management (E/M) Services (CPT Codes 9X075, 9X076, 9X077, 9X078, 9X079, 9X080, 9X081, 9X082, 9X083, 9X084, 9X085, 9X086, 9X087, 9X088, 9X089, 9X090, and 9X091)

In February 2023, the CPT Editorial Panel added a new Evaluation and Management (E/M) subsection to the draft CPT codebook for Telemedicine Services. The Panel added 17 codes for reporting telemedicine E/M services: CPT code 9X075 (*Synchronous audio-video visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 15 minutes must be met or exceeded.*); CPT code 9X076 (*Synchronous audio-video visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and low medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.*); CPT code 9X077 (*Synchronous audio-video visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and moderate medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.*); CPT code 9X078 (*Synchronous audio-video visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and high medical decision making. When using total time on the date of the encounter for code selection, 60 minutes must be met or exceeded. (For services 75 minutes or longer, use prolonged services code 99417));* CPT code 9X079 (*Synchronous audio-video visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 10 minutes must be met or exceeded.*); CPT code 9X080 (*Synchronous audio-video visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low medical decision making. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.*); CPT code 9X081 (*Synchronous audio-video visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.*); CPT code 9X082 (*Synchronous audio-video visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and high medical decision making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.*); CPT code 9X083 (*Synchronous audio-only visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination, straightforward medical decision making, and more*

than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 15 minutes must be met or exceeded.)); CPT code 9X084 (*Synchronous audio-only visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination, low medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.)*); CPT code 9X085 (*Synchronous audio-only visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination, moderate medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.*); CPT code 9X086 (*Synchronous audio-only visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination, high medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 60 minutes must be met or exceeded. (For services 75 minutes or longer, use prolonged services code 99417));* CPT code 9X087 (*Synchronous audio-only visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination, straightforward medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 10 minutes must be exceeded.)*); CPT code 9X088 (*Synchronous audio-only visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination, low medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.)*); CPT code 9X089 (*Synchronous audio-only visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination, moderate medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.)*) CPT code 9X090 (*Synchronous audio-only visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination, high medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded. (For services 55 minutes or longer, use prolonged services code 99417));* CPT code 9X091 (*Brief communication technology-based service (e.g., virtual check-in) by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related evaluation and management service provided within the previous 7 days nor leading to an evaluation and management service or procedure within the next 24 hours or soonest available appointment, 5–10 minutes of medical discussion)).*

In April 2023, the AMA–RUC noted that the survey instrument they used to develop valuation recommendations for the telemedicine E/M codes did not include the time (when time is used for code selection) in the new telemedicine E/M services descriptors, or the E/M services displayed on the reference service list. The AMA–RUC made interim valuation recommendations and conducted a new survey for September 2023, which included the minimum required times in the code descriptors, and those minimum times were the same as appear in existing O/O E/M services code descriptors (CPT codes 99202–99205, 99212–99215); the new survey in September 2023 included code descriptors and times approved by the CPT Editorial Panel in May 2023. Also, additional specialties who perform E/M services participated in the second round of this survey. For CY 2025, the RUC recommended the following work RVUs: a work RVU of 0.93 for CPT code 9X075, a work RVU of 1.6 for CPT code 9X076, a work RVU of 2.6 for CPT code 9X077, a work RVU of 3.50 for CPT code 9X078, a work RVU of 0.70 for CPT code 9X079, a work RVU of 1.30 for CPT code 9X080, a work RVU of 1.92 for CPT code 9X081, a work RVU of 2.60 for CPT code 9X082, a work RVU of 0.90 for CPT code 9X083, a work RVU of 1.60 for CPT code 9X084, a work RVU of 2.42 for CPT code 9X085, a work RVU of 3.20 for CPT code 9X086, a work RVU of 0.65. for CPT code 9X087, a work RVU of 1.20 for CPT code 9X088.

In April 2023, the AMA–RUC Practice Expense Subcommittee approved the direct practice expense inputs as recommended by the specialty societies without modification, and CMS received these inputs as recommendations from the RUC. The specialty societies detailed their methodology for making some changes to specific clinical activity codes to adapt those clinical activity codes for telemedicine. The AMA edited both CA009 and CA013. The AMA revision to CA009 deletes, ''*greet patient, provide gowning*''; the AMA revision to CA013 deletes, ''Prepare room, equipment and supplies''. CA009 now reads, ''*Ensure appropriate medical records are available*'' and CA013 now reads, ''*Prepare patient for the visit (i.e., check audio and/or visual*''. The RUC, using the Practice Expense subcommittee recommendations, also recommended to CMS that a camera and microphone ''should be considered typical in the computer contained in the indirect overhead expense.'' This determination is consistent with CMS' longstanding position that items that are not specifically attributable to the individual services should not be included for valuation of specific codes.

The AMA–RUC recommended the direct practice expense inputs as submitted by the AMA-member specialty societies, and as affirmed by the AMA–RUC Practice Expense Subcommittee. All supply and equipment costs were zeroed out from the reference services, and as a result, the new telemedicine E/M codes did not include any supply or equipment costs in the recommended direct practice expense inputs that the AMA submitted to CMS. The direct PE inputs removed from the reference services to create the new telemedicine E/M codes are: CA010 (obtain vital signs), CA024 (clean room/equipment by clinical staff), SA047 (pack, EM visit), SM022 sanitizing cloth-wipe (surface, instruments, equipment), EQ189 (otoscope-ophthalmoscope [wall unit]), EF048 (Portable stand-on scale), and EF023 (table, exam).

Sixteen of the telemedicine E/M codes describe use of either audio-video or audio-only telecommunications technology to furnish the individual service. The CPT Editorial Panel finalized eight codes for synchronous audio-video services (CPT codes 9X075 to 9X082), and eight codes for synchronous audio-only services (CPT codes 9X083 to 9X0890), and one code for an asynchronous service (CPT code 9X091). The audio-video and audio-only code family subsets have parallel codes for new patients and established patients. Like other E/M codes, these codes may be reported based on the level of medical decision making (MDM) or total time on the date of the encounter. For each set of four codes, there is a code that may be reported for a straightforward, low, moderate and high level of MDM.

The CPT Editorial Panel also established new CPT code 9X091 describing a brief virtual check-in encounter that is intended to evaluate the need for a more extensive visit (that is, a visit described by one of the office/outpatient E/M codes). The code descriptor for CPT code 9X091 mirrors existing HCPCS code G2012 (*Brief communication technology-based service, e.g., virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion*) and, per the CPT Editorial Panel materials, is intended to replace that code. As described in CPT Editorial Panel final edits, CPT code 9X091 does not require the use of audio or video technology and is expected to be patient-initiated. Furnishing the complete service described by CPT code 9X091 must involve 5–10 minutes of medical discussion (and the code descriptor does not include MDM as means of code selection). CPT code 9X091 should not be reported if it originates from a related E/M service furnished within the previous 7 days, or, if the clinical interaction leads to another E/M or procedure within the next 24 hours or the soonest available appointment. The final CPT Editorial Panel draft language explains that if the virtual check-in described by CPT 9X091 leads to an E/M visit in the next 24 hours, and if that E/M is reported based on time, then the time from the virtual check-in may be added to the time of the resulting E/M visit to determine the total time on the date of encounter for the resulting E/M. The RUC recommended a work RVU of 0.30 for 9X091.

The CPT Editorial Panel also deleted three codes (99441–99443) for reporting telephone E/M services. We note that CPT codes 99441, 99442, and 99443, each are assigned provisional status on the Medicare telehealth services list, and would return to bundled status when the telehealth flexibilities expire on December 31, 2024. For further background, we refer readers to our discussions in previous rulemaking, where CMS explains the rationale for this policy (88 FR 78871–78878).

CMS has a long-standing interpretation of section 1834(m) of the Act as specifying the circumstances under which Medicare makes payment for services that would otherwise be furnished in person but are instead furnished via telecommunications technology. Specifically, section 1834(m)(2)(A) of the Act expressly requires payment to the distant site physician or practitioner of an amount equal to the amount that such physician or practitioner would have been paid had such service been furnished without the use of a telecommunications system. This means that we must pay an equal amount for a service furnished using a ''telecommunications system'' as for a service furnished in person (without the use of a telecommunications system). In the CY 2019 PFS final rule, we stated that ''[w]e have come to believe that section 1834(m) of the Act does not apply to all kinds of physicians' services whereby a medical professional interacts with a patient via remote communication technology. Instead, we believe that section 1834(m) of the Act applies to a discrete set of physicians' services that ordinarily involve, and are defined, coded, and paid for as if they were furnished during an in-person encounter between a patient and a health care professional'' (83 FR 59483). Under this interpretation, services that are coded and valued based on the understanding that they are not ordinarily furnished in person, such as remote monitoring services and communication technology-based services, are not considered Medicare telehealth services under section 1834(m) of the Act and thus not subject to the geographic, site of service, and practitioner restrictions included therein.

Information provided to CMS from the RUC indicates that CPT codes 9X075–9X090 describe services that would otherwise be furnished in person, and as such the services described by these codes are subject to section 1834(m) of the Act. In the summary of the coding changes, the AMA states that these services are ''patterned after the in-person office visit codes.'' The draft CPT prefatory language states that ''[t]elemedicine services are used in lieu of an in-person service when medically appropriate to address the care of the patient and when the patient and/or family/caregiver agree to this format of care.'' The draft CPT prefatory language likewise states that when a telemedicine E/M is billed on the same day as another E/M service ''the elements and time of these services are summed and reported in aggregate, ensuring that any overlapping time is only counted once,'' which indicates that the work of the telemedicine E/M service is identical to the work associated with an in-person, non-telehealth E/M. The code descriptors and requirements for billing the codes generally mirror the existing office/outpatient E/M codes with the exception of the technological modality used to furnish the service. The audio-video telemedicine E/M codes have nearly identical recommended work RVUs to parallel office/outpatient E/M codes. In general, the audio-only telemedicine E/M codes have lower recommended work RVUs than parallel office/outpatient E/M codes. The RUC stated that this is because, when surveyed, specialty societies indicated that ''the audio-video and in-person office visits require more physician work than the audio-only office visits.''

Table 10 describes the similarities between 16 of 17 telemedicine E/M codes and the parallel office/outpatient E/M codes. The table shows that except for the element of ''modality'' (that is, audio-video or audio-only), the service elements of the new telemedicine E/M code family are no different than the O/O E/M codes (for each enumerated row 1 through 16 the columns display the analogous elements). When comparing code descriptors, as described at the start of this section, the only difference (as represented in Table 10 when comparing the elements of E/M services represented by columns C, D, E, and F) is that these new telemedicine E/M code descriptors lead with the phrase ''synchronous audio-video'' or ''synchronous audio only'' before describing the visit in full exactly as the existing office/outpatient E/M visit codes describe a visit in the long descriptor of the analogous service.

BILLING CODE P

TABLE 10: Comparison of Elements and Work RVU between Telemedicine E/M Codes (9X075 through 9X090) and Office/Outpatient E/M Codes (99202 through 99215)

	A	B	C	D	E	F	G	H
	Telemedicine E/M HCPCS	RUC-recommended Work RVU	Modality	Level of Medical Decision-Making	Time Threshold (minutes)	New or Established Patient?	Analogous Current Office/Outpatient E/M Code	Current Work RVU
1	9X075	0.93	Audio/Video (A/V)	Straightforward	15	new	99202	0.93
2	9X076	1.60	A/V	Low	30	new	99203	1.60
3	9X077	2.60	A/V	Moderate	45	new	99204	2.60
4	9X078	3.50	A/V	High	60	new	99205	3.50
5	9X079	0.70	A/V	Straightforward	10	established	99212	0.70
6	9X080	1.30	A/V	Low	20	established	99213	1.30
7	9X081	1.92	A/V	Moderate	30	established	99214	1.92
8	9X082	2.60	A/V	High	40	established	99215	2.80
9	9X083	**0.90**	Audio-only	Straightforward	15	new	99202	0.93
10	9X084	1.60	Audio-only	Low	30	new	99203	1.60
11	9X085	**2.42**	Audio-only	Moderate	45	new	99204	2.60
12	9X086	**3.20**	Audio-only	High	60	new	99205	3.50
13	9X087	**0.65**	Audio-only	Straightforward	10	established	99212	0.70
14	9X088	**1.20**	Audio-only	Low	20	established	99213	1.30
15	9X089	**1.75**	Audio-only	Moderate	30	established	99214	1.92
16	9X090	**2.60**	Audio-only	High	40	established	99215	2.80

BILLING CODE C

There are services already describing audio-video and audio-only telemedicine E/M codes on the Medicare telehealth services list—the office/outpatient E/M code set—that can be furnished via synchronous two-way, audio/video communication technology generally and via audio-only communication technology under certain circumstances to furnish Medicare telehealth services in the patient's home for the purpose of diagnosis and treatment of a mental health disorder or SUD. Additionally, as stated above, section 1834(m)(2)(A) of the Act requires us to pay an equal amount for a service furnished using a ''telecommunications system'' as for a service furnished in person (without the use of a telecommunications system). Were we to accept the AMA's recommendations and add the telemedicine E/M codes to the Medicare telehealth services list, we would need to establish RVUs for the telemedicine E/M codes to equal the corresponding non-telehealth services to satisfy the requirements for payment under section 1834(m)(2)(A) of the Act.

We do not believe that there is a programmatic need to recognize the audio/video and audio-only telemedicine E/M codes for payment under Medicare. We are proposing to assign CPT codes 9X075–9X090 a Procedure Status indicator of ''I'', meaning that there is a more specific code that should be used for purposes of Medicare, which in this case would be the existing office/outpatient E/M codes currently on the Medicare telehealth services list when billed with the appropriate POS code to identify the location of the beneficiary and, when applicable, the appropriate modifier to identify the service as being furnished via audio-only communication technology.

Section 4113 of the Consolidated Appropriations Act (CAA), 2023 extended the availability of Medicare telehealth services to beneficiaries regardless of geographic location or site of service by temporarily removing such statutory restrictions under section 1834(m) of the Act until the end of 2024. Under the current statute, the geographic location and site of service restrictions on Medicare telehealth services will once again take effect for services furnished beginning January 1, 2025. Although there are some important exceptions, including for behavioral health services and ESRD-related clinical assessments, most

Medicare telehealth services will once again, in general, be available only to beneficiaries in rural areas and only when the patient is located in certain types of medical settings. As previously discussed, the introduction of new CPT coding to describe telemedicine E/M services does not change our authority to pay for visits furnished through interactive communications technology in accordance with section 1834(m) of the Act. We recognize that there are significant concerns about maintaining access to care through the use of Medicare telehealth services with the expiration of the statutory flexibilities that were successively extended by legislation following the PHE for COVID–19. We understand that millions of Medicare beneficiaries have utilized interactive communications technology for visits with practitioners for a broad range of health care needs for almost 5 years. We are seeking comment from interested parties on our understanding of the applicability of section 1834(m) of the Act to the new telemedicine E/M codes, and how we might potentially mitigate negative impact from the expiring telehealth flexibilities, preserve some access, and assess the magnitude of potential reductions in access and utilization. On the latter point, we note that we have developed proposed PFS payment rates for CY 2025, including the statutory budget neutrality adjustment, based on the presumption that changes in telehealth utilization will not affect overall service utilization. We also note that historically we have not considered changes in the Medicare telehealth policies to result in significant impact on utilization such that a budget neutrality adjustment would be warranted. However, we are unsure of the continuing validity of that premise under the current circumstances where patients have grown accustomed over several years to broad access to services via telehealth. We are seeking comment on what impact, if any, the expiration of the current flexibilities would be expected to have on overall service utilization for CY 2025. We refer readers to section IV.B. of this proposed rule for our discussion of budget neutrality adjustments.

Given the similarity between CPT code 9X091 and HCPCS code G2012, we are proposing to accept the RUC-recommended values for CPT code 9X091, and we are proposing to delete HCPCS code G2012. For CPT code 9X091, we propose to accept the RUC-recommended work RVU of 0.30, and are proposing the RUC-recommended direct PE inputs. We note that our proposal does maintain the same direct PE inputs, which the RUC recommendations leave unchanged from the current G2012 in total amount, and allocate the same 3 minutes of time to the same level of staff (Clinical Staff code L037D, RN/LPN/MTA). We believe that the coding and payment recommendations for CPT code 9X091, submitted to CMS by the AMA RUC, accurately reflect the resources associated with this service and believe that maintaining separate coding for purposes of Medicare payment could create confusion. We note that, similar to our current policy for payment of HCPCS code G2012, CPT code 9X091 would be considered a communication technology-based service that is not subject to the requirements in section 1834(m) of the Act applicable to Medicare telehealth services.

(19) Genetic Counseling Services (CPT Code 9X100)

In September 2023, the CPT Editorial Panel deleted CPT code 96040 (*Medical genetics and genetic counseling services, each 30 minutes face-to-face with patient/family*) and created CPT code 9X100 (*Medical genetics and genetic counseling services, each 30 minutes of total time provided by the genetic counselor on the date of the encounter*) for medical genetics and genetic counseling services to be provided by the genetic counselor. Prior to its deletion, CPT code 96040 would only be reported by genetic counselors for genetic counseling services, though genetic counselors are not among the practitioners who can bill Medicare directly for their professional services. As we stated in the CY 2012 PFS final rule (76 FR 73096 through 73097), physicians and NPPs who may independently bill Medicare for their services and who are counseling individuals would generally report office or other outpatient E/M CPT codes for office visits that involve significant counseling, including genetic counseling; therefore CPT code 96040 was considered bundled into O/O E/M visits.

For CPT code 9X100, we are proposing the RUC-recommended direct PE inputs. We note that the code descriptor now specifies that the service is provided by a genetic counselor, therefore we considered assigning Procedure Status ''X'' to CPT code 9X100. Because the PE RVUs would not display for the code with that assignment and that may impact access to the service with other payors, we are instead proposing bundled status (Procedure Status ''B'') for CPT code 9X100 to maintain the status of predecessor CPT code 96040, and we are seeking feedback from interested parties regarding the appropriate procedure status for this code. CPT guidelines for CPT code 9X100 state that a physician or other qualified healthcare professional (QHP) who may report evaluation and management services would not be able to report CPT code 9X100. Instead, these physicians and QHPs would use the appropriate evaluation and management code.

(20) COVID Immunization Administration (CPT Code 90480)

On August 14, 2023, new CPT codes were created to consolidate over 50 previously implemented codes and streamline the reporting of immunizations for the novel coronavirus (SARS-CoV–2, also known as COVID–19). The CPT Editorial Panel approved the addition of a single administration code (CPT code 90480) for administration of new and existing COVID–19 vaccine products. The RUC reviewed the specialty societies' recommendations for this code at the September 2023 RUC meeting.

We are proposing the RUC-recommended work RVU of 0.25 for CPT code 90480 (*Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2) (coronavirus disease [COVID–19]) vaccine, single dose*). We are also proposing the RUC-recommended direct PE inputs for CPT code 90480 without refinement.

(21) Optical Coherence Tomography (CPT Codes 92132, 92133, 92134, and 9X059)

At the February 2023 CPT Editorial Panel meeting, CPT code 9X059 (*Computerized ophthalmic diagnostic imaging (eg, optical coherence tomography [OCT]), posterior segment, with interpretation and report, unilateral or bilateral; retina including OCT angiography*) was created in response to new technology that allows imaging of the retina using optical coherence tomography (OCT) with and without non-dye OCT angiography (OCT–A). This code family also includes CPT code 92132 (*Computerized ophthalmic diagnostic imaging (eg, optical coherence tomography [OCT]), anterior segment, with interpretation and report, unilateral or bilateral*), CPT code 92133 (*Computerized ophthalmic diagnostic imaging (eg, optical coherence tomography [OCT]), posterior segment, with interpretation and report, unilateral or bilateral; optic nerve*), and CPT code 92134 (*Computerized*

ophthalmic diagnostic imaging (eg, optical coherence tomography [OCT]), posterior segment, with interpretation and report, unilateral or bilateral; retina). These codes were reviewed at the April 2023 RUC meeting. The RUC determined the survey results were inaccurate due to underestimation of time, so the entire code family was re-surveyed and reviewed at the September 2023 RUC meeting.

We are proposing the RUC-recommended work RVUs for all codes within the Optical Coherence Tomography code family. We are proposing a work RVU of 0.29 for CPT code 92132, a work RVU of 0.31 for CPT code 92133, a work RVU of 0.32 for CPT code 92134, and a work RVU of 0.64 for CPT code 9X059. We are also proposing the RUC-recommended direct PE inputs for all four codes in the family.

(22) Transcranial Doppler Studies (CPT Codes 93886, 93888, 93892, 93893, 93X94, 93X95, 93X96, and 93890)

The RUC's Relativity Assessment Workgroup (RAW) requested action plans in September 2022 to determine if specific code bundling solutions should occur for CPT codes 93890/93886, 93890/93892, 93892/93886, and 93892/93890. The RAW referred this issue to the CPT Editorial Panel which created three new add-on codes to report when additional studies are performed on the same date of services as a complete transcranial Doppler study. The RUC reviewed these three new add-on codes, as well as CPT codes 93886, 93888, 93892 and 93893 for the September 2023 RUC meeting.

We are proposing the RUC-recommended work RVU for all seven codes in the Transcranial Doppler Studies code family. We are proposing a work RVU of 0.90 for CPT code 93886 (*Transcranial Doppler study of the intracranial arteries; complete study*), a work RVU of 0.73 for CPT code 93888 (*Transcranial Doppler study of the intracranial arteries; limited study*), a work RVU of 1.15 for CPT code 93892 (*Transcranial Doppler study of the intracranial arteries; emboli detection without intravenous microbubble injection*), a work RVU of 1.15 for CPT code 93893 (*Transcranial Doppler study of the intracranial arteries; venous-arterial shunt detection with intravenous microbubble injection*), a work RVU of 0.81 for CPT code 93X94 (*Vasoreactivity study performed with transcranial Doppler study of intracranial arteries, complete*), a work RVU of 0.73 for CPT code 93X95 (*Emboli detection without intravenous microbubble injection performed with transcranial Doppler study of intracranial arteries, complete*), and a work RVU of 0.85 for CPT code 93X96 (*Venous-arterial shunt detection with intravenous microbubble injection performed with transcranial Doppler study of intracranial arteries, complete*). We are also proposing the direct PE inputs as recommended by the RUC for all seven codes in this family.

We note that the billing instructions for this code family specify that the three new add-on codes should be used in conjunction with CPT code 93886, and that CPT code 93888 should not be used in conjunction with CPT codes 93886, 93892, 93893, 93X94, 93X95, and 93X96. However, we believe that it would be beneficial for the CPT Editorial Panel to state more explicitly that CPT code 93X95 should not be used in conjunction with CPT code 93892 and that CPT code 93X96 should not be used in conjunction with CPT code 93893. The work performed in the add-on codes would be duplicative of the base codes in these situations and result in unnecessary overbilling of services.

(23) RSV Monoclonal Antibody Administration (CPT Codes 96380 and 96381)

At the September 2023 CPT meeting, the CPT Editorial Panel created two codes to report passive administration of respiratory syncytial virus, monoclonal antibody, seasonal dose, with and without counseling. CPT codes 96380 and 96381 were reviewed the following week at the September 2023 RUC meeting and the RUC submitted recommendations to CMS.

We are proposing the RUC-recommended work RVU of 0.24 for CPT code 96380 (*Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection, with counseling by physician or other qualified health care professional*) and the RUC-recommended work RVU of 0.17 for CPT code 96381 (*Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection*). We understand that these are interim work recommendations from the RUC, and that the RUC intends to conduct a more complete review at a future RUC meeting which we would then consider in future rulemaking. We are also proposing the direct PE inputs as recommended by the RUC for both codes.

(24) Hyperthermic Intraperitoneal Chemotherapy (CPT Codes 96547 and 96548)

In September 2022, the CPT Editorial Panel created two time-based add-on Category I codes, CPT code 96547 (*Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; first 60 minutes (List separately in addition to code for primary procedure)*) and CPT code 96548 (*Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; each additional 30 minutes (List separately in addition to code for primary procedure)*), to report HIPEC procedures for 2024. At the January 2023 RUC meeting, the RUC reached the conclusion that the survey data was flawed due to a lack of work definition and guidelines, and the RUC recommended contractor pricing for CPT codes 96547 and 96548 for CY 2024 with further clarification from the CPT editorial panel. CMS proposed and finalized contractor pricing for CPT codes 96547 and 96548 for 2024. At the May 2023 CPT Editorial Panel meeting, new guidelines and descriptions of work activities were approved and the codes were resurveyed for the September 2023 RUC meeting with recommendations for national pricing.

We are proposing the RUC-recommended work RVU of 6.53 for CPT code 96547 and the RUC-recommended work RVU of 3.00 for CPT code 96548. The RUC did not recommend, and we are not proposing, any direct PE inputs for the Hyperthermic Intraperitoneal Chemotherapy codes (CPT codes 96547 and 96548).

(25) Laser Treatment—Skin (CPT Codes 96920, 96921, and 96922)

In April 2022, the RUC referred CPT codes 96920 (*Excimer laser treatment for psoriasis; total area less than 250 sq cm*), 96921 (*Excimer laser treatment for psoriasis; 250 sq cm to 500 sq cm*), and 96922 (*Excimer laser treatment for psoriasis; over 500 sq cm*) to the CPT Editorial Panel to capture expanded indications beyond what was currently noted in the codes' descriptions to include laser treatment for other inflammatory skin disorders such as vitiligo, atopic dermatitis, and alopecia areata, which could result in changed physician work based on the expanded indications. The coding change application was subsequently withdrawn from the September 2023 CPT Editorial meeting when it was determined that existing literature was insufficient and did not support expanded indications at that time. Therefore, these CPT codes were re-surveyed and reviewed at the April

2023 RUC meeting without any revisions to their code descriptors.

We disagree with the RUC-recommended work RVUs for CPT codes 96920, 96921, and 96922 of 1.00, 1.07, and 1.32, respectively. The RUC noted that there have been multiple reviews of these CPT codes, and the valuation of the codes is currently based on the original valuation over two decades ago in 2002 where the physician time values were lower than the current times. A subsequent review in 2012 adopted new survey times while maintaining the work RVUs from 2002 for CPT codes 96920 and 96922. The RUC noted that, for both CPT code 96920 and 96922 with the largest treatment area, the total times have not changed since first implemented more than 20 years ago. While we understand that the physician times have fluctuated over the course of several years and several reviews, yet the work RVUs have remained mostly constant as shown in Table 11, this was not addressed in the 2012 recommendations, and we believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The work times currently associated with codes play a very important role in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had been routinely over or underestimated, this would undermine the relativity of the work RVUs on the PFS in general, in light of the fact that codes are often valued based on comparisons to other codes with similar work times. We also believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs.

TABLE 11: Physician Time and RVUs for CPT Codes 96920, 96921, and 96922

CPT Code		Intraservice Time	Total Time	RUC Recommended Work RVU
96920	2002	17	27	1.15
	Current (from 2012)	23	35	1.15
	Recommended	10	23	1.00
96921	2002	20	30	1.17
	Current (from 2012)	30	42	1.30
	Recommended	12	25	1.07
96922	2002	30	40	2.10
	Current (from 2012)	45	57	2.10
	Recommended	18	31	1.32

For CPT code 96920, we are proposing a work RVU of 0.83 based on a crosswalk to CPT code 11104 (*Punch biopsy of skin (including simple closure, when performed); single lesion*), which has the same 10 minutes of intraservice time and 23 minutes of total time as CPT code 96920. We note that of the 15 other 000-day global codes with a total time of 20 to 25 minutes, only four codes fall above the RUC-recommended work RVU of 1.00. While we understand that commenters will dispute the validity of the current time values, we note that the 2002 intraservice time was 17 minutes, which yields an intraservice time ratio between the 2002 intraservice time and the recommended intraservice time of 10 minutes of 0.68 work RVUs ((10 minutes/17 minutes) * 1.15). We note our proposed work RVU of 0.83 maintains the intensity associated with the 2002 review of CPT code 96920, which we believe to be more appropriate than the significant increase in intensity that results from the RUC-recommended work RVU of 1.00 which nearly doubles the current intensity of the code. We have no evidence to indicate that the intensity of CPT code 96920 is increasing to this degree given how the surveyed work time is substantially decreasing.

For CPT code 96921, we are proposing a work RVU of 0.90 based on a total time ratio to CPT code 96920 ((25/23) * 0.83) and a crosswalk to CPT code 11301 (*Shaving of epidermal or dermal lesion, single lesion, trunk, arms or legs; lesion diameter 0.6 to 1.0 cm*), which has 3 additional minutes of intraservice time and 1 additional minute of total time compared to CPT code 96921. We also note that our proposed work RVU of 0.90 for CPT code 96921 maintains the RUC-recommended incremental difference between CPT codes 96920 and 96921 of 0.07 work RVUs. Like CPT code 96920, we understand that commenters will dispute the validity of the current time values, but we note that the 2002 intraservice time was 20 minutes, which yields an intraservice time ratio between the 2002 intraservice time and the recommended intraservice time of 12 minutes of 0.70 work RVUs ((12 minutes/20 minutes) * 1.17). Like CPT code 96920, we note that proposed work RVU of 0.90 for CPT code 96921 maintains the intensity associated with the 2002 review of CPT code 96921, which we believe is more appropriate than the intensity increase that results from the RUC-recommended work RVU of 1.07 which again nearly doubles the current intensity of the code.

For CPT code 96922, we are proposing a work RVU of 1.15 based on the RUC-recommended incremental difference between CPT codes 96921 and 96922 of 0.25 work RVUs. Like CPT code 96920 and 96921, we understand that commenters will dispute the validity of the current time values, but we note that the 2002 intraservice time was 30 minutes, which yields an intraservice time ratio between the 2002 intraservice time and the recommended intraservice time of 18 minutes of 1.26 work RVUs ((18 minutes/30 minutes) * 2.10). We note that the RUC recommended CPT code 96922 as having the lowest intensity of the three codes in this family and that our proposed work RVU of 1.15 maintains in relationship to the other codes.

For the direct PE inputs, we are proposing to refine the clinical staff

time for the CA024 activity ''Clean room/equipment by clinical staff'' to the standard of 3 minutes for CPT codes 96920, 96921, and 96922. We note that 3 minutes is the current CA024 time for these three CPT codes. A rationale for extending clinical staff beyond the standard 3 minutes for the CA024 activity was absent from the PE Summary of Recommendations, therefore we believe the current and standard 3 minutes is more appropriate than the RUC-recommended 5 minutes. We are also proposing equipment times of 36, 38, and 44 minutes for the power table (EF031) and exam light (EQ168) equipment for CPT codes 96920, 96921, and 96922, respectively, to account for the proposed refinement for CA024 to the standard 3 minutes.

We also disagree with the RUC-recommended creation of new supply items for the excimer laser and are proposing to re-include the equipment time for the excimer laser (EQ161) using the current methodology where its cost is accounted for in the equipment of these CPT codes' direct PE. The RUC submitted recommendations to change this equipment item to new supply items to account for the per-use cost to rent the equipment, stating that the business model has changed from the standard equipment ownership that CMS recognizes using standardized equipment formulas to a per-use rental or subscription model. While we understand that there may have been a change in business model, we do not believe a rental, subscription, or per-use fee of an equipment item that is still available to be purchased and is already accounted for with our equipment methodology is appropriate, especially given its implications for direct PE costs for these CPT codes. Therefore, we are proposing reincorporating equipment times of 36, 38, and 44 minutes for the EQ161 equipment for CPT codes 96920, 96921, and 96922, respectively, based on the refined service period clinical labor times. We are proposing to remove the three pay-per-use excimer lasers listed as supplies and recommended by the RUC for these three codes.

We have repeatedly stated in past rulemaking that rental and licensing fees are typically considered forms of indirect PE under our methodology. In the CY 2020 PFS final rule, we omitted the inclusion of several invoices for the monthly rental price of a PET infusion cart (ER109), and only accounted for the four purchase invoices for the equipment. We noted as well for future reference that although we appreciated the submission of the rental invoices, we were unable to use invoices for a monthly rental fee to determine the typical purchase price for equipment. We believe that invoices for a monthly rental fee would not be representative of the purchase price for equipment, in the same fashion that the rental fee for a car differs from its purchase price (84 FR 62771). Similarly, while we appreciate the submission of per-use, rental, and partnership invoices for the excimer laser, we believe that the excimer laser is appropriately and adequately accounted for in the equipment formula, and note that EQ161 has a very high cost per minute of $0.5895/minute. Compared to the nearly 700 other equipment items in our database, only 55 equipment items have higher costs per minute (based on our standardized formula which accounts for years of useful life, utilization rate, purchase price, and minutes per year of use, discussed in detail in section II.B. of this proposed rule, Determination of PE RVUs) and only 53 equipment items have higher purchase prices than the excimer laser at $151,200. We do not believe that CPT codes 96920 through 96922 should be valued based on a significantly more expensive pay-per-use rental version of the excimer laser when the same treatment is cheaper and available as a purchasable form of equipment.

Therefore, we are seeking comment on the difference in direct PE costs between the purchase and per-use rental of the laser. We note that using the equipment cost per minute formula, discussed in detail of section II.B. of this proposed rule, Determination of PE RVUs, yields direct PE costs of about $21.22, $22.40, and $25.94 for CPT codes 96920, 96921, 96922, respectively. Alternatively, the new supply items for the per-use fee of the laser yielded direct PE costs of $80, $83, and $100 for CPT codes 96920, 96921, 96922, respectively. These direct PE disparities represent a 277 percent, 270.5 percent, and 285.5 percent increase for CPT codes 96920, 96921, 96922, respectively. Given this, we are interested in feedback from interested parties on the payment disparity between this equipment as a per-use or rental versus how we currently account for the purchase of equipment using the standard equipment formula, as we understand that both manufacturers and physicians may be inclined to shift to a per-use or rental business models to limit overhead for purchase and maintenance of expensive equipment.

(26) Physical Medicine and Rehabilitation (CPT Codes 97012, 97014, 97016, 97018, 97022, 97032, 97033, 97034, 97035, 97110, 97112, 97113, 97116, 97140, 97530, 97533, 97535, 97537, and 97542 and HCPCS Code G0283)

The RUC's Health Care Professionals Advisory Committee (HCPAC) previously reviewed 19 physical medicine and rehabilitation codes in February 2017. In the CY 2024 PFS proposed rule, CMS received public nominations on these same 19 therapy codes as potentially misvalued (88 FR 78851–78852). An interested party asserted that the direct PE clinical labor minutes reflected inappropriate multiple procedure payment reductions (MPPR), which were duplicative of the CMS MPPR policy implemented in CMS' claims processing systems. CMS reviewed the clinical labor time entries for these 19 therapy codes and concluded that a payment reduction should not have been applied in some instances to the 19 nominated therapy codes' clinical labor time entries since the payment valuation reduction would be duplicative of the MPPR applied during claims processing. CMS indicated that the valuation of these services would benefit from additional review through the RUC's HCPAC valuation process; they were therefore reviewed by the HCPAC for PE only, with no work review, at the January 2024 RUC meeting for inclusion in the CY 2025 PFS proposed rule.

The HCPAC's direct PE recommendations were based on the typical number of services reported per session, which was 3.5 units according to CMS data, to ensure that there was no duplication in the standard inputs for preservice and postservice time. To account for the MPPR, the HCPAC determined that 3.5 codes are billed per session, with the first paid at 100% and the second and subsequent units paid at half and so forth for PE (for example, 1.00 + 0.5 + 0.5 + 0.25 = 2.25). This resulted in the HCPAC recommending that many of the standard clinical labor times be divided by 2.25 to account for the MPPR, such as taking the standard 3 minutes for greeting and gowning the patient and dividing it by 2.25 to arrive at the recommended time of 1.33 minutes (1.33 + 0.67 + 0.67 + 0.34 = 3 minutes). In most cases, the HCPAC recommended using the standard equipment time formula aside from a few exceptions such as the use of the whirlpool in CPT code 97022 which would require additional time for the cleaning of the equipment.

Following the January 2024 RUC meeting, representatives from the American Physical Therapy Association (APTA) and the American Occupational Therapy Association (AOTA) met with CMS to express concern with the HCPAC's recommended direct PE inputs for this family of codes. Representatives from these trade associations stated that the HCPAC had inappropriately recommended too few equipment minutes for these procedures. These interested parties requested utilizing an alternate equipment time formula for the 19 reviewed therapy codes based on adding together the intraservice work time together with the clinical labor for the preservice and postservice portion of the service period. For 17 of the 19 reviewed therapy codes, this alternate equipment time formula would result in an increase over the HCPAC's equipment time recommendations. Table 12 lists the direct PE costs of each HCPCS code under their current pricing, under the HCPAC recommendations, and the alternate APTA and AOTA recommendations:

TABLE 12: Direct PE Costs for Physical Medicine and Rehabilitation Codes

HCPCS	Current	HCPAC	APTA/AOTA	Utilization
97012	2.62	3.22	3.30	434,921
97014	3.60	4.16	4.33	ProcStat "I"
97016	2.94	3.50	3.67	876,440
97018	2.29	2.92	2.96	146,909
97022	8.04	7.27	7.18	135,480
97032	2.61	3.17	3.34	621,599
97033	6.61	6.74	6.90	33,953
97034	4.08	4.17	4.17	6,964
97035	4.03	4.41	4.65	1,358,936
97110	8.42	8.63	9.11	61,204,041
97112	10.23	9.87	11.08	24,990,205
97113	13.89	14.65	14.61	1,588,852
97116	8.35	8.58	9.03	4,011,592
97140	7.25	8.09	8.21	28,413,744
97530	15.01	14.38	16.40	29,187,934
97533	35.72	36.56	36.69	60,507
97535	11.50	11.64	12.67	3,118,258
97537	9.69	10.09	10.78	15,556
97542	9.26	9.41	10.42	98,989
G0283	3.60	4.16	4.33	5,721,078

After consideration of these recommendations, we are proposing the direct PE inputs as recommended by the HCPAC for all 19 codes in the Physical Medicine and Rehabilitation code family. We believe that the HCPAC's equipment time recommendations better maintain relativity with the rest of the fee schedule through primarily using standard equipment time formulas, along with limited exceptions for additional equipment time in cases where more time for equipment cleaning or patient positioning would be typical. We also believe that the alternate equipment time formula recommended by APTA and AOTA leads to inconsistent equipment times for many of these procedures, such as recommending 23.98 equipment minutes for CPT code 97110 which is a timed code billed in 15-minute increments. Although we agree that some additional equipment time beyond the timed 15 minutes would be typical for setup and cleaning, 9 additional minutes for each billing of CPT code 97110 would not appear to reflect typical equipment usage.

Given the complexity of determining appropriate direct PE inputs across multiple billings of these therapy codes, and the need to factor in the MPPR, we believe that this code family may benefit from additional review, specifically review focused on the subject of appropriate equipment minutes. The HCPAC review of these codes was primarily focused on the clinical labor portion of the PE inputs and the equipment times did not receive the same degree of scrutiny as the clinical labor. We believe that the HCPAC's recommended direct PE inputs are the most accurate values based on the current information that we have available, however this is a topic that may warrant additional review to ensure that this family of codes is properly valued.

(27) Acupuncture—Electroacupuncture (CPT Codes 97810, 97811, 97813, and 97814)

In September 2022, the RUC's Relativity Assessment Workgroup identified the acupuncture codes with 2020 Medicare utilization over 10,000 where the service was surveyed by one specialty but is now performed by a different specialty. CPT codes 97810–97814 were selected and surveyed for the April 2023 RUC meeting.

For CY 2025, we are proposing the RUC-recommended work RVUs for all four CPT codes. We are proposing a work RVU of 0.61 for CPT code 97810 (*Acupuncture, 1 or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient*), a work RVU of 0.46 for CPT code 97811 (*Acupuncture, 1 or more needles; without electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for*

primary procedure)), a work RVU of 0.74 for CPT Code 97813 (*Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient*), and a work RVU of 0.47 for CPT code 97814 (*Acupuncture, 1 or more needles; with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)*). We are also proposing the RUC-recommended direct PE inputs for CPT codes 97810, 97811, 97813 and 97814 without refinement.

(28) Annual Alcohol Screening (HCPCS Codes G0442 and G0443)

In April 2022, the Relativity Assessment Workgroup identified services with Medicare utilization of 10,000 or more that have increased by at least 100 percent from 2015 through 2020, including HCPCS codes G0442 (*Annual alcohol misuse screening, 5 to 15 minutes*) and G0443 (*Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes*). In September 2022, the RUC recommended that these services be surveyed for April 2023 after CMS published the revised code descriptor for HCPCS code G0442 in the CY 2023 PFS final rule (87 FR 69523).

We are proposing the RUC-recommended work RVU of 0.18 for HCPCS code G0442 (*Annual alcohol misuse screening, 5 to 15 minutes*). We are also proposing the RUC-recommended work RVU of 0.60 for HCPCS code G0443 (*Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes*).

The RUC recommended an increase in the work RVU for HCPCS code G0443 from 0.45 to 0.60 which we believe is warranted based on time and intensity of the service in preventing alcohol misuse. In valuing this code, the time and work valuation is for separate and distinct services from same-day E/M services since HCPCS codes G0442 and G0443 are typically billed with an annual wellness visit (AWV) or office visit. We believe that the codes in the adjacent Behavioral Counseling & Therapy family, which includes HCPCS codes G0445 (*High intensity behavioral counseling to prevent sexually transmitted infection; face-to-face, individual, includes: education, skills training and guidance on how to change sexual behavior; performed semi-annually, 30 minutes*), G0446 (*Annual, face-to-face intensive behavioral therapy for cardiovascular disease, individual, 15 minutes),* and G0447 (*Face-to-face behavioral counseling for obesity, 15 minutes*), may be undervalued as their respective intensities may be lower than what is warranted for these services. We believe that the intensity for these G-codes may be more in line with the intensity of HCPCS code G0443 which we noted had an increase in intensity as recommended by the RUC. As such, we believe that the Behavioral Counseling & Therapy codes may benefit from additional review in the future to recognize the intensity of these services.

We are proposing to maintain the current 15 minutes of clinical labor time for the CA021 ''Perform procedure/service—NOT directly related to physician work time'' activity for HCPCS code G0442. This clinical labor activity is specifically noted as not corresponding to the surveyed work time of 5 minutes, and we do not believe that it would be typical for the clinical staff to administer the questionnaire, clarify questions as needed, and record the answers in the patient's electronic medical record in the RUC-recommended 5 minutes. We believe that the current 15 minutes of clinical labor time would be more typical to ensure the accuracy of this screening procedure. We are also proposing to maintain 15 minutes of corresponding equipment time for the EF023 exam table as a result of our proposed clinical labor time refinement. We are proposing the RUC-recommended direct PE inputs for HCPCS code G0443 without refinement.

We thank the RUC for their review of this code family and for highlighting an important consideration specifically for services that fall under the Medicare preventive services benefit. We are now considering how best to implement and maintain payment for preventive services and may develop new payment policies in future rulemaking to address this issue more comprehensively to ensure consistent access to these services. We considered the recommended PE inputs for this code family, as well as for the Annual Depression Screening (HCPCS code G0444) and Behavioral Counseling & Therapy services (HCPCS codes G0445, G0446, and G0447) within this context, as noted below.

(29) Annual Depression Screening (HCPCS Code G0444)

In 2012, HCPCS code G0444 (*Annual depression screening, 5 to 15 minutes*) was added to the PFS (77 FR 68955 and 68956) to report annual depression screening for adults in primary care settings that have staff-assisted depression care supports in place to assure accurate diagnosis, treatment and follow up. In April 2022, the Relativity Assessment Workgroup identified this service with Medicare utilization of 10,000 or more that have increased by at least 100 percent from 2015 through 2020. In September 2022, the RUC recommended that this service be surveyed for April 2023 after CMS published the revised code descriptor in the CY 2023 PFS final rule (87 FR 69523).

We are proposing the RUC-recommended work RVU of 0.18 for HCPCS code G0444.

We are proposing to maintain the current 15 minutes of clinical labor time for the CA021 ''Perform procedure/service—NOT directly related to physician work time'' activity for HCPCS code G0444. This clinical labor activity is specifically noted as not corresponding to the surveyed work time of 5 minutes, and we do not believe that it would be typical for the clinical staff to administer the questionnaire, clarify questions as needed, and record the answers in the patient's electronic medical record in the RUC-recommended 5 minutes. We believe that the current 15 minutes of clinical labor time would be more typical to ensure the accuracy of this screening procedure. We are also proposing to maintain 15 minutes of corresponding equipment time for the EF023 exam table as a result of our proposed clinical labor time refinement.

(30) Behavioral Counseling & Therapy (HCPCS Codes G0445, G0446, and G0447)

CMS created HCPCS codes G0445 (*High intensity behavioral counseling to prevent sexually transmitted infection; face-to-face, individual, includes education, skills training and guidance on how to change sexual behavior; performed semi-annually, 30 minutes*), G0446 (*Annual, face-to-face intensive behavioral therapy for cardiovascular disease, individual, 15 minutes*), and G0447 (*Face-to-face behavioral counseling for obesity, 15 minutes*) effective with the 2012 Medicare PFS (77 FR 68892). HCPCS codes G0445–G0447 were identified to be reviewed at the April 2023 RUC meeting because they were services with Medicare utilization of 10,000 or more that had increased by at least 100% from 2015 through 2020.

The specialty societies surveyed HCPCS codes G0445–G0447 for the April 2023 RUC meeting but did not obtain the required number of survey responses. After the resurvey, which occurred after the April 2023 RUC meeting, the specialty societies were again unable to achieve the required minimum number of survey responses

for any of the codes in this family for the September 2023 RUC meeting. The RUC reviewed HCPCS codes G0445–G0447 at the September 2023 RUC meeting. Given the insufficient number of survey responses and considering that these are CMS-created time-based codes, the RUC determined it would be most appropriate to maintain the current work values and flagged these codes for review in 3 years. We are proposing the RUC-recommended work RVU of 0.45 for each of these three HCPCS codes, G0445–G0447.

We are not proposing the RUC-recommended direct PE inputs for these codes because of the insufficient number of survey responses, and further, we do not agree with some of the RUC's refinements to the direct PE inputs for this service. We are not proposing the RUC-recommended direct PE inputs for G0445, G0446, and G0447, which include the SK062 patient education booklet being eliminated in favor of the SK057 paper, laser printing (each sheet) in the amount of 10 sheets and the equipment minutes being modified to equal the sum of clinical staff time plus the physician/QHP time as reflected by the survey median. We do not agree that these changes are substantiated given the insufficient number of survey responses and we are proposing to maintain the current values for each of these direct PE inputs.

We are proposing the RUC recommended refinements to clinical staff time for HCPCS code G0445. We are proposing to move two minutes from CA021 Perform procedure/service—NOT directly related to physician work time to CA035 Review home care instructions, coordinate visits/prescriptions. We agree with the RUC that this more accurately reflects the clinical work involved in arranging follow-up and/or referrals with clinical and community resources and providing educational materials. Currently, for HCPCS code G0445, PE includes a whip mixer (EP086) and biohazard hood (EP016) among the equipment assigned to the code. We are also proposing the RUC recommendations to eliminate both of these pieces of equipment from the PE for HCPCS code G0445.

We note that the Behavioral Counseling & Therapy code family (HCPCS codes G0445–G0447) should be reviewed in the future by the RUC and we anticipate the recommendations that will come from the review for this family.

(31) Autologous Platelet Rich Plasma (HCPCS Code G0465)

HCPCS code G0465 (*Autologous platelet rich plasma (prp) or other blood-derived product for diabetic chronic wounds/ulcers, using an fda-cleared device for this indication, (includes as applicable administration, dressings, phlebotomy, centrifugation or mixing, and all other preparatory procedures, per treatment)*) was created for CY 2022 (retroactively dated back to the effective date of the policy, April 13, 2021) and assigned contractor pricing (NCD 270.3, CR 12403).

Following the publication of the CY 2023 PFS proposed rule, we received two comments on the pricing of HCPCS code G0465, and the 3C patch system supply which is topically applied for the management of exuding cutaneous wounds, such as leg ulcers, pressure ulcers, and diabetic ulcers and mechanically or surgically debrided wounds (87 FR 69420). One commenter submitted invoices associated with the pricing of the 3C patch system (SD343) supply for which we established a price of $625.00 in the CY 2021 PFS final rule (85 FR 84498). The commenter requested that CMS update its supply database based on invoices submitted for SD343 to reflect an updated price of $750.00 per unit. The commenter also requested national pricing for HCPCS code G0465, expressing concern that insufficient payment disproportionately impacts vulnerable populations. The commenter requested a payment rate of $1,408.90 for HCPCS G0465 in the office setting, stating that this rate would appropriately account for the purchase of the 3C patch, as well as the other related costs and supply inputs required for point of care creation and administration.

In response, we stated in the CY 2023 PFS final rule that we did not have enough information to establish national pricing at this time for HCPCS code G0465 (87 FR 69420). We stated that we would consider the commenters' feedback for future rulemaking while maintaining contractor pricing for CY 2023, which would allow for more flexibility for contractors to establish appropriate pricing using available information. We appreciated the invoice submission with additional pricing information for the SD343 supply and we updated our supply database for supply code SD343 at a price of $678.57 based on an average of the submitted invoices.

Since the publication of the CY 2023 PFS final rule, interested parties have continued to request national pricing for HCPCS code G0465 due to their perception of inconsistent and insufficient payment for this service by the MACs. CMS has asked the interested parties to engage with the MACs to establish adequate payment for HCPCS code G0465. The interested parties have continued to state that most MACs have not established consistent payment rates and the rates are heterogeneous; some are significantly below the cost of performing this service, leading to an unpredictable process and inadequate rates, creating barriers to access this service.

Due to these concerns, we are therefore proposing to establish national pricing for HCPCS code G0465 for CY 2025. We are proposing to value HCPCS code G0465 using a crosswalk to CPT code 15271 (*Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area*), drawing from a selection of relevant studies.[17] [18] [19] [20] We are proposing a work RVU of 1.50 for HCPCS code G0465 based on the crosswalk to CPT code 15271 because wound surface area sizes in current literature appear to be less than 100 sq cm for patients with diabetes and/or chronic ulcers. We are also proposing to use the direct PE inputs included with CPT code 15271 for valuing HCPCS code G0465, with the additional inclusion of the 3C patch system (SD343) supply that we priced in CY 2023. We note that the payment includes debridement, which may involve a wound reaching the bone. Therefore, debridement may not be billed separately. In addition, we are currently seeking comments on other available crosswalks from the broader medical community. For example, CPT code 15277 (*Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children*) with a work RVU of 4.00 and CPT code 15273 (*Application of skin substitute graft to*

[17] Gethin, G et al. ''The profile of patients with venous leg ulcers: A systematic review and global perspective.'' *Journal of tissue viability* vol. 30,1 (2021): 78–88. *doi:10.1016/j.jtv.2020.08.003.*

[18] Sheehan, Peter et al. ''Percent change in wound area of diabetic foot ulcers over a 4-week period is a robust predictor of complete healing in a 12-week prospective trial.'' *Plastic and reconstructive surgery* vol. 117,7 Suppl (2006): 239S–244S. *doi:10.1097/01.prs.0000222891.74489.33.*

[19] Oyibo, S O et al. ''The effects of ulcer size and site, patient's age, sex and type and duration of diabetes on the outcome of diabetic foot ulcers.'' Diabetic medicine: a journal of the British Diabetic Association vol. 18,2 (2001): 133–8. *doi:10.1046/j.1464–5491.2001.00422.x.*

[20] Patry, Jérôme et al. ''Outcomes and prognosis of diabetic foot ulcers treated by an interdisciplinary team in Canada.'' *International wound journal* vol. 18,2 (2021): 134–146. *doi:10.1111/iwj.13505.*

trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children) with a work RVU of 3.50 could also be viable crosswalk options. We are soliciting comments regarding our selection of CPT code 15271 as a crosswalk code, as well as general comments and available studies regarding the appropriate valuation of HCPCS code G0465.

(32) Temporary Female Intraurethral Valve-Pump (CPT Codes 0596T and 0597T)

In the CY 2024 PFS proposed rule, an interested party nominated two Category III CPT codes, CPT codes 0596T (*Initial insertion of temporary valve-pump in female urethra*) and 0597T (*Replacement of temporary valve-pump in female urethra*), as potentially misvalued. The nominator expressed concern about variability in MAC pricing for the contractor-priced service. Additionally, the nominator highlighted that the payment amounts determined by MACs were inadequately low and did not account for the time and effort required to furnish the services. In their submission, the nominator discussed their anticipated inputs for both codes. For CPT code 0596T, the nominator stated that a physician typically spends 60 minutes inserting the Vesiflo inFlow System. The nominator stated that CPT code 0596T included various supplies, equipment, and clinical labor time totaling $1,902.76, with the inflow supply items making up about 99 percent of the total cost of supplies. For CPT code 0597T, the nominator stated that a physician spends 25 minutes replacing the Vesiflo inFlow System and PE items were similar, with supplies, equipment and clinical labor time costing $505.30, with the inflow supply items making up about 98 percent of the total cost of supplies. We direct interested parties to the CY 2024 PFS final rule (88 FR 78850) for more detailed submission information regarding CPT codes 0596T and 0597T. After reviewing, we concluded that these codes were not potentially misvalued because they are Category III codes describing relatively new and low-volume services. Category III codes are contractor priced under the PFS, meaning that each MAC can establish pricing for the code within its jurisdiction, resulting in variability in payments.

This year, the nominator newly informed CMS that their analysis of national payment rates showed that in most CMS jurisdictions, not only are these codes misvalued, but in most cases, they are not valued at all, with fee schedule amounts in most CMS jurisdictions at or near zero dollars. The nominator further emphasized that three physician experts, all employed in major university medical centers, have highlighted the challenges posed by the combination of high supply costs and inadequate fee schedule payments, which have hindered their ability to provide services covered by these codes over several years. According to the nominator, these selected physicians also expressed frustration with the reluctance of MACs to address or discuss this issue. Moreover, the nominator highlighted high access barriers as a significant concern. These barriers primarily affect Medicare's most vulnerable beneficiaries, particularly women experiencing permanent urinary retention (PUR), although we note that no quantifiable evidence was provided to support these statements. We acknowledge and appreciate the nominator's efforts in reaching out to experts in the field and patients who rely on these services to elucidate their significant needs.

Since these two Category III CPT codes were not identified as potentially misvalued and were consequently priced by contractors, each MAC can set pricing for the code within its jurisdiction. This could result in inevitable variability in MAC pricings until they receive a higher number of claims, as stated by the nominator. Through our engagement with MACs, we found that claims for the two Category III CPT codes are reviewed on a case-by-case basis for medical necessity. If the claim is payable, the price will be determined at that time by the MAC. Additionally, these codes were a topic of discussion within the MAC pricing workgroup, and we observed that there was not a significant difference among the MACs in terms of allowances based on the proposed pricing methodologies. However, there is variance in how MACs load pricing for Category III codes. For instance, some MACs publish the price for the service before they receive any claims, while others set the price only after they receive claims that help determine the appropriate pricing. If a MAC does not load a price for a code before receiving any claims, the service can still be paid, but the allowance has not been published.

We continue to hear concerns about these payment inconsistencies for CPT codes 0596T and 0597T. As a result, we are recommending that the MACs establish more consistency in pricing, enabling the appropriate inclusion of the Vesiflo system in the code's PE valuation. Therefore, for CY 2025, we encourage interested parties to provide more accurate and appropriate cost data, along with additional information regarding work RVU, work time, indicators, and utilization estimates for the MACs. This should complement the information provided by the nominator in the CY 2024 final rule (88 FR 78850) and will facilitate the process. To aid in this process, we are adding three new supplies to our direct PE database based on invoices submitted by interested parties: the inFlow Measuring Device at a price of $140 (SD370), the inFlow Valve-Pump Device at a price of $495 (SD371), and the inFlow Activator Kit at a price of $1,250 (SD372). Although we are not proposing national pricing for these two Category III codes, we do note for the benefit of the MACs that CPT code 0596T would typically include one of each of these supplies, whereas CPT code 0597T would typically include only one of the supplies (SD371).

We encourage the MACs to continue to engage with interested parties by providing information on how they price these services. We welcome additional comments from the broader medical community regarding the usage of this service, particularly concerning its safety and effectiveness, as well as potential factors contributing to its low utilization.

(33) PE-Only Replacement Code for Heart Failure System

Interested parties have expressed concern about the lack of coding and a billing mechanism when practitioners incur costs replacing identified components of the CardioMEMS™ Heart Failure System used in the physician service described by CPT code 33289 (*Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed*).

The CardioMEMS™ Heart Failure System furnished during this service allows practitioners treating heart failure patients to wirelessly monitor and measure pulmonary artery pressure and heart rate in patients with heart failure and transmit the information to the physician to inform the treatment plan for the patient. The system includes two critical components: first, a miniaturized, wireless monitor, which is implanted into a patient's pulmonary artery, and second, a smart pillow (the CardioMEMS™ Patient Electronics System), which captures and transmits

readings via safe radio frequency from the patient's implanted CardioMEMS™ Heart Failure System. Overall, the CardioMEMS™ Heart Failure System enables patients to transmit critical heart failure status information to clinicians regularly, potentially eliminating the need for frequent clinic or hospital visits.

Interested parties have highlighted the critical importance of the device for heart failure patients who require close monitoring of weight and blood pressure to prevent fluid buildup around the heart, and have requested that CMS establish coding to describe when practitioners incur costs during clinical scenarios when crucial components of the system require replacement. Given that these components are crucial for system functionality and there is no existing coding framework to address their replacement, we believe that establishing appropriate coding and payment mechanisms can facilitate the provision of these services more effectively in the office and hospital settings. Given provided information, we propose assigning contractor pricing to this PE-only code for CY 2025. We are proposing a new code, HCPCS code GMEM1 (Provision of replacement patient electronics system (for example, system pillow) for home pulmonary artery pressure monitoring including provision of materials for use in the home and reporting of test results to physician or qualified health care professional). We are seeking feedback from interested parties on our contractor pricing approach with the aim of establishing national pricing through future rulemaking that can be billed under the OPPS and PFS specifying an ongoing care visit for the CardioMEMS™ Heart Failure System along with the provision of the replacement part. We are specifically looking for information from the broader medical community regarding direct costs from invoices for the replacement component referenced above, utilization estimates, and potential indicators. Additionally, we solicit comments on additional direct PE inputs that we should consider.

(34) Portable X-Ray (HCPCS Codes R0070–R0075)

Several Portable X-Ray (PXR) suppliers and trade organizations continue to express longstanding concerns with how payment is established for transportation related to these services (HCPCS codes R0070–R0075). CMS has worked with interested parties over the past several years to understand the costs of these services while taking into consideration the MACs perspective on pricing of these costs. Through recent ongoing discussions with interested parties, we learned that interested parties are concerned with the recognition of costs incurred from PXR services and are wanting more consistency in the pricing of these services, including the application of an inflation factor.

We acknowledge the interested parties' concerns and clarify that interested parties may best engage with the MACs through appropriate reporting of cost data in the MAC requested format. This information provided by interested parties can help MACs establish payment rates that are more reflective of costs incurred. MACs are then able to consider this cost information and apply an inflation factor to update changes in costs year over year.

However, CMS recognizes that we should maintain consistency in pricing these services that are more indicative of changes in costs that occur yearly. While still preserving MAC discretion, CMS highlights the usage of an ambulance inflation factor (AIF) that is typically used to adjust ambulance services, which include transportation costs. The AIF is updated annually, and we believe MACs may consider using the AIF to price PXR services when establishing payment rates that are more consistent and reflective of costs incurred.

Additionally, interested parties highlighted inconsistency with language found in our manual and program memoranda policies related to transportation costs. Therefore, to remain consistent and transparent in the pricing of PXR services, we are proposing to revise language in our Medicare Claims Processing manual (Chapter 13, 90.3 and Chapter 23, 30.5) to reflect any updates to our guidance for these services.

(35) Non-Chemotherapy Administration

CMS received inquiries from several external parties with concerns that MACs have developed local coverage determinations (LCDs) and local coverage articles (LCAs) that down code or restrict payment for complex and non-chemotherapeutic drug administration for CPT code series 96401–96549, when used for the administration of several biologic and infusion drugs, including drugs furnished to treat, for example, rheumatology related conditions.

CMS requested information in the CY 2024 PFS proposed rule (88 FR 52837) seeking public feedback regarding the concerns of down coding or denials for the administration of non-chemotherapeutic infusion drugs. We received comments that asked for additional clarification from CMS regarding the payment guidelines for the complex non-chemotherapeutic administration code series and updates to the IOM. Commenters urged CMS to provide additional guidance clarifying the conditions under which these complex infusion drugs should be payable.

In response to the comments received, and in response to continuing inquiries on downcoding and or restrictions on payment for non-chemotherapy complex infusion services, we are proposing an updated policy based largely on the IOM Medicare Claims Processing Manual, Chapter 12, section 30.5, to include language currently consistent with CPT code definitions for the complex non-chemotherapy infusion code series stating that the administration of infusion for particular kinds of drugs and biologics can be considered complex and may be appropriately reported using the chemotherapy administration CPT codes 96401–96549. We note that CPT guidance describes requirements for these non-chemotherapy complex drugs or biologic agents to include the need for staff with advanced practice training and competency, such as, a physician or other qualified health care professional to monitor the patient during these infusions due to the incidence of severe adverse reactions. There are also special considerations for preparation, dosage, or disposal for these infusion drugs. These services do involve serious patient risk which requires frequent consults with a physician or other qualified healthcare professional. Based on these facts and comments, we are proposing to update our subregulatory guidance accordingly.

This will also provide complex clinical characteristics for the MACs to consider as criteria when determining payment of claims for these services. The current IOM language does not include the unique characteristics of the administration of these drugs that could provide additional context to the MACs when they are determining appropriate payment. Updating the IOM with the increased detail of these codes would be responsive to the concerns and requests of external parties and will ensure the IOM is consistent with published guidance.

Therefore, we are soliciting and welcome comments on our proposal to revise the IOM to better reflect how complex non-chemotherapeutic drug administration infusion services are furnished and billed.

(36) Hospital Inpatient or Observation (I/O) Evaluation and Management (E/M) Add-On for Infectious Diseases (HCPCS Code GIDXX)

Interested parties have continued to engage with CMS and provide recommendations to recognize the increased work associated with diagnosis, management, and treatment of infectious diseases that may not be adequately accounted for in current hospital inpatient or observation E/M codes. Infectious diseases are unique in that they present infection control risks for the patient and close contacts, including healthcare staff, that require attention to safely care for the patient. They present unique challenges in diagnosis in that any previous healthcare interaction could affect the individual resistance patterns of pathogens infecting the individual patient and require close contact with public health agencies since resistance patterns are constantly changing, so a much more extensive medical review is required. Additionally, individual decisions regarding treatment are unique in that use in one patient affects resistance patterns of the entire population, which requires additional expertise to inform antimicrobial selection and management.

We believe that the timing is appropriate for establishing a payment rate for infectious disease physician services since the COVID–19 PHE has ignited a hypervigilance for infectious diseases. Therefore, for CY 2025, we are proposing a new HCPCS code to describe intensity and complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease performed by a physician with specialized training in infectious diseases. The full proposed descriptor for the hospital I/O E/M visit complexity add-on code is HCPCS code GIDXX (*Visit complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease by an infectious diseases consultant, including disease transmission risk assessment and mitigation, public health investigation, analysis, and testing, and complex antimicrobial therapy counseling and treatment. (add-on code, list separately in addition to hospital inpatient or observation evaluation and management visit, initial, same day discharge, or subsequent*). We anticipate that HCPCS code GIDXX would be reported by physicians with specialized infectious disease training.

We do not believe we should limit the scope of codes with which this proposed add-on HCPCS code could be billed based on visit level; or initial, same day discharge, or subsequent hospital inpatient or observation codes. We are proposing HCPCS code GIDXX as an add-on code (ZZZ global period) separately reportable in addition to CPT codes 99221 (*Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level medical decision making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.*), 99222 (*Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 55 minutes must be met or exceeded.*), 99223 (*Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 75 minutes must be met or exceeded.*), 99231 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 25 minutes must be met or exceeded.*), 99232 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded.*), 99233 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 50 minutes must be met or exceeded.*), 99234 (*Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.*), 99235 (*Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 70 minutes must be met or exceeded.*), and 99236 (*Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 85 minutes must be met or exceeded.*). Based on feedback from commenters on the CY 2022 PFS proposed rule comment solicitation regarding infectious diseases (86 FR 65125 through 65126) and feedback from interested parties, HCPCS code GIDXX would include the following proposed service elements:

1. Disease Transmission Risk Assessment and Mitigation

- Developing, following, and supervising specialized, individualized infection control protocols for an individual patient based on their diagnosis and risks in order to reduce risk of disease transmission.
- Coordinating with human resources regarding infection prevention and control measures to enable healthcare facility staff to safely care for patient.
- Counseling patients, family members and caregivers regarding infection prevention.
- Managing infection prevention and treatment protocols associated with transitions of care for complex patients.

2. Public Health Investigation, Analysis, and Testing

- In-depth patient chart review that entails going back farther in time and assessing the complete breadth of all health care interactions, with higher-level synthesis for complex diagnoses.
- Communicating with the clinical microbiology lab and directly reviewing specimens.
- Coordinating specialized diagnostic evaluations (for example, identifying and facilitating diagnostic laboratory tests only available at specialized laboratories, the state health

department, and/or the Centers for Disease Control & Prevention).

- Coordinating with Federal, State and local public health agencies and laboratories to assist with contact tracing, obtaining specimens for specialized testing, and/or identifying prior testing and treatment for communicable diseases in other jurisdictions.

3. Complex Antimicrobial Therapy Counseling & Treatment

- Counseling patients, family members, and caregivers regarding antimicrobial stewardship and resistance for the patient.
- Engaging in complex medical decision-making associated with antimicrobial prescribing including considerations such as antimicrobial resistance patterns, emergence of new variants/strains, recent antibiotic exposure, interactions/complications from comorbidities including concurrent infections, public health considerations to minimize development of antimicrobial resistance, and emerging and re-emerging infections.

For HCPCS code GIDXX, we are proposing a work RVU of 0.89 based on the work RVU for HCPCS code G2211 (*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)*), which is 0.33, multiplied by a ratio of the work RVUs for CPT codes 99223 and 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.*), 3.50 and 1.30, respectively. (This ratio is the work RVU of CPT code 99223 divided by the work RVU of CPT code 99213, 3.50 divided by 1.30, which equals 2.69. Multiplying the 0.33 work RVU of HCPCS code G2211 times 2.69 results in our proposed work RVU of 0.89.) We believe the relationship between the complexity add-on HCPCS code G2211 and a common base code for the add-on code, CPT code 99213, would strike the correct balance to estimate the time and complexity associated with the new HCPCS code GIDXX, compared to what we believe will be a common base code for this new add-on code, CPT code 99223. HCPCS code G2211 has a total time of 11 minutes, therefore, we are proposing a total time of 30 minutes for HCPCS code GIDXX based on the same ratio (11 minutes times the same 2.69 ratio equals 30 minutes). HCPCS code G2211 has no direct PE inputs, and we are proposing the same for HCPCS code GIDXX.

We believe that the proposed work RVU appropriately falls between the following bracket add-on codes: HCPCS code G0316 (*Prolonged hospital inpatient or observation care evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99223, 99233, and 99236 for hospital inpatient or observation care evaluation and management services). (do not report g0316 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 99418, 99415, 99416). (do not report g0316 for any time unit less than 15 minutes)*) with a work RVU of 0.61 and the professional principal care management, chronic care management, and complex chronic care management CPT codes 99425 (*Principal care management services, for a single high-risk disease, with the following required elements: one complex chronic condition expected to last at least 3 months, and that places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death, the condition requires development, monitoring, or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen and/or the management of the condition is unusually complex due to comorbidities, ongoing communication and care coordination between relevant practitioners furnishing care; each additional 30 minutes provided personally by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)*), 99437 (*Chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; each additional 30 minutes by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)*), and 99489 (*Complex chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored, moderate or high complexity medical decision making; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)*) with work RVUs of 1.00.

To help inform whether our proposed descriptor is appropriate and reflects the typical service, we are seeking comment on the typical amount of time infectious disease physicians spend on the proposed service elements and the relative intensity compared to similar service elements of other CPT codes. We note that the valuation of HCPCS code GIDXX is meant to capture the visit complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease by an infectious diseases consultant that is not accounted for in the appropriate hospital inpatient or observation E/M base code billed by the infectious disease physician.

Interested parties have stated that consultations are a common E/M service performed by infectious disease clinicians, particularly in the inpatient setting, but stated that these services are no longer recognized by Medicare. Interested parties have also stated that this has resulted in a significant reduction in reporting and payment for infectious disease physician services. We note that we address this in the CMS Claims Processing Manual, Chapter 12, section 30.6.9 F, stating that ''Physicians may bill initial hospital care service codes (99221–99223), for services that were reported with CPT consultation codes (99241–99255) prior to January 1, 2010, when the furnished service and documentation meet the minimum key component work and/or medical necessity requirements. Physicians may report a subsequent hospital care CPT code for services that were reported as CPT consultation codes (99241–99255)

prior to January 1, 2010, where the medical record appropriately demonstrates that the work and medical necessity requirements are met for reporting a subsequent hospital care code (under the level selected), even though the reported code is for the provider's first E/M service to the inpatient during the hospital stay.'' Accordingly, we are seeking comment on any potential barriers for infectious disease physicians to use the initial and subsequent day hospital inpatient or observation codes, CPT codes 99221 through 99223 and 99231 through 99233, for consultations if they meet the coding requirements for time and/or medical decision making (MDM). We note that understanding the barriers to utilizing these codes is important, as these codes will serve as the base codes for HCPCS code GIDXX, and will need to be billed by the infectious disease physician prior to billing HCPCS code GIDXX.

Finally, we recognize that historically, the CPT Editorial Panel has frequently created CPT codes describing services that we originally established using G codes and adopted them through the CPT Editorial Panel process. We note that we would consider using any newly available CPT coding to describe services similar to those described here in future rulemaking.

(37) Preexposure Prophylaxis (PrEP) of Human Immunodeficiency Virus (HIV)

To facilitate prompt beneficiary access to PrEP for CY 2024, we established 3 HCPCS G codes that describe the service of counseling and administration of Human Immunodeficiency Virus (HIV) pre-exposure prophylaxis drugs. Specifically, HCPCS codes G0011 (*Individual counseling for pre-exposure prophylaxis (PrEP) by physician or QHP to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence, 15–30 minutes*) and G0013 (*Individual counseling for pre-exposure prophylaxis (PrEP) by clinical staff to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence*) describe the counseling portion of the service, and G0012 (*Injection of pre-exposure prophylaxis (PrEP) drug for HIV prevention, under skin or into muscle*) describes the injection of the medication.

CMS released a Proposed NCD for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention on July 12, 2023. This proposed NCD announced CMS' intent to cover and pay for those drugs under the 1861(ddd) additional preventive services authority, and a final decision on the NCD is forthcoming. For CY 2025, we are proposing national rates for these HCPCS codes that reflect the relative resource costs associated with the counseling and drug administration portions of the service, pending finalization of the NCD. For HCPCS code G0011, we are proposing a work RVU of 0.45 based off work and direct PE inputs crosswalked from HCPCS code G0445 (*High intensity behavioral counseling to prevent sexually transmitted infection; face-to-face, individual, includes: education, skills training and guidance on how to change sexual behavior; performed semi-annually, 30 minutes*). For HCPCS code G0012, we are proposing a work RVU of 0.17 based on the work and direct PE crosswalked from CPT code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*), and for HCPCS code G0013 we are proposing a work RVU of 0.18 based on the work and direct PE inputs crosswalked from CPT code 99211 (*Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional*). We appreciate having this opportunity for interested parties to provide feedback on the most accurate way to value these services.

(38) Opfolda

For CY 2024, to facilitate beneficiary access to treatment of late-onset Pompe disease with miglustat in combination with cipaglucosidae alfa-atga, we created a new HCPCS code, G0138, describing the service of administration of cipaglucosidase alfa-atga (Pombiliti), which includes the intravenous administration of cipaglucosidase alfa-atga, the provider or supplier's acquisition cost of miglustat, clinical supervision, and oral administration of miglustat. HCPCS code G0138 (*Intravenous infusion of cipaglucosidase alfaatga, including provider/supplier acquisition and clinical supervision of oral administration of miglustat in preparation of receipt of cipaglucosidase alfa-atga*) was added to the PFS effective April 1, 2024, as a contractor priced service. More information regarding the creation of HCPCS code G0138 can be found at *https://www.cms.gov/files/document/2023-hcpcs-application-summary-quarter-4-2023-drugs-and-biologicals-updated-1/30/2024.pdf*.

For CY 2025, we are proposing national pricing for this service that reflects the relative resource costs associated with the infusion administration of Cipaglucosidae alfa-atga and clinical supervision and provision of Miglustat oral with acquisition costs. We are proposing a work RVU of 0.21 for HCPCS code G0138 based on a crosswalk from CPT code 96365 (*Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour*). This includes a crosswalked total time of 9 minutes and an intraservice time of 5 minutes. We are also proposing to crosswalk the direct PE inputs from CPT code 96365 for use in valuing HCPCS code G0138. However, we are adding 1 minute of L056A clinical staff time during the preservice portion of the service period to capture the RN/OCN observation of the patient during administration of the Opfolda pill. In addition, to account for the cost of the provision of the self-administered Opfolda as a direct PE input, we are incorporating the wholesale acquisition cost (WAC) data from the most recent available quarter. We are proposing a price of $32.50 for the supply input that describes a 65mg capsule of Opfolda (supply code SH111). We are seeking feedback from interested parties on our proposal of national pricing, as well as our proposed work RVU and direct PE inputs for HCPCS code G0138 to ensure proper payment for this service.

(39) Payment for Caregiver Training Services

a. Background

In the CY 2017 PFS final rule (81 FR 80330 through 80331), we finalized payment for new CPT code(s) describing administration of a patient-focused health risk assessment instrument as well as administration of a caregiver-focused health risk assessment instrument. In the CY 2024 PFS final rule (88 FR 78914), we finalized the assignment of a payable status for caregiver training services (CTS) for therapy and behavior management/modification services (without the patient present) and finalized the RUC-recommended valuations for these services to better recognize the role that caregivers play in reasonable and necessary care for Medicare beneficiaries. These codes allow treating practitioners to report the training furnished to a caregiver, in tandem with the diagnostic and treatment services furnished directly to the patient, in

strategies and specific activities to assist the patient in carrying out the treatment plan.

We finalized in the CY 2024 PFS final rule that payment may be made for CTS services when the treating practitioner identifies a need to involve and train one or more caregivers to assist the patient in carrying out a patient-centered treatment plan. We also finalized that because CTS services are furnished outside the patient's presence, the treating practitioner must obtain the patient's (or representative's) consent for the caregiver to receive the CTS. Additionally, we finalized that the identified need for CTS and the patient's (or representative's) consent for one or more specific caregivers to receive CTS must be documented in the patient's medical record. These finalized policies apply to current CTS coding and we are also proposing for them to apply to the newly proposed CTS coding that follows. We continue to receive questions and requests from interested parties about how we can refine payment for these services.

b. Caregiver Assessment

In response to interested parties' requests for assessment of a caregiver's knowledge to be included in caregiver training, we are clarifying that when reasonable and necessary, assessing the caregiver's skills and knowledge for the purposes of caregiver training services could be included in the service described by CPT code 96161 *(Administration of caregiver-focused health risk assessment instrument (e.g., depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument)* to determine if caregiver training services are needed. We also note that CPT code 96161 is currently on the Medicare Telehealth list.

We note that, as specified in the CY 2017 PFS final rule (81 FR 80330), in particular cases, caregiver-focused health risk assessments can be necessary components of services furnished to Medicare beneficiaries. Examples where this service may be reasonable and necessary may include assessment of maternal depression in the active care of infants, assessment of parental mental health as part of evaluating a child's functioning, assessment of caretaker conditions as indicated where atypical parent/child interactions are observed during care, and assessment of caregivers as part of care management for adults whose physical or cognitive status renders them incapable of independent living and dependent on another adult caregiver. Commenters cited that some examples of such individuals might include intellectually disabled adults, seriously disabled military veterans, and adults with significant musculoskeletal or central nervous system impairments (81 FR 80331).

We are proposing that because the caregiver-focused health risk assessment may be furnished outside the patient's presence, the treating practitioner must obtain the patient's (or representative's) consent for the caregiver to receive the assessment. We are also proposing that the definition of ''caregiver'' specified in the CY 2024 PFS final rule (88 FR 78917) will be the same for caregiver training services and the caregiver-focused health risk assessment.

We are seeking comment on these proposals and clarifications.

c. Proposals and New Coding

(A) Proposed Direct Care Caregiver Training Services

i. Coding

We are proposing to establish new coding and payment for caregiver training for direct care services and supports. The topics of training could include, but would not be limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control. Unlike other caregiver training codes that are currently paid under the PFS, the caregiver training codes for direct care services and support focus on specific clinical skills aimed at the caregiver effectuating hands-on treatment, reducing complications, and monitoring the patient. For example, in the direct care CTS codes, a caregiver could be taught how to properly change wound dressings to promote healing and prevent infection. This skill, among other direct care services, would not fall into the categories of CTS codes that currently exist (behavior management/modification or strategies and techniques to facilitate the patient's functional performance in the home or community) but is integral in effectuating the patient's treatment plan. Like other codes describing caregiver training services, these proposed new codes would reflect the training furnished to a caregiver, in tandem with the diagnostic and treatment services furnished directly to the patient, in strategies and specific activities to assist the patient to carry out the treatment plan. We believe that CTS may be reasonable and necessary when they are integral to a patient's overall treatment and furnished after the treatment plan is established. The CTS themselves need to be congruent with the treatment plan and designed to effectuate the desired patient outcomes. We believe this is especially the case in medical treatment scenarios where assistance by the caregiver receiving the CTS is necessary to ensure a successful treatment outcome for the patient—for example, when the patient cannot follow through with the treatment plan for themselves.

We are proposing three new HCPCS codes: GCTD1 (*Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to-face; initial 30 minutes*), GCTD2 (*Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service) (Use GCTD2 in conjunction with GCTD1)*), and GCTD3 (*Group caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to-face with multiple sets of caregivers)*).

We continue to believe that CTS may be reasonable and necessary when they are integral to a patient's overall treatment and furnished after the treatment plan is established. The medical or direct care CTS themselves need to be congruent with the treatment plan and designed to effectuate the desired patient outcomes. We believe this is especially the case in medical treatment scenarios where assistance by the caregiver receiving the CTS is necessary to ensure a successful treatment outcome for the patient—for example when the patient cannot follow through with the treatment plan for themselves. Direct care training for caregivers of Medicare beneficiaries should be directly relevant to the person-centered treatment plan for the patient in order for the services to be considered reasonable and necessary under the Medicare program. Each training activity should be clearly identified and documented in the treatment plan. Additionally, this would not be billable for patients under home

health plan of care, receiving at-home therapy, or receiving DME services for involved medical equipment and supplies.

We are seeking additional information from commenters about potential service overlaps and potential examples of direct care services to receive caregiver training to inform our final policy. We are soliciting public comment on each of our proposals for direct care CTS.

ii. Valuation

For GCTM1, we propose a direct crosswalk to CPT Code 97550 (*Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [iADLs], transfers, mobility, communication, swallowing, feeding, problem-solving, safety practices) (without the patient present), face to face; initial 30 minutes*), with a work RVU of 1.00 as we believe this service reflects the resource costs associated when the billing practitioner performs HCPCS code GCTM1. CPT code 97550 has an intraservice time of 30 minutes, and the physician work is of similar intensity to our proposed HCPCS code GCTM1. Therefore, we are proposing a work time of 30 minutes intraservice time (40 minutes of total time) for HCPCS code GCTM1 based on this same crosswalk to CPT 97550. We are also proposing to use this crosswalk to establish the direct PE inputs for HCPCS code GCTM1.

For GCTM2, we are proposing a direct crosswalk to CPT Code 97551 (*Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [iADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face to face; each additional 15 minutes (List separately in addition to code for primary service)*), with a work RVU of 0.54 as we believe this service reflects the resource costs associated when the billing practitioner performs HCPCS code GCTM2. CPT code 97551 has an intraservice time of 17 minutes, and the physician work is of similar intensity to our proposed HCPCS code GCTM2. Therefore, we are proposing a work time of 17 minutes for HCPCS code GCTM2 based on this same crosswalk to CPT 97551. We also propose to use this crosswalk to establish the direct PE inputs for HCPCS code GCTM2.

For GCTM3, we propose a direct crosswalk to CPT Code 97552 (*Group caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [iADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face to face with multiple sets of caregivers*), with a work RVU of 0.23 as we believe this service reflects the resource costs associated when the billing practitioner performs HCPCS code GCTM3. CPT code 97552 has an intraservice time of 9 minutes, and the physician work is of similar intensity to our proposed HCPCS code GCTM1. Therefore, we are proposing a work time of 9 minutes intraservice time (14 minutes total time) for HCPCS code GCTM3 based on this same crosswalk to CPT 97552. We are also proposing to use this crosswalk to establish the direct PE inputs for HCPCS code GCTM3.

We are seeking comment on supplies/equipment that would be typical for the newly created direct care strategies and techniques CTS codes.

We believe these services would largely involve contact between the billing practitioner and the caregiver through in-person interactions, which could be conducted via telecommunications, as appropriate. Therefore, we are proposing to add these codes to the Medicare Telehealth Services List to accommodate a scenario in which the practitioner completes the caregiver training service via telehealth. Please see section II.D. for more information on Medicare Telehealth Services.

We are seeking comments on these proposals.

(B) Individual Behavior Management/Modification Caregiver Training Services

i. Coding

We are proposing to establish new coding and payment for caregiver behavior management and modification training that could be furnished to the caregiver(s) of an individual patient. Current CPT coding (CPT 96202 and 96203) allows for ''multiple-family group behavior management/modification training services,'' meaning that this caregiver training service can only be furnished in a group setting with multiple sets of caregivers of multiple beneficiaries (please reference 88 FR 78818 for discussion of CPT 96202 and 96203). We are proposing two new HCPCS codes: GCTB1 (*Caregiver training in behavior management/modification for caregiver(s) of a patient with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; initial 30 minutes*) and GCTB2 (*Caregiver training in behavior management/modification for caregiver(s) of a patient with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service) (Use GCTB2 in conjunction with GCTB1)*).

We continue to believe that CTS may be reasonable and necessary when they are integral to a patient's overall treatment and furnished after the treatment plan is established. The behavior management/modification CTS themselves need to be congruent with the treatment plan and designed to effectuate the desired patient outcomes. We believe this is especially the case in medical treatment scenarios where assistance by the caregiver receiving the CTS is necessary to ensure a successful treatment outcome for the patient—for example when the patient cannot follow through with the treatment plan for themselves. Behavior management/modification training for caregivers of Medicare beneficiaries should be directly relevant to the person-centered treatment plan for the patient in order for the services to be considered reasonable and necessary under the Medicare program. Each training activity should be clearly identified and documented in the treatment plan. All other policies and procedures surrounding CPT 96202 and 96203 will also apply to these services (88 FR 78914–78920).

We are seeking comment on these proposals.

ii. Valuation

For GCTB1, we propose a direct crosswalk to CPT Code 97550 (*Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [iADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face to face; initial 30 minutes*), with a work RVU of 1.00 as we believe this service reflects the resource costs associated when the billing practitioner performs HCPCS code GCTB1. CPT code 97550 has an intraservice time of 30 minutes, and the physician work is of similar intensity to our proposed HCPCS code GCTB1. Therefore, we are proposing a work time of 30 minutes

intraservice time (40 minutes of total time) for HCPCS code GCTB1 based on this same crosswalk to CPT 97550. We also propose to use this crosswalk to establish the direct PE inputs for HCPCS code GCTB1. We are seeking comment on supplies/equipment that would be typical for the newly created individual behavior management/modification CTS codes.

For GCTB2, we propose a direct crosswalk to CPT Code 97551 (*Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [iADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face to face; each additional 15 minutes (List separately in addition to code for primary service)*), with a work RVU of 0.54 as we believe this service reflects the resource costs associated when the billing practitioner performs HCPCS code GCTB2. CPT code 97551 has an intraservice time of 17 minutes, and the physician work is of similar intensity to our proposed HCPCS code GCTB2. Therefore, we are proposing a work time of 17 minutes for HCPCS code GCTB2 based on this same crosswalk to CPT 97551. We also propose to use this crosswalk to establish the direct PE inputs for HCPCS code GCTB2.

We are seeking comment on supplies/equipment that would be typical for the newly created individual behavior management/modification CTS codes.

We believe these services would largely involve contact between the billing practitioner and the caregiver through in-person interactions, which could be conducted via telecommunications as appropriate. Therefore, we are proposing to add these codes to the Medicare Telehealth Services List to accommodate a scenario in which the practitioner completes the caregiver training service via telehealth. Please see section II.D. for more information on Medicare Telehealth Services.

We are seeking comments on these proposals.

(C) Patient Consent

In the CY 2024 PFS final rule (88 FR 78916), we finalized a requirement that the treating practitioner must obtain the patient's (or representative's) consent for the caregiver to receive the CTS and that the identified need for CTS and the patient's (or representative's) consent for one or more specific caregivers to receive CTS be documented in the patient's medical record.

We are proposing that consent for CTS can be provided verbally by the patient (or representative). This would align consent requirements with other services paid under the PFS that may be furnished without the patient present, such as certain care management services. This proposal would apply to CPT codes 97550, 97551, 97552, 96202, and 96203, as well as any caregiver training services HCPCS codes finalized in this year's rule, and any subsequently created caregiver training service codes. We are seeking comment on this proposal.

(D) Addition to Telehealth List

Please see section II.D. of this proposed rule, Payment for Medicare Telehealth Services, for the discussion related to proposals to add CTS to the Medicare Telehealth list.

(40) Request for Information for Services Addressing Health-Related Social Needs (Community Health Integration (G0019, G0022), Principal Illness Navigation (G0023, G0024), Principal Illness Navigation—Peer Support (G0140, G0146), and Social Determinants of Health Risk Assessment (G0136))

a. Background

In the CY 2024 PFS final rule (88 FR 78920), we finalized G-codes to reflect new coding and payment for services describing Community Health Integration (CHI), G0019 (Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month), and G0022 (Community health integration services, each additional 30 minutes per calendar month), which may include a community health worker (CHW), incident to the professional services and under the general supervision of the billing practitioner. We finalized a new stand-alone G code describing a SDOH Risk Assessment, G0136 (Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5–15 minutes, not more often than every 6 months). SDOH risk assessment refers to a review of the individual's SDOH or identified social risk factors that influence the diagnosis and treatment of medical conditions. We also finalized PIN services, described by HCPCS code G0023 (Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month) and G0024 (*Principal Illness Navigation services, additional 30 minutes per calendar month*); G0140 (*Principal Illness Navigation—Peer Support by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a certified peer specialist; 60 minutes per calendar month*) and G0146 (*Principal Illness Navigation—Peer Support, additional 30 minutes per calendar month*), to better recognize through coding and payment policies when certified or trained auxiliary personnel under the direction of a billing practitioner, which may include a patient navigator or certified peer support specialist, are involved in the patient's health care navigation as part of the treatment plan for a serious, high-risk disease expected to last at least 3 months, that places the patient at significant risk of hospitalization or nursing home placement, acute exacerbation/decompensation, functional decline, or death.

b. Request for Information on Services Addressing Health-Related Social Needs

For CY 2025 we are issuing a broad request for information (RFI) on the newly implemented Community Health Integration (CHI) (HPCCS codes G0019, G0022), Principal Illness Navigation (PIN) (HCPCS codes G0023, G0024), Principal Illness Navigation—Peer Support (PIN–PS) (HCPCS codes G0140, G0146), and Social Determinants of Health Risk Assessment (SDOH RA) (HCPCS code G0136) services to engage interested parties on additional policy refinements for CMS to consider in future rulemaking.

We are interested in better addressing the social needs of beneficiaries and requesting information on the codes we created and finalized beginning in CY 2024 to fully encompass what interested parties and commenters believe should be included in the coding and payment we recently established. We are seeking comment on any related services that may not be described by the current coding that we finalized in the CY 2024 PFS final rule and that are medically reasonable and necessary ''for the diagnosis or treatment of illness or injury'' under section 1862(a)(1)(A) of the Act. We believe we can work within the current coding framework and explore additional opportunities to create codes that describe reasonable and necessary services furnished by billing practitioners and the auxiliary personnel under their general supervision. We are interested in feedback regarding any barriers to furnishing the services addressing health-related social needs, and if the

service described by the codes we established are allowing practitioners to better address unmet social needs that interfere with the practitioners' ability to diagnose and treat the patient. This could include barriers specific to certain populations, including rural and tribal communities, residents of the U.S. Territories, individuals with disabilities, individuals with limited English proficiency, or other populations who experience specific unmet social needs.

In response to the CY 2024 PFS proposed rule, we heard from commenters that CSWs often connect individuals with community-based resources to address unmet social needs that affect the diagnosis and treatment of medical problems. CSWs can bill Medicare directly for services they personally perform for the diagnosis or treatment of mental illness but are not authorized by statute to bill for services that are provided by auxiliary personnel incident to their professional services. Since CHI and PIN codes are typically provided by auxiliary personnel supervised by the billing practitioner, CSWs could serve as the auxiliary personnel. CSWs could not directly bill Medicare for CHI and PIN services if they were provided by auxiliary personnel, as they are not authorized to supervise, bill, and be paid directly by Medicare for services that are provided by auxiliary personnel incident to their professional services. We believe the current CHI and PIN coding accurately captures the services CSWs currently provide, including the work involved in connecting beneficiaries with community-based resources for unmet social needs that affect the diagnosis or treatment of medical problems. As we stated previously in the CY 2024 PFS final rule (88 FR 78926), ''the codes do not limit the types of other health care professionals, such as registered nurses and social workers, that can perform CHI services (and PIN services, as we discuss in the next section) incident to the billing practitioner's professional services, so long as they meet the requirements to provide all elements of the service included in the code, consistent with the definition of auxiliary personnel at § 410.26(a)(1).'' We are clarifying that when we refer to ''certified or trained auxiliary personnel'' in the following codes: G0019, G0022, G0023, G0024, G0140, G0146, this also includes CSWs.

We are requesting information if there are other types of auxiliary personnel, other certifications, and/or training requirements that are not adequately captured in current coding and payment for these services. We are also interested in hearing more about what types of auxiliary personnel are typically furnishing these services, including the certifications and/or licensure that they have. We are also interested in whether there are nuances or considerations that CMS should understand related to auxiliary personnel and training, certifications or licensure barriers or requirements that are specifically experienced by practitioners serving underserved communities. This could include settings such as community mental health centers, community health clinics including FQHCs and RHCs, tribal health centers, migrant farmworker clinics, or facilities located in and serving rural and geographically isolated communities including the U.S. Territories.

As noted in the CY 2023 PFS final rule (87 FR 69790) and explained in the CY 2023 PFS proposed rule (87 FR 46102), when we refer to community-based organizations, we mean public or private not-for-profit entities that provide specific services to the community or targeted populations in the community to address the health and social needs of those populations. They may include community-action agencies, housing agencies, area agencies on aging, centers for independent living, aging and disability resource centers or other non-profits that apply for grants or contract with healthcare entities to perform social services. They may receive grants from other agencies in the U.S. Department of Health and Human Services, including Federal grants administered by the Administration for Children and Families (ACF), Administration for Community Living (ACL), the Centers for Disease Control and Prevention (CDC), the Substance Abuse and Mental Health Services Administration (SAMHSA), or State-funded grants to provide social services. We stated that, generally, we believe such organizations know the populations and communities they serve and may have the infrastructure or systems in place to assist practitioners to provide CHI and PIN services. We stated that we understood that many community-based organizations (CBOs) provide social services and do other work that is beyond the scope of CHI and PIN services, but we believed they are well-positioned to develop relationships with practitioners for providing reasonable and necessary CHI and PIN services.

We are interested in hearing more about CBOs and their collaborative relationships with billing practitioners. The new codes for CHI and PIN services recognized CBOs and their role in providing auxiliary personnel under the general supervision of the billing practitioners. We are seeking comment regarding the extent to which practitioners are contracting with CBOs (including current or planned contracting arrangements) for auxiliary personnel purposes, and if there is anything else CMS should do to clarify services where auxiliary personnel can be employed by the CBO, so long as they are under the general supervision of the billing practitioner. Given that the CHI and PIN services may be provided incident to the billing practitioner's professional services, we are also seeking comment on whether the incident to billing construct is appropriate for CBOs to supplement pre-existing staffing arrangements and the CBO/provider interface. We are also seeking comment on CBOs' roles, the extent to which practitioners are contracting with CBOs, incident to billing, and auxiliary personnel employed by CBOs under general supervision of practitioners serving and located in rural, tribal and geographically isolated communities, including the U.S. Territories.

We are also interested in any comments from interested parties across provider types and from practitioners in geographically isolated communities (for example, rural, tribal, and island communities) and otherwise underserved communities about coding Z codes on claims associated with billing for CHI, PIN, and SDOH risk assessment codes. We recognize that when screening for social needs, such needs may be identified and are interested in learning whether practitioners are also capturing unmet social needs on claims using Z codes for social risk factors or in some other way, and any barriers or opportunities to increase coding of Z codes when social risk factors screen positive.

Over the past several years, we have worked to develop payment mechanisms under the PFS to improve the accuracy of valuation and payment for the services furnished by physicians and other health care professionals, especially in the context of evolving models of care and addressing unmet social needs that affect the diagnosis and treatment of medical problems. Given the Agency's broader policy goals of increasing access to care, we are requesting information from interested parties and commenters on anything else that we should consider in the context of these codes and what else we could consider to be included in this newly established code set.

We are seeking comments on ways to identify specific services and to recognize possible barriers to improved access to these kinds of high-value,

potentially underutilized services by Medicare beneficiaries.

We are seeking public comment to understand more clearly how often evidence-based care for persons with fractures, for example, is not provided and the reasons for this, and how recent or new PFS codes, or their revaluation, might help resolve specific barriers to its provision. The PFS currently includes many codes that pay for various components of care to manage patients with fractures over a course of treatment, such as transitional care management (TCM) and other care management services, evaluation and management visits (including the inherent complexity add-on for office/outpatient visits), principal illness navigation services, community health integration services, and the social determinants of health risk assessment. We refer readers to our recent guidance on these services on the CMS website at *https://www.cms.gov/files/document/health-related-social-needs-faq.pdf*.

Medicare also pays for bone mass measurement/density tests (*MLN006559—https://www.cms.gov/medicare/prevention/prevntiongeninfo/medicare-preventive-services/mps-quickreferencechart-1.html#BONE_MASS*, and for outpatient osteoporosis medication under Part D and, in some cases, Part B (*https://www.medicare.gov/coverage/osteoporosis-drugs*). These services can be billed on their own, or in combination, where applicable. We note that in the CY 2020 PFS final rule (84 FR 62685) and CY 2021 PFS final rule (85 FR 84547), CMS indicated that TCM may be billed concurrently with other care management codes when relevant, medically necessary, and not duplicative.

We are proposing new coding in other sections of this CY 2025 proposed rule that might be used to bill for managing fractures under a treatment plan, including the global post-operative add-on code, HCPCS code GPOC1, in section II.G.5 of this proposed rule and the advanced primary care management codes in section II.G.2 of this proposed rule. Interested parties have indicated that orthopedic surgeons, skilled nursing facilities (SNFs), and other practitioners and providers may not be providing comprehensive patient centered fracture management care for quality, payment, or administrative reasons, and that there is inadequate ''hand-off'' when post-discharge fracture care is transferred to practitioners in the community. They indicate a systemic disconnect on which provider and/or specialty is responsible for osteoporosis diagnosis and treatment, and that global surgical periods focus on acute fracture recovery rather than addressing osteoporosis. We are interested in hearing if the proposed global postop add-on code could help resolve these issues.

BILLING CODE P

TABLE 13: CY 2025 Work RVUs for New, Revised, and Potentially Misvalued Codes

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
15XX1	Harvest of skin for skin cell suspension autograft; first 25 sq cm or less	NEW	3.00	C	Yes
15XX2	Harvest of skin for skin cell suspension autograft; each additional 25 sq cm or part thereof (List separately in addition to code for primary procedure)	NEW	2.00	C	Yes
15XX3	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin	NEW	2.51	C	Yes
15XX4	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; each additional 25 sq cm of harvested skin or part thereof (List separately in addition to code for primary procedure)	NEW	2.00	C	Yes
15XX5	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; first 480 sq cm or less	NEW	10.97	C	Yes
15XX6	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; each additional 480 sq cm or part thereof (List separately in addition to code for primary procedure)	NEW	2.50	C	Yes
15XX7	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 480 sq cm or less	NEW	12.50	C	Yes
15XX8	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 480 sq cm or part thereof (List separately in addition to code for primary procedure)	NEW	3.00	C	Yes
25310	Tendon transplantation or transfer, flexor or extensor, forearm and/or wrist, single; each tendon	8.08	9.50	9.00	No
25447	Arthroplasty, intercarpal or carpometacarpal joints; interposition (eg, tendon)	11.14	11.14	10.50	No
26480	Transfer or transplant of tendon, carpometacarpal area or dorsum of hand; without free graft, each tendon	6.90	9.50	9.00	No
2X005	Arthroplasty, intercarpal or carpometacarpal joints; suspension, including transfer or transplant of tendon, with interposition, when performed	NEW	13.90	11.85	No
36514	Therapeutic apheresis; for plasma pheresis	1.81	1.81	1.81	No
36516	Therapeutic apheresis; with extracorporeal immunoadsorption, selective adsorption or selective filtration and plasma reinfusion	1.56	1.56	1.56	No
36522	Photopheresis, extracorporeal	1.75	1.75	1.75	No
3X018	Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day	NEW	1.94	1.94	No
3X019	Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)	NEW	0.79	0.79	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
3X020	Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration	NEW	0.80	0.80	No
3X021	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous	NEW	3.00	3.00	No
4X015	Excision or destruction, open, intra-abdominal (ie, peritoneal, mesenteric, retroperitoneal), primary or secondary tumor(s) or cyst(s), sum of the maximum length of tumor(s) or cyst(s); 5 cm or less	NEW	22.00	22.00	No
4X016	Excision or destruction, open, intra-abdominal (ie, peritoneal, mesenteric, retroperitoneal), primary or secondary tumor(s) or cyst(s), sum of the maximum length of tumor(s) or cyst(s); 5.1 to 10 cm	NEW	28.65	28.65	No
4X017	Excision or destruction, open, intra-abdominal (ie, peritoneal, mesenteric, retroperitoneal), primary or secondary tumor(s) or cyst(s), sum of the maximum length of tumor(s) or cyst(s); 10.1 to 20 cm	NEW	34.00	34.00	No
4X018	Excision or destruction, open, intra-abdominal (ie, peritoneal, mesenteric, retroperitoneal), primary or secondary tumor(s) or cyst(s), sum of the maximum length of tumor(s) or cyst(s); 20.1 to 30 cm	NEW	45.00	40.00	No
4X019	Excision or destruction, open, intra-abdominal (ie, peritoneal, mesenteric, retroperitoneal), primary or secondary tumor(s) or cyst(s), sum of the maximum length of tumor(s) or cyst(s); greater than 30 cm	NEW	55.00	50.00	No
59200	Insertion of cervical dilator (eg, laminaria, prostaglandin) (separate procedure)	0.79	1.20	1.20	No
5X006	Insertion of transurethral ablation transducer for delivery of thermal ultrasound for prostate tissue ablation, including suprapubic tube placement during the same session and placement of an endorectal cooling device, when performed	NEW	4.05	4.05	No
5X007	Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation;	NEW	9.80	9.80	No
5X008	Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation; with insertion of transurethral ultrasound transducer for delivery of thermal ultrasound, including suprapubic tube placement and placement of an endorectal cooling device, when performed	NEW	11.50	11.50	No
5XX05	Cystourethroscopy with insertion of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate	NEW	3.10	3.10	No
5XX06	Catheterization with removal of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate	NEW	1.48	1.48	No
64486	Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) unilateral; by injection(s) (includes imaging guidance, when performed)	1.27	1.20	1.20	No
64487	Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) unilateral; by continuous infusion(s) (includes imaging guidance, when performed)	1.48	1.39	1.39	No
64488	Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) bilateral; by injections (includes imaging guidance, when performed)	1.60	1.40	1.40	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
64489	Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) bilateral; by continuous infusions (includes imaging guidance, when performed)	1.80	1.75	1.75	No
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver	5.10	5.10	5.10	No
64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array	3.79	3.79	3.79	No
66680	Repair of iris, ciliary body (as for iridodialysis)	6.39	10.25	7.97	No
66682	Suture of iris, ciliary body (separate procedure) with retrieval of suture through small incision (eg, McCannel suture)	7.33	10.87	8.74	No
6X004	Implantation of iris prosthesis, including suture fixation and repair or removal of iris, when performed	NEW	12.80	10.67	No
6XX00	Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation of target, intracranial, including stereotactic navigation and frame placement, when performed	NEW	18.95	16.60	No
6XX01	Ablation of 1 or more thyroid nodule(s), one lobe or the isthmus, percutaneous, including imaging guidance, radiofrequency	NEW	5.75	5.75	No
6XX02	Ablation of 1 or more thyroid nodule(s), additional lobe, percutaneous, including imaging guidance, radiofrequency (List separately in addition to code for primary procedure)	NEW	4.25	4.25	No
6XX07	Thoracic fascial plane block, unilateral; by injection(s), including imaging guidance, when performed	NEW	1.50	1.50	No
6XX08	Thoracic fascial plane block, unilateral; by continuous infusion(s), including imaging guidance, when performed	NEW	1.74	1.74	No
6XX09	Thoracic fascial plane block, bilateral; by injection(s), including imaging guidance, when performed	NEW	1.67	1.67	No
6XX10	Thoracic fascial plane block, bilateral; by continuous infusion(s), including imaging guidance, when performed	NEW	1.83	1.83	No
6XX11	Lower extremity fascial plane block, unilateral; by injection(s), including imaging guidance, when performed	NEW	1.34	1.34	No
6XX12	Lower extremity fascial plane block, unilateral; by continuous infusion(s), including imaging guidance, when performed	NEW	1.67	1.67	No
76981	Ultrasound, elastography; parenchyma (eg, organ)	0.59	0.59	0.59	No
76982	Ultrasound, elastography; first target lesion	0.59	0.59	0.59	No
76983	Ultrasound, elastography; each additional target lesion	0.50	0.47	0.47	No
77012	Computed tomography guidance for needle placement (eg, biopsy, aspiration, injection, localization device), radiological supervision and interpretation	1.50	1.50	1.50	No
7XX00	MR safety implant and/or foreign body assessment by trained clinical staff, including identification and verification of implant components from appropriate sources (eg, surgical reports, imaging reports, medical device databases, device vendors, review of prior imaging), analyzing current MR conditional status of individual components and systems, and consulting published professional guidance with written report; initial 15 minutes	NEW	0.00	0.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
7XX01	MR safety implant and/or foreign body assessment by trained clinical staff, including identification and verification of implant components from appropriate sources (eg, surgical reports, imaging reports, medical device databases, device vendors, review of prior imaging), analyzing current MR conditional status of individual components and systems, and consulting published professional guidance with written report; each additional 30 minutes (List separately in addition to code for primary procedure)	NEW	0.00	0.00	No
7XX02	MR safety determination by a physician or other qualified health care professional responsible for the safety of the MR procedure, including review of implant MR conditions for indicated MR examination, analysis of risk vs clinical benefit of performing MR examination, and determination of MR equipment, accessory equipment, and expertise required to perform examination, with written report	NEW	0.60	0.60	No
7XX03	MR safety medical physics examination customization, planning and performance monitoring by medical physicist or MR safety expert, with review and analysis by physician or other qualified health care professional to prioritize and select views and imaging sequences, to tailor MR acquisition specific to restrictive requirements or artifacts associated with MR conditional implants or to mitigate risk of non-conditional implants or foreign bodies, with written report	NEW	0.76	0.76	No
7XX04	MR safety implant electronics preparation under supervision of physician or other qualified health care professional, including MR-specific programming of pulse generator and/or transmitter to verify device integrity, protection of device internal circuitry from MR electromagnetic fields, and protection of patient from risks of unintended stimulation or heating while in the MR room, with written report	NEW	0.75	0.75	No
7XX05	MR safety implant positioning and/or immobilization under supervision of physician or other qualified health care professional, including application of physical protections to secure implanted medical device from MR-induced translational or vibrational forces, magnetically induced functional changes, and/or prevention of radiofrequency burns from inadvertent tissue contact while in the MR room, with written report	NEW	0.60	0.60	No
90480	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, single dose	X	0.25	0.25	No
92132	Computerized ophthalmic diagnostic imaging (eg, optical coherence tomography [OCT]), anterior segment, with interpretation and report, unilateral or bilateral	0.30	0.29	0.29	No
92133	Computerized ophthalmic diagnostic imaging (eg, optical coherence tomography [OCT]), posterior segment, with interpretation and report, unilateral or bilateral; optic nerve	0.40	0.31	0.31	No
92134	Computerized ophthalmic diagnostic imaging (eg, optical coherence tomography [OCT]), posterior segment, with interpretation and report, unilateral or bilateral; retina	0.45	0.32	0.32	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
93886	Transcranial Doppler study of the intracranial arteries; complete study	0.91	0.90	0.90	No
93888	Transcranial Doppler study of the intracranial arteries; limited study	0.50	0.73	0.73	No
93892	Transcranial Doppler study of the intracranial arteries; emboli detection without intravenous microbubble injection	1.15	1.15	1.15	No
93893	Transcranial Doppler study of the intracranial arteries; venous-arterial shunt detection with intravenous microbubble injection	1.15	1.15	1.15	No
93X94	Vasoreactivity study performed with transcranial Doppler study of intracranial arteries, complete (List separately in addition to code for primary procedure)	NEW	0.81	0.81	No
93X95	Emboli detection without intravenous microbubble injection performed with transcranial Doppler study of intracranial arteries, complete (List separately in addition to code for primary procedure)	NEW	0.73	0.73	No
93X96	Venous-arterial shunt detection with intravenous microbubble injection performed with transcranial Doppler study of intracranial arteries, complete (List separately in addition to code for primary procedure)	NEW	0.85	0.85	No
96380	Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection, with counseling by physician or other qualified health care professional	0.24	0.24	0.24	No
96381	Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection	0.17	0.17	0.17	No
96547	Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; first 60 minutes (List separately in addition to code for primary procedure)	C	6.53	6.53	No
96548	Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; each additional 30 minutes	C	3.00	3.00	No
96920	Excimer laser treatment for psoriasis; total area less than 250 sq cm	1.15	1.00	0.83	No
96921	Excimer laser treatment for psoriasis; 250 sq cm to 500 sq cm	1.30	1.07	0.90	No
96922	Excimer laser treatment for psoriasis; over 500 sq cm	2.10	1.32	1.15	No
97012	Application of a modality to 1 or more areas; traction, mechanical	0.25	0.25	0.25	No
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)	0.18	0.18	0.18	No
97016	Application of a modality to 1 or more areas; vasopneumatic devices	0.18	0.18	0.18	No
97018	Application of a modality to 1 or more areas; paraffin bath	0.06	0.06	0.06	No
97022	Application of a modality to 1 or more areas; whirlpool	0.17	0.17	0.17	No
97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes	0.25	0.25	0.25	No
97033	Application of a modality to 1 or more areas; iontophoresis, each 15 minutes	0.26	0.26	0.26	No
97034	Application of a modality to 1 or more areas; contrast baths, each 15 minutes	0.21	0.21	0.21	No
97035	Application of a modality to 1 or more areas; ultrasound, each 15 minutes	0.21	0.21	0.21	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility	0.45	0.45	0.45	No
97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities	0.50	0.50	0.50	No
97113	Therapeutic procedure, 1 or more areas, each 15 minutes; aquatic therapy with therapeutic exercises	0.48	0.48	0.48	No
97116	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)	0.45	0.45	0.45	No
97140	Manual therapy techniques (eg, mobilization/ manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes	0.43	0.43	0.43	No
97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes	0.44	0.44	0.44	No
97533	Sensory integrative techniques to enhance sensory processing and promote adaptive responses to environmental demands, direct (one-on-one) patient contact, each 15 minutes	0.48	0.48	0.48	No
97535	Self-care/home management training (eg, activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes	0.45	0.45	0.45	No
97537	Community/work reintegration training (eg, shopping, transportation, money management, avocational activities and/or work environment/modification analysis, work task analysis, use of assistive technology device/adaptive equipment), direct one-on-one contact, each 15 minutes	0.48	0.48	0.48	No
97542	Wheelchair management (eg, assessment, fitting, training), each 15 minutes	0.48	0.48	0.48	No
97810	Acupuncture, 1 or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient	0.60	0.61	0.61	No
97811	Acupuncture, 1 or more needles; without electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with insertion of needle(s) (List separately in addition to code for primary procedure)	0.50	0.46	0.46	No
97813	Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient	0.65	0.74	0.74	No
97814	Acupuncture, 1 or more needles; with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with insertion of needle(s) (List separately in addition to code for primary procedure)	0.55	0.47	0.47	No
9X059	Computerized ophthalmic diagnostic imaging (eg, optical coherence tomography [OCT]), posterior segment, with interpretation and report, unilateral or bilateral; retina, including OCT angiography	NEW	0.64	0.64	No
9X075	Synchronous audio-video visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the	NEW	0.93	I	Yes

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	date of the encounter for code selection, 15 minutes must be met or exceeded.				
9X076	Synchronous audio-video visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and low medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.	NEW	1.60	I	Yes
9X077	Synchronous audio-video visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and moderate medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.	NEW	2.60	I	Yes
9X078	Synchronous audio-video visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and high medical decision making. When using total time on the date of the encounter for code selection, 60 minutes must be met or exceeded.	NEW	3.50	I	Yes
9X079	Synchronous audio-video visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 10 minutes must be met or exceeded.	NEW	0.70	I	Yes
9X080	Synchronous audio-video visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low medical decision making. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.	NEW	1.30	I	Yes
9X081	Synchronous audio-video visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.	NEW	1.92	I	Yes
9X082	Synchronous audio-video visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and high medical decision making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.	NEW	2.60	I	Yes
9X083	Synchronous audio-only visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination, straightforward medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 15 minutes must be met or exceeded.	NEW	0.90	I	Yes

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
9X084	Synchronous audio-only visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination, low medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.	NEW	1.55	I	Yes
9X085	Synchronous audio-only visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination, moderate medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.	NEW	2.42	I	Yes
9X086	Synchronous audio-only visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination, high medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 60 minutes must be met or exceeded.	NEW	3.20	I	Yes
9X087	Synchronous audio-only visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination, straightforward medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 10 minutes must be exceeded.	NEW	0.65	I	Yes
9X088	Synchronous audio-only visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination, low medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.	NEW	1.20	I	Yes
9X089	Synchronous audio-only visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination, moderate medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.	NEW	1.75	I	Yes
9X090	Synchronous audio-only visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination, high medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.	NEW	2.60	I	Yes
9X091	Brief communication technology-based service (eg, virtual check-in) by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related evaluation and management service provided within the previous 7 days nor leading to an evaluation and management service or procedure within the	NEW	0.30	0.30	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	next 24 hours or soonest available appointment, 5-10 minutes of medical discussion				
9X100	Medical genetics and genetic counseling services, each 30 minutes of total time provided by the genetic counselor on the date of the encounter	NEW	0.00	0.00	No
G0138	Intravenous infusion of cipaglucosidase alfaatga, including provider/supplier acquisition and clinical supervision of oral administration of miglustat in preparation of receipt of cipaglucosidase alfa-atga	C	-	0.21	Yes
G0168	Wound closure utilizing tissue adhesive(s) only	0.31	0.31	0.31	No
G0283	Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care	0.18	0.18	0.18	No
G0442	Annual alcohol misuse screening, 5 to 15 minutes	0.18	0.18	0.18	No
G0443	Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes	0.45	0.60	0.60	No
G0444	Annual depression screening, 5 to 15 minutes	0.18	0.18	0.18	No
G0445	High intensity behavioral counseling to prevent sexually transmitted infection; face-to-face, individual, includes: education, skills training and guidance on how to change sexual behavior; performed semi-annually, 30 minutes	0.45	0.45	0.45	No
G0446	Annual, face-to-face intensive behavioral therapy for cardiovascular disease, individual, 15 minutes	0.45	0.45	0.45	No
G0447	Face-to-face behavioral counseling for obesity, 15 minutes	0.45	0.45	0.45	No
G0465	Autologous platelet rich plasma (prp) or other blood-derived product for diabetic chronic wounds/ulcers, using an fda-cleared device for this indication, (includes as applicable administration, dressings, phlebotomy, centrifugation or mixing, and all other preparatory procedures, per treatment)	C	-	1.50	Yes
G0516	Insertion of non-biodegradable drug delivery implants, 4 or more (services for subdermal rod implant)	1.82	1.82	1.82	No
G0517	Removal of non-biodegradable drug delivery implants, 4 or more (services for subdermal implants)	2.10	2.10	2.10	No
G0518	Removal with reinsertion, non-biodegradable drug delivery implants, 4 or more (services for subdermal implants)	3.55	3.55	3.55	No
GMBT1	Supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan	NEW	-	C	No
GMBT2	First 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing data generated from the DMHT device from patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month	NEW	-	0.62	No
GMBT3	Each additional 20 minutes of monthly treatment management services directly related to the patient's	NEW	-	0.61	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing data generated from the DMHT device from patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month				
GCDRA	Administration of a standardized, evidence-based Atherosclerotic Cardiovascular Disease (ASCVD) Risk Assessment, 5-15 minutes, not more often than every 12 months	NEW	-	0.18	No
GCDRM	Atherosclerotic Cardiovascular Disease (ASCVD) risk management services; clinical staff time; per calendar month	NEW	-	0.18	No
GCTB1	Caregiver training in behavior management/modification for caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; initial 30 minutes	NEW	-	1.00	No
GCTB2	Caregiver training in behavior management/modification for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; each additional 15 minutes	NEW	-	0.54	No
GCTD1	Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (without the patient present), face-to-face; initial 30 minutes	NEW	-	1.00	No
GCTD2	Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (without the patient present), face-to-face; each additional 15 minutes	NEW	-	0.54	No
GCTD3	Group caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (without the patient present), face-to-face with multiple sets of caregivers	NEW	-	0.23	No
GFCI1	Post discharge telephonic follow-up contacts performed in conjunction with a discharge from the emergency department for behavioral health or other crisis encounter, 4 calls per calendar month.	NEW	-	1.00	No
GIDXX	Visit complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease by an infectious diseases consultant, including disease transmission risk assessment and mitigation, public health investigation, analysis, and testing, and complex antimicrobial therapy counseling and treatment. (add-on code, list separately in addition to hospital inpatient or observation evaluation and management visit, initial, same day discharge, or subsequent	NEW	-	0.89	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
GIPC1	Interprofessional telephone/Internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a verbal and written report to the patient's treating/requesting practitioner; 5-10 minutes of medical consultative discussion and review	NEW	-	0.35	No
GIPC2	Interprofessional telephone/Internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a verbal and written report to the patient's treating/requesting practitioner; 11-20 minutes of medical consultative discussion and review	NEW	-	0.70	No
GIPC3	Interprofessional telephone/Internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a verbal and written report to the patient's treating/requesting practitioner; 21-30 minutes of medical consultative discussion and review	NEW	-	1.05	No
GIPC4	Interprofessional telephone/Internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a verbal and written report to the patient's treating/requesting practitioner; 31 or more minutes of medical consultative discussion and review	NEW	-	1.40	No
GIPC5	Interprofessional telephone/Internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a written report to the patient's treating/requesting practitioner, 5 minutes or more of medical consultative time	NEW	-	0.70	No
GIPC6	Interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, 30 minutes	NEW	-	0.70	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
GPCM1	Advanced primary care management services furnished to patients requiring primary care provided by clinical staff/physician/other qualified health care professionals who are responsible for all primary care and serve as the continuing focal point for all needed health care services, per calendar month, with the following elements: • Development, implementation, revision, and maintenance of a patient-centered electronic care plan; • Overall comprehensive care management; o Systematic needs assessment (medical and psychosocial) o Ensure receipt of preventive services o Medication reconciliation, management and oversight of self-management • Ongoing communication and care coordination between relevant practitioners furnishing care (e.g., community-based care); o Coordinate with any home- and community-based clinical service providers, and document communication with them regarding psychosocial needs and functional deficits • Timely management of care transitions (e.g., ED visit and hospital discharges) and referrals; o Create/exchange continuity of care document(s) timely (format not prescribed) o Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 7 calendar days of discharge • Enhanced communications opportunities and digital access o Offer asynchronous non-face-to-face methods other than telephone, such as secure email or patient portal o Ensure access to virtual visits and consultations and digital health communication technology-based services, such as interprofessional consultations with other practitioners, virtual check-ins, e-visits, and remote evaluation of images, to maintain ongoing communication with patient, as appropriate.).	NEW	-	0.17	No
GPCM2	Advanced primary care management services furnished to patients with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff/physician/other qualified health care professionals who are responsible for all primary care and serve as the continuing focal point for all needed health care services, per calendar month, with the elements included in GPCM1	NEW	-	0.77	No
GPCM3	Advanced primary care management services furnished to Qualified Medicare Beneficiaries with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff/physician/other qualified health care professionals who are responsible for all primary care and serve as the continuing focal point for all needed health	NEW	-	1.67	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	care services, per calendar month, with the elements included in GPCM1				
GPOC1	Post-operative follow-up visit complexity inherent to evaluation and management services addressing surgical procedure(s), provided by a physician or qualified health care professional who is not the practitioner who performed the procedure (or in the same group practice), and is of a different specialty than the practitioner who performed the procedure, within the 090-day global period of the procedure(s), once per 090-day global period, when there has not been a formal transfer of care and requires the following required elements, when possible and applicable: ● Reading available surgical note to understand the relative success of the procedure, the anatomy that was affected, and potential complications that could have arisen due to the unique circumstances of the patient's operation. ● Research the procedure to determine expected post-operative course and potential complications (in the case of doing a post-op for a procedure outside the specialty). ● Evaluate and physically examine the patient to determine whether the post-operative course is progressing appropriately. ● Communicate with the practitioner who performed the procedure if any questions or concerns arise. (List separately in addition to office/outpatient evaluation and management visit, new or established)	NEW	-	0.16	No
GSPI1	Safety planning interventions, including the following elements: recognizing warning signs of an impending suicidal crisis; employing internal coping strategies; utilizing social contacts and social settings as a means of distraction from suicidal thoughts; utilizing family members or friends to help resolve the crisis; contacting mental health professionals or agencies; and restricting access to lethal means; (List separately in addition to an E/M visit or psychotherapy).	NEW	-	1.09	No

TABLE 14: CY 2025 Direct PE Refinements

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
64486	Tap block unil by injection	L037D	RN/LPN/MTA	NF	Assist physician or other qualified healthcare professional---directly related to physician work time (67% of physician intra-service time)	7.5	7	L13: Refined to correct rounding error in clinical labor calculation	-0.27
6XX07	Thrc fascial pln blk uni njx	L037D	RN/LPN/MTA	NF	Assist physician or other qualified healthcare professional---directly related to physician work time (67% of physician intra-service time)	7.5	7	L13: Refined to correct rounding error in clinical labor calculation	-0.27
6XX11	Lwr xtr fscl pln blk uni njx	L037D	RN/LPN/MTA	NF	Assist physician or other qualified healthcare professional---directly related to physician work time (67% of physician intra-service time)	7.5	7	L13: Refined to correct rounding error in clinical labor calculation	-0.27
77012	Ct scan for needle biopsy	EL007	room, CT	NF		26	9	E11: Refined equipment time to conform with other codes in the family	-51.17
7XX00	Mr sfty implt&/fb asmt stf 1	L047A	MRI Technologist	NF	Document procedure (nonPACS) (e.g. mandated reporting, registry logs, EEG file, etc.)	2	1	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family	-0.76

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
7XX01	Mr sfty mplt&/fb asmt stf ca	ED050	Technologist PACS workstation	NF		45	32	E16: No equipment times were included; aligned equipment time with assist physician time	-0.29
7XX01	Mr sfty mplt&/fb asmt stf ea	L047A	MRI Technologist	NF	Document procedure (nonPACS) (e.g. mandated reporting, registry logs, EEG file, etc.)	2	1	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family	-0.76
7XX01	Mr sfty mplt&/fb asmt stf ca	L047A	MRI Technologist	NF	Perform procedure/service---NOT directly related to physician work time	27	14	G1: See preamble text	-9.88
7XX02	Mr safety deter phys/qhp	L047A	MRI Technologist	NF	Document procedure (nonPACS) (e.g. mandated reporting, registry logs, EEG file, etc.)	2	1	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family	-0.76
7XX03	Mr sfty med physics xm cstmz	ED053	Professional PACS Workstation	F		13	0	G1: See preamble text	-0.80
7XX04	Mr safety implant elec prepj	L047A	MRI Technologist	NF	Clean room/equipment by clinical staff	2	1	G1: See preamble text	-0.76
7XX04	Mr safety implant elec prepj	L047A	MRI Technologist	NF	Document procedure (nonPACS) (e.g. mandated reporting, registry logs, EEG file, etc.)	2	1	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family	-0.76
7XX05	Mr safcty implt pos&/immoblj	L047A	MRI Technologist	NF	Document procedure (nonPACS) (e.g.	2	1	L3: Refined clinical labor time to conform with	-0.76

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					mandated reporting, registry logs, EEG file, etc.)			identical labor activity in other codes in the family	
7XX05	Mr safety implt pos&/immoblj	L047A	MRI Technologist	NF	Clean room/equipment by clinical staff	2	1	G1: See preamble text	-0.76
7XX05	Mr safety implt pos&/immoblj	SL082	impression material, dental putty (per bite block)	NF		1	0	S4: Supply not mentioned in SOR work description	-2.14
96920	Excimer lsr psriasis<250sqcm	EQ161	laser, excimer	NF		0	36	E13: Equipment item replaces another item; see preamble text	21.22
96920	Excimer lsr psriasis<250sqcm	L037D	RN/LPN/MTA	NF	Clean room/equipment by clinical staff	5	3	L1: Refined time to standard for this clinical labor task	-1.08
96920	Excimer lsr psriasis<250sqcm	SD363	laser, excimer, pay per use (under 250 cm2)	NF		1	0	S7: Supply item replaced by another item; see preamble	-80.00
96921	Excimer lsr psriasis 250-500	EQ161	laser, excimer	NF		0	38	E13: Equipment item replaces another item; see preamble text	22.40
96921	Excimer lsr psriasis 250-500	L037D	RN/LPN/MTA	NF	Clean room/equipment by clinical staff	5	3	L1: Refined time to standard for this clinical labor task	-1.08
96921	Excimer lsr psriasis 250-500	SD364	laser, excimer, pay per use (250-500 cm2)	NF		1	0	S7: Supply item replaced by another item; see preamble	-83.00
96922	Excimer lsr psriasis>500sqcm	EQ161	laser, excimer	NF		0	44	E13: Equipment item replaces another item; see preamble text	25.94
96922	Excimer lsr psriasis>500sqcm	L037D	RN/LPN/MTA	NF	Clean room/equipment by clinical staff	5	3	L1: Refined time to standard for this clinical labor task	-1.08
96922	Excimer lsr psriasis>500sqcm	SD365	laser, excimer, pay per use (> 500cm2)	NF		1	0	S7: Supply item replaced by another item; see preamble	-100.00
G0442	Annual alcohol screen 15 min	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly	5	15	G1: See preamble text	5.40

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					related to physician work time				
G0444	Depression screen annual	L037D	RN/LPN/MTA	NF	Perform procedure/service--NOT directly related to physician work time	5	15	G1: See preamble text	
G0445	High inten beh couns std 30m	EF023	table, exam	NF		17	20	G1: See preamble text	0.03
G0445	High inten beh couns std 30m	SK057	paper, laser printing (each sheet)	NF		10	0	S7: Supply item replaced by another item; see preamble	-0.20
G0445	High inten beh couns std 30m	SK062	patient education booklet	NF		0	0.5	S8: Supply item replaces another item; see preamble	1.40
G0446	Intens behave ther cardio dx	EF023	table, exam	NF		12	15	G1: See preamble text	0.03
G0446	Intens behave ther cardio dx	SK057	paper, laser printing (each sheet)	NF		10	0	S7: Supply item replaced by another item; see preamble	-0.20
G0446	Intens behave ther cardio dx	SK062	patient education booklet	NF		0	0.5	S8: Supply item replaces another item; see preamble	1.40
G0447	Behavior counsel obesity 15m	EF023	table, exam	NF		17	15	G1: See preamble text	-0.02
G0447	Behavior counsel obesity 15m	SK057	paper, laser printing (each sheet)	NF		10	0	S7: Supply item replaced by another item; see preamble	-0.20
G0447	Behavior counsel obesity 15m	SK062	patient education booklet	NF		0	0.5	S8: Supply item replaces another item; see preamble	1.40

TABLE 15: CY 2025 Direct PE Refinements – Equipment Refinements Conforming to Changes in Clinical Labor Time

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
64486	Tap block unil by injection	EF018	stretcher	NF		25.5	25	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64486	Tap block unil by injection	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		25.5	25	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
6XX07	Thrc fascial pln blk uni njx	EF018	stretcher	NF		25.5	25	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
6XX07	Thrc fascial pln blk uni njx	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		25.5	25	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
6XX11	Lwr xtr fscl pln blk uni njx	EF018	stretcher	NF		25.5	25	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
6XX11	Lwr xtr fscl pln blk uni njx	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		25.5	25	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
7XX04	Mr safety implant elec prepj	EL008	room, MR	NF		21	20	E15: Refined equipment time to conform to changes in clinical labor time	-3.28
7XX04	Mr safety implant elec prepj	EQ412	Vitals monitoring system (MR Conditional)	NF		21	20	E15: Refined equipment time to conform to changes in clinical labor time	-0.32

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
7XX05	Mr safety implt pos&/immobl j	EL008	room, MR	NF		24	23	E15: Refined equipment time to conform to changes in clinical labor time	-3.28
7XX05	Mr safety implt pos&/immobl j	EQ412	Vitals monitoring system (MR Conditional)	NF		24	23	E15: Refined equipment time to conform to changes in clinical labor time	-0.32
96920	Excimer lsr psriasis<250s qcm	EF031	table, power	NF		38	36	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
96920	Excimer lsr psriasis<250s qcm	EQ168	light, exam	NF		38	36	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
96921	Excimer lsr psriasis 250-500	EF031	table, power	NF		40	38	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
96921	Excimer lsr psriasis 250-500	EQ168	light, exam	NF		40	38	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
96922	Excimer lsr psriasis>500s qcm	EF031	table, power	NF		46	44	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
96922	Excimer lsr psriasis>500s qcm	EQ168	light, exam	NF		46	44	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
G0442	Annual alcohol screen 15 min	EF023	table, exam	NF		10	15	E15: Refined equipment time to conform to changes in clinical labor time	0.05
G0444	Depression screen annual	EF023	table, exam	NF		10	15	E15: Refined equipment time to	0.05

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								conform to changes in clinical labor time	

TABLE 16: CY 2025 Invoices Received for Existing Direct PE Inputs

CPT/HCPCS codes	Item Name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
30140, 30901, 30903,30905, 30906, 31231, 31237, 31238, 43197, 43198	Atomizer tips (disposable)	SL464	$0.00	2.66	-	1	625,876
65778	human amniotic membrane allograft mounted on a non-absorbable self-retaining ring	SD248	$931.33	$1,149.00	23%	30	52,203
88341	Anti CD45 Monoclonal Antibody	SL495	$5.15	$8.73	70%	3	1,094,158
88341, 88342, 88344, 88360, 88361	Benchmark ULTRA automated slide preparation system	EP112	$125,040.59	$130,000.00	4%	2	2,683,605
88341, 88342, 88344, 88360, 88361	Reaction buffer 10X (Ventana 950-300)	SL478	$0.037	$0.045	22%	3	2,683,605
88341, 88342, 88344, 88360, 88361	Liquid coverslip (Ventana 650-010)	SL479	$0.051	$0.084	65%	3	2,683,605
88341, 88342, 88344, 88360, 88361	SSC (10X) (Ventana 950-110)	SL480	$0.051	$0.069	35%	2	2,683,605
88341, 88342, 88344, 88360, 88361	Cell Conditioning 1 (Ventana 950-124)	SL482	$0.560	$0.937	67%	3	2,683,605
88342	Confirm anti-CD15 Mouse Monoclonal Antibody (Ventana 760-2504)	SL474	$4.90	$9.24	89%	3	1,157,793
92240, 92242	indocyanine green (25ml uou)	SL083	$76.94	$125.11	63%	8	36,974

CPT/HCPCS codes	Item Name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
93241, 93243, 93245, 93247	extended external ECG patch, medical magnetic tape recorder	SD339	$260.35	$292.50	12%	20	510,943
97810, 97811, 97813, 97814	needle, acupuncture	SC075	$0.10	$0.199	99%	1	263,591
306 codes	pack, cleaning and disinfecting, endoscope	SA042	$19.43	31.29	61%	2	-
7 codes	pack, drapes, cystoscopy	SA045	$17.33	$14.99	-14%	2	-
Deleted from all codes	pack, drapes, laparotomy (chest-abdomen)	SA046	$7.26	-	-	-	-
67221	pack, ocular photodynamic therapy	SA049	$16.35	$26.35	61%	2	1,062
38 codes	pack, urology cystoscopy visit	SA058	$113.70	$37.63	-67%	2	-
145 codes	pack, ophthalmology visit (w-dilation)	SA082	$3.91	$2.33	-40%	1	-

TABLE 17: CY 2025 New Invoices

CPT/HCPCS codes	Item Name	CMS code	Average price	No. of Invoices	NF Allowed Services
5X006, 5X007, 5X008	TULSA-PRO TDC Cart	EQ410	1,638.60	1	2,300
5X007, 5X008	TULSA-PRO Disposable Kit	SA136	8,967.00	2	847
5XX05	iTIND device	SD366	2,695.00	2	295
6XX01	RF Electrodes 18 Gauge 70 mm Length	SD368	1,995.00	3	10
6XX01, 6XX02	RF Ablation System V1000 and RF Pump	EQ411	49,950.00	2	11
7XX04, 7XX05	Disposable oximeter probe and clip (MR Conditional)	SD369	6.40	1	19,215
7XX04, 7XX05	Vitals monitoring system (MR Conditional)	EQ412	85,182.60	1	19,215
7XX05	Thermoplastic splint material 6"x9" (MR Safe)	SG100	21.75	1	76
96920, 96921, 96922	Mupirocin 2% Topical Ointment 22 grams	SJ095	0.139	1	108,634
96920	laser, excimer, pay per use (under 250 cm2)	SD363	80.00	5	73,369
96921	laser, excimer, pay per use (250-500 cm2)	SD364	83.00	4	21,696
96922	laser, excimer, pay per use (> 500cm2)	SD365	100.00	3	13,569
9X059	tomographic device, optical coherence angiography (OCTA)	EQ409	164,500.00	2	360,890
G0138	Opfolda (65 mg capsule)	SH111	32.50	0	3,955
No codes	inFlow Measuring Device	SD370	140.00	1	-
No codes	inFlow Valve-Pump Device	SD371	495.00	1	-
No codes	inFlow Activator Kit	SD372	1,250.00	1	-
306 codes (component of SA042)	ortho-phthalaldehyde 0.55% (eg, Cidex OPA)	SM030	0.554	1	-
306 codes (component of SA042)	ortho-phthalaldehyde test strips	SM031	1.556	1	-
7 codes (component of SA045)	drape, surgical, legging	SB057	3.284	1	-
7 codes (component of SA045)	drape, surgical, split, impervious, absorbent	SB058	8.424	1	-
22510, 22511, 22513, 22514	Abdominal Drape Laparotomy Drape Sterile (100 in x 72 in x 124 in)	SB056	8.049	1	12,721
67221 (component of SA049)	kit, ocular photodynamic therapy (PDT)	SA137	26.00	1	1,062
67221 (component of SA049)	y-adapter cap	SD367	0.352	1	1,062
145 codes (component of SA082)	post-mydriatic spectacles	SB059	0.328	1	-

TABLE 18: CY 2025 No PE Refinements

HCPCS	Description
15XX1	Hrv skn cll ssp agrft 1st 25
15XX2	Hrv skn cll ssp agrft ea add
15XX3	Prepj skn cll ssp agrft 1st
15XX4	Prepj skn cll ssp agrft ea
15XX5	App skn cl ssp agrft t/a/l 1
15XX6	App skn cl ssp agrf t/a/l ea
15XX7	App skn cll ssp f/n/g/hf 1st
15XX8	App skn cll ssp f/n/g/hf ea
25310	Transplant forearm tendon
25447	Repair wrist joints
26480	Transplant hand tendon
2X005	Arthrp ntrcrpl/crp/mtcrp ssp
36514	Apheresis plasma
36516	Apheresis immunoads slctv
36522	Photopheresis
3X018	Car-t hrv bld-drv t lymphcyt
3X019	Car-t prep t lymphcyt f/trns
3X020	Car-t receipt&prepj admn
3X021	Car-t admn autologous
4X015	Opn exc/dstr ntra-abd 5 cm/<
4X016	Opn exc/dstr ntra-abd 5.1-10
4X017	Opn exc/dst ntra-abd 10.1-20
4X018	Opn exc/dst ntra-abd 20.1-30
4X019	Opn exc/dstr ntra-abd >30 cm
59200	Insert cervical dilator
5X006	Ins trurl ablt trnsdc thr us
5X007	Ablt trurl prst8 tis thrm us
5X008	Ablt trurl prst8 tis trnsdcr
5XX05	Cysto insj dev ischmc rmdlg
5XX06	Cathj rmvl dev ischmc rmdlg
64487	Tap block uni by infusion
64488	Tap block bi injection
64489	Tap block bi by infusion
64590	Ins/rpl prph sac/gstr npg/r
64595	Rev/rmv prph sac/gstr npg/r
66680	Repair iris & ciliary body
66682	Repair iris & ciliary body
6X004	Implantation iris prosthesis
6XX00	Mrgfus strtctc ablt trgt icr
6XX01	Abltj 1/−thyr ndul 1lobe prq
6XX02	Abltj 1/−thyr ndul addl prq

HCPCS	Description
6XX08	Thrc fascial pln blk uni nfs
6XX09	Thrc fascial pln blk bi njx
6XX10	Thrc fascial pln blk bi nfs
6XX12	Lwr xtr fscl pln blk uni nfs
76981	Use parenchyma
76982	Use 1st target lesion
76983	Use ea addl target lesion
90480	Admn sarscov2 vacc 1 dose
92132	Cmptr ophth dx img ant segmt
92133	Cmptr ophth img optic nerve
92134	Cptr ophth dx img post segmt
93886	Intracranial complete study
93888	Intracranial limited study
93892	Tcd emboli detect w/o inj
93893	Tcd emboli detect w/inj
93X94	Vsrctv std tcd icr art compl
93X95	Emboli detcj wo iv mbubb njx
93X96	Ven-artl shunt det mbubb njx
96380	Admn rsv monoc antb im cnsl
96381	Admn rsv monoc antb im njx
97012	Mechanical traction therapy
97014	Electric stimulation therapy
97016	Vasopneumatic device therapy
97018	Paraffin bath therapy
97022	Whirlpool therapy
97032	Appl modality 1+estim ea 15
97033	App mdlty 1+iontphrsis ea 15
97034	App mdlty 1+cntrst bth ea 15
97035	App mdlty 1+ultrasound ea 15
97110	Therapeutic exercises
97112	Neuromuscular reeducation
97113	Aquatic therapy/exercises
97116	Gait training therapy
97140	Manual therapy 1/> regions
97530	Therapeutic activities
97533	Sensory integration
97535	Self care mngment training
97537	Community/work reintegration
97542	Wheelchair mngment training
97810	Acupunct w/o stimul 15 min
97811	Acupunct w/o stimul addl 15m
97813	Acupunct w/stimul 15 min
97814	Acupunct w/stimul addl 15m

HCPCS	Description
9X059	Cptrz oph img pst sg rta oct
9X075	Synch audio-video new sf 15
9X076	Synch audio-video new low 30
9X077	Synch audio-video new mod 45
9X078	Synch audio-video new hi 60
9X079	Synch audio-video est sf 10
9X080	Synch audio-video est low 20
9X081	Synch audio-video est mod 30
9X082	Synch audio-video est hi 40
9X083	Synch audio-only new sf 15
9X084	Synch audio-only new low 30
9X085	Synch audio-only new mod 45
9X086	Synch audio-only new high 60
9X087	Synch audio-only est sf 10
9X088	Synch audio-only est low 20
9X089	Synch audio-only est mod 30
9X090	Synch audio-only est high 40
9X091	Brief comunicaj tech-bsd svc
9X100	Genetic counseling svc ea 30
G0168	Wound closure by adhesive
G0283	Elec stim other than wound
G0443	Brief alcohol misuse counsel
G0516	Insert drug del implant, >=4
G0517	Remove drug implant
G0518	Remove w insert drug implant

F. Evaluation and Management (E/M) Visits

1. Office/Outpatient (O/O) Evaluation and Management (E/M) Visit Complexity Add-On

In the CY 2024 PFS final rule (88 FR 78970 through 78982), we finalized separate payment for the O/O E/M visit complexity add-on code. The full descriptor for the O/O E/M visit complexity add-on code, HCPCS code G2211, is (*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)*).

The O/O E/M visit complexity add-on code ''reflects the time, intensity, and PE resources involved when practitioners furnish the kinds of O/O E/M visit services that enable them to build longitudinal relationships with all patients (that is, not only those patients who have a chronic condition or single high-risk disease) and to address the majority of a patient's health care needs with consistency and continuity over longer periods of time.'' (88 FR 78970

through 78971). We explained in the CY 2024 PFS final rule that it is the relationship between the patient and the practitioner that is the determining factor for when the add-on code should be billed. The add-on code captures the inherent complexity of the visit that is derived from the longitudinal nature of the practitioner and patient relationship. The first part of the code descriptor, the ''continuing focal point for all needed health care services,'' describes a relationship between the patient and the practitioner when the practitioner is the continuing focal point for all health care services that the patient needs. The second part of the add-on code also describes a relationship involving medical services that are part of ongoing care related to a patient's single, serious condition or a complex condition. There is previously unrecognized but important cognitive effort of utilizing the longitudinal relationship in making a diagnosis, developing a treatment plan, and weighing the factors that affect a longitudinal doctor-patient relationship. The practitioner must decide what course of action and choice of words in the visit itself would lead to the best health outcome in the single visit while simultaneously building up an effective, trusting longitudinal relationship with the patient. Weighing these various factors, even for a seemingly simple condition, makes the entire visit inherently complex, which is what this add-on code is intended to capture (88 FR 78973 through 78974).

We responded to concerns raised by commenters about potential duplicative payment and potential misreporting of the code, noting that when procedures or other services are reported on the same day by the same billing practitioner as a significant, separately identifiable O/O E/M visit (the base codes that the visit complexity add-on code can be billed with), we believed that the services involve resources that are sufficiently distinct from the costs associated with furnishing stand-alone O/O E/M visits to warrant a different payment policy (88 FR 78971). We finalized our proposal that the O/O E/M visit complexity add-on code is not payable when the O/O E/M visit is reported with CPT Modifier–25, which denotes a significant, separately identifiable O/O E/M visit by the same physician or other qualified health care professional on the same day as a procedure or other service (88 FR 78974).

Some commenters expressed concern about our proposal to exclude payment for the visit complexity add-on code when the O/O E/M base code is reported with Modifier–25 because some preventive services such as the annual wellness visit (AWV) or a preventive vaccine are often provided on the same day as a separately identifiable O/O E/M visit, appropriately billed with Modifier–25. The commenters were concerned that practitioners might avoid the policy by not providing a preventive service on the same day as another O/O E/M service. We acknowledged that immunizations and AWVs were sometimes furnished on the same day as an O/O E/M visit and that our policy would prevent payment of the add-on code with such office visits billed with Modifier–25 and indicated that we would monitor utilization of the visit complexity add-on code and continue engagement with interested parties as the policy is implemented (88 FR 78975).

We have begun to monitor utilization of HCPCS code G2211 and are continuing to engage with interested parties. We continue to hear from some practitioners that our non-payment of the O/O E/M visit complexity add-on code when the O/O E/M base code is reported on the same day as a preventive immunization or other Medicare preventive service is disruptive to the way such care is usually furnished and contrary to our policy objective for establishing the add-on payment. An early analysis of practitioner claims from the first few months of 2024 shows relatively few Medicare preventive services being billed on the day preceding or following an O/O E/M visit. We cannot conclude from this analysis that our policy to deny payment of the O/O E/M visit complexity add-on code when the O/O E/M base code is reported on the same day as a preventive immunization or other Medicare preventive service is disruptive to the way such care is usually furnished. However, we do agree with practitioners expressing concerns that the current policy is not well-aligned with our policy objective for establishing the add-on payment.

In response to these concerns, we are proposing to refine our current policy for services furnished beginning in CY 2025. We are proposing to allow payment of the O/O E/M visit complexity add-on code when the O/O E/M base code is reported by the same practitioner on the same day as an AWV, vaccine administration, or any Medicare Part B preventive service furnished in the office or outpatient setting. Allowing payment for the O/O E/M visit complexity add-on code in this scenario as proposed would support our policy aims, which include paying for previously unaccounted resources inherent in the complexity of all longitudinal primary care office visits. In part, the O/O E/M visit complexity add-on code recognizes the inherent costs of building trust in the practitioner-patient relationship. We believe that trust-building in the longitudinal relationship is more significant than ever in making decisions about the administration of immunizations and other Medicare Part B preventive services. We welcome comments on this proposal.

G. Enhanced Care Management

1. Background

The CMS Center for Medicare and Medicaid Innovation (CMS Innovation Center) tests innovative payment and service delivery models to reduce program expenditures while preserving or enhancing quality of care. CMS Innovation Center models are assessed for their impact on quality of care and expenditures under Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) and the scope and duration of the model test may be expanded through rulemaking if expected to either reduce spending without compromising quality of care or enhance quality of care without increasing spending (section 1115A of the Act). After more than a decade of testing over 50 innovative payment and service delivery models, the CMS Innovation Center has enabled broad transformative changes to service delivery and payment in the Medicare, Medicaid, and CHIP programs which inspire additional transformation throughout the health care delivery system. Participants in CMS Innovation Center models have demonstrated improvements in care delivery and patient experience. The CMS Innovation Center undertook a retrospective review and synthesis of select model evaluations where care delivery changes have been observed, and the review indicated demonstrable evidence of enhanced care delivery in several areas, such as care coordination, team-based care, and leveraging data to risk-stratify patients.[21]

Under the Medicare Physician Fee Schedule (PFS) statute at section 1848 of the Act, we establish payment

[21] Fowler, Ph.D., JD, E., Rudolph, MPH, N., Davidson, LCSW, MSW, K., Finke, MD, B., Flood, S., Bernheim, MD, Ph.D., S. M., & Rawal, Ph.D., P. (2023). Accelerating Care Delivery Transformation—The CMS Innovation Center's Role in the Next Decade. *New England Journal of Medicine, 4*(11). *https://doi.org/10.1056/cat.23.0228*. CMS. Synthesis of Evaluation Results across 21 Medicare Models, 2012–2020. Fowler, Ph.D. 2022. *https://www.cms.gov/priorities/innovation/data-and-reports/2022/wp-eval-synthesis-21models*.

amounts for covered physicians' services, and update our payment policies to address changes, including changes in medical practice. In this proposed rule, we are proposing to incorporate key payment and service delivery elements from CMS Innovation Center models tested and evaluated over the prior decade into permanent coding and payment under the PFS. Specifically, we are proposing to recognize a primary care practice delivery model trend which we will refer to as ''advanced primary care'' and which we propose to define using the 2021 National Academies of Sciences, Engineering, and Medicine (NASEM) report on Implementing High-Quality Care as: ''whole-person, integrated, accessible, and equitable health care by interprofessional teams that are accountable for addressing the majority of an individual's health and wellness needs across settings and through sustained relationships with patients, families, and communities.'' [22] Using this definition, we are proposing to recognize the resources involved in furnishing services using an ''advanced primary care'' approach to care under the PFS.[23] Under this approach, the delivery of care is supported by a team-based care structure and involves a restructuring of the primary care team, which includes the billing practitioner and the auxiliary personnel under their general supervision, within practices. This restructuring creates several advantages for patients, and provides more broad accessibility and alternative methods for patients to communicate with their care team/practitioner about their care outside of in-person visits (for example, virtual, asynchronous interactions, such as online chat), which can lead to more timely and efficient identification of, and responses to, health care needs (for example, practitioners can route patients to the optimal clinician and setting—to a synchronous visit, an asynchronous chat, or a direct referral to the optimal site of care).[24] Practitioners using an advanced primary care delivery model can more easily collaborate across clinical disciplines through remote interprofessional consultations with specialists as well as standardize condition management into evidence-based clinical workflows, which allow for closed-loop follow-up and more real-time management for patients with acute or evolving complex issues. Practitioners can then use synchronous interactions to build rapport with patients and families, partner on complex decisions, and personalize their patients' care plans.

Specifically, we are proposing to adopt coding and payment policies to recognize advanced primary care management (APCM) services for use by practitioners who are providing services under this specific model of advanced primary care, when the practitioner is the continuing focal point for all needed health care services and responsible for all primary care services. This new proposed coding and payment makes use of lessons learned from the CMS Innovation Center's testing of a series of advanced primary care models, such as Comprehensive Primary Care (CPC),[25] Comprehensive Primary Care Plus (CPC+),[26] and Primary Care First (PCF) [27] [28] (see discussion in section II.G.2.a.(1) in this proposed rule) to inform the elements upon which the delivery of APCM services under an advanced primary care delivery model depend. As detailed below in sections II.G.2.b. through II.G.2.d., this proposed coding and payment will incorporate elements of several specific, existing care management and communication technology-based services (CTBS) into a bundle of services, that reflects the essential elements of the delivery of advanced primary care, for payment under the PFS starting in 2025.

In the context of the proposal, we are also interested in feedback on other related policies for our consideration in future rulemaking. To gather information from interested parties to inform potential future proposals, we have included an Advanced Primary Care Hybrid Payment Request for Information (RFI) (Advanced Primary Care RFI) in this proposed rule. The Advanced Primary Care RFI seeks feedback on whether and how we should consider additional payment policies that reflect our efforts to recognize the delivery of advanced primary care, including bundling of additional individual services, which may currently be furnished together as primary care services but paid separately. This focused approach to seeking feedback on advanced primary care payment policies is an important step in our ongoing efforts to emphasize accountable care and supports CMS' goal of having 100 percent of Traditional Medicare beneficiaries in accountable care relationships by 2030.[29]

In addition to recognizing advanced primary care, this proposed rule also recognizes physician and practitioner work that draws from evidence generated by the CMS Innovation Center's Million Hearts® model.[30] The Million Hearts® model found that quantitative assessment of patients' atherosclerotic cardiovascular disease (ASCVD) risk and providing high-risk beneficiaries with cardiovascular-focused care management services improved quality of care, including mortality.[31] We discuss a proposal in this section to establish coding and PFS payment for these services based in part on the evidence generated by the Million Hearts® model.

2. Advanced Primary Care Management (APCM) Services (HCPCS Codes GPCM1, GPCM2, and GPCM3)

a. Background

We have been analyzing opportunities to strengthen and invest in primary care in alignment with the goals of the U.S. Department of Health and Human Services (HHS) Initiative to Strengthen Primary Care.[32] Research has

[22] National Academies of Sciences, Engineering, and Medicine. 2021. Implementing high-quality primary care: Rebuilding the foundation of health care. Washington, DC: The National Academies Press. *https://doi.org/10.17226/25983.*

[23] Team-based approaches to care can achieve improved provider and care team satisfaction, improved team communication, improved patient safety, and improved patient and family engagement in care. Coleman, M. Dexter. D., & Nankivill, N. (2015, August). Factors affecting physician satisfaction and Wisconsin Medical Society strategies to drive change. Wisconsin Medical Journal. 114(4), 135–142. Retrieved from *https://www.wisconsinmedicalsociety.org/professional/wmj/archives/volume-114-issue-4-august-2015/.*

[24] Ellner, A., Basu, N. & Phillips, R.S. From Revolution to Evolution: Early Experience with Virtual-First, Outcomes-Based Primary Care. J GEN INTERN MED 38, 1975–1979 (2023). *https://doi.org/10.1007/s11606-023-08151-1.*

[25] *https://www.cms.gov/priorities/innovation/innovation-models/comprehensive-primary-care-initiative.*

[26] *https://www.cms.gov/priorities/innovation/innovation-models/comprehensive-primary-care-plus.*

[27] *https://www.cms.gov/priorities/innovation/innovation-models/primary-care-first-model-options.*

[28] Finke, Bruce, et al. ''Addressing Challenges in Primary Care—Lessons to Guide Innovation.'' *JAMA Health Forum,* vol. 3, no. 8, 19 Aug. 2022, p. e222690, *https://doi.org/10.1001/jamahealthforum.2022.2690.*

[29] CMS White Paper on CMS Innovation Center's Strategy: Driving Health System Transformation—A Strategy for the CMS Innovation Center's Second Decade (*https://www.cms.gov/priorities/innovation/strategic-direction-whitepaper*).

[30] *https://www.cms.gov/priorities/innovation/innovation-models/million-hearts-cvdrrm.*

[31] Peterson G, Steiner A, Powell R, et al. Evaluation of the Million Hearts® Cardiovascular Disease Risk Reduction Model: Fourth Annual Report. Mathematica. February 2022. *https://www.cms.gov/priorities/innovation/data-and-reports/2022/mhcvdrrm-fourthannevalrpt.*

[32] U.S. Department of Health and Human Services. (2023). Primary Care: Our First Line of Defense. *https://www.hhs.gov/sites/default/files/primary-care-issue-brief.pdf.*

demonstrated that greater primary care physician supply is associated with improved population-level mortality and reduced disparities,[33] and also, that establishing a long-term relationship with a primary care provider leads to reduced emergency department (ED) visits,[34] improved care coordination, and increased patient satisfaction.[35] HHS recognizes that effective primary care is essential for improving access to healthcare, for the health and wellbeing of individuals, families, and communities, and for achieving health equity. The first coordinated set of HHS-wide actions to strengthen primary care, as part of the Initiative, is in primary care payment; for example, adjusting payment to ensure it supports delivery of advanced primary care. CMS Innovation Center models, described in section II.G.2.a.(1) in this proposed rule, reflect the ongoing work within HHS and the unified, comprehensive approach to HHS primary care activities that we are accomplishing through our current statutory authorities and funding.

Over the last decade, we have updated PFS payment policies as appropriate, and we remain committed to improving how Medicare payment recognizes the resources involved in furnishing covered services that encompass aspects of advanced primary care furnished by interprofessional care teams and typically concentrating on the delivery of appropriate preventive care to patients and the management of individuals' chronic conditions as they progress over time. As part of the CY 2014 PFS final rule, we reaffirmed our support of primary care and recognized care management as one of the critical components of primary care that contributes to better health outcomes for individuals and reduced expenditure growth, and explained our prioritization of the development and implementation of several initiatives (such as those discussed in section II.G.2.a.(1) in this proposed rule) (77 FR 68978). Since then, we have implemented coding and payment for many care management services to better recognize the resources involved in furnishing medically necessary care management activities that generally are performed outside the context of a face-to-face, in-person visit—most often by the billing practitioner's clinical staff on behalf of patients with complex health care needs, including transitional care management in the CY 2013 PFS final rule (77 FR 68979); non-complex and complex chronic care management (CCM) in the CY 2015, 2017, and 2019 PFS final rules (78 FR 74414, 83 FR 58577, and 81 FR 80244); and principal care management (PCM) in the CY 2020 PFS final rule (84 FR 62962). The CCM and PCM code families now include 5 sets of codes which are reported monthly on a timed basis, each set with a base code of 20 to 60 minutes and an add-on code for each additional 30 minutes. The code sets vary by the degree of complexity of patient conditions (that is, non-complex and complex CCM for multiple chronic conditions or PCM for a single high-risk condition), and whether the number of minutes spent by clinical staff or the physician or non-physician practitioner (NPP) is used to meet time thresholds for billing.

Additionally, we have established coding and payment for certain services where a medical professional evaluates a patient's medical information remotely using communication technology. As discussed in the CY 2019 PFS final rule, this set of services is defined by and inherently involves the use of communications technology, and includes certain remote patient monitoring services, virtual check-in services, remote evaluation of pre-recorded patient information, remote interpretations of diagnostic imaging tests, and interprofessional consultations. We recognize that technological advances have changed and continue to change the practitioner-patient care delivery interaction. We have recognized these technology-enabled interactions through separately billable CTBS over the last several years. However, we acknowledge, as we learn more about how advanced primary care services are furnished to patients, that in some clinical care delivery scenarios, practitioners furnishing the type of care highlighted in this discussion may furnish certain aspects of the CTBS services in complement to care management services (for example, by allowing interprofessional care teams to answer patient questions, refer patients to higher levels of care, view and interpret patient images, order needed treatments, and offer reassurance or advice), in an effort to more efficiently manage the quantity and quality of medical information that is necessary to support effective patient-centered treatment plans.

Despite these important steps to pay separately for these care management services, there has been limited uptake of care management services and Medicare still overwhelmingly pays for primary care through traditional office/outpatient (O/O) Evaluation and Management (E/M) visit codes, which describe a broad range of physicians' services but do not fully distinguish and account for the resources associated with primary care and other longitudinal care. As we stated in the CY 2024 PFS final rule, we believe that because E/M visit codes are intended to be used very broadly, the complexity of services required to provide this type of care is not fully incorporated as part of the valuation of the work RVUs when the E/M code itself is used as the primary way to report the work of the professional (88 FR 78972). In the CY 2024 PFS final rule, we took steps to better recognize the inherent complexity of visits associated with primary and longitudinal care of patients by finalizing a new add-on code (HCPCS code G2211) for use by practitioners furnishing services as the continuing focal point for all the patient's needed health care services, such as a primary care practitioner (88 FR 78969). When furnishing primary and longitudinal care, practitioners must be attuned to the factors that develop and maintain trusting practitioner-patient relationships that enable effective diagnosis, management, and treatment on an ongoing basis. In finalizing the O/O E/M visit complexity add-on code, we recognized the feedback from interested parties indicating that the care management codes alone may not have mitigated the deficiencies in the ability of existing E/M codes to reflect the time and resources involved in furnishing visits in the context of longitudinal care—of which, advanced primary care is one model. Many commenters responded, as reflected in the CY 2024 PFS final rule, that they did not view the coding and payment currently available under the PFS as capable of recognizing the broad range of elements that define primary care (88 FR 52326). Other commenters responded that they did not believe that the existing E/M service codes alone reflect the work and resources involved in furnishing non-

[33] Basu S, Berkowitz SA, Phillips RL, Bitton A, Landon BE, Phillips RS. Association of Primary Care Physician Supply With Population Mortality in the United States, 2005–2015. *JAMA Intern Med.* 2019;179(4):506–514. doi:10.1001/jamainternmed.2018.7624. *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2724393.*

[34] Willemijn L.A. Schäfer et al, ''Are People's Health Care Needs Better Met When Primary Care Is Strong? A Synthesis of the Results of the QUALICOPC Study in 34 Countries,'' Primary Health Care Research and Development 20 (2019): e104. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6609545/.*

[35] Michael J. van den Berg, Tessa van Loenen, and Gert P Westert, ''Accessible and Continuous Primary Care May Help Reduce Rates of Emergency Department Use: An International Survey in 34 Countries,'' Family Practice 33, no. 1 (Feb. 2016): 42–50. *https://academic.oup.com/fampra/article/33/1/42/2450446.*

procedural care to Medicare beneficiaries (88 FR 78976).

Over the years, interested parties have focused attention on the ongoing need to improve how practitioners are paid, in and outside of payment bundles, including but not limited to the possibility of E/M codes designed specifically to be billed in conjunction with care management codes and the elimination of multiple disparities between the payment for E/M services in global periods and those furnished individually. Based on feedback from the physician and practitioner community, we understand that advanced primary care encompasses the work of interprofessional teams who are accountable for addressing the majority of an individual's health and wellness needs across settings and through sustained relationships, which necessarily involves time spent by primary care practitioners and their clinical staff outside of individual E/M visits.

As with many services paid under the PFS, we balance making payment that recognizes and supports technological developments in healthcare and the resources involved in evolving medical practice to allow for appropriate and expanded access to innovative technologies and newer services with promoting stability and efficiency in coding and billing rules for practitioners and institutions. We recognize the important role of gathering input and information from the CMS Innovation Center models (described in more detail in section II.G.2.a.(1) in this proposed rule), comment solicitations, research from other public and private entities, the work of all parties involved in furnishing primary care, and from the public at large. As previously noted, interested parties have given ample feedback over the years to inform our recognition of care management services; for example, as part of the CY 2022 PFS rulemaking, interested parties specifically requested our consideration of a ''30-day global period bundling care management services'' and we responded that we would consider this suggestion for future rulemaking (86 FR 65118). We have continued to incorporate feedback into our rulemaking and strengthen our care management code sets with the goal of better recognizing the elements of advanced primary care as part of a multi-year strategy. Based on this feedback, we are proposing to establish a set of codes to better describe advanced primary care management services broadly, to provide more stability in payment and coding for practitioners in the context of continued evolution in advanced primary care, as well as to provide us with a mechanism for continued and intentional improvements to advanced primary care payment.

(1) Key Care Delivery Methods in Select CMS Innovation Center Models

We have prioritized the implementation or testing of a series of initiatives designed to improve payment for, and encourage long-term investment in, primary care and care management services. By supporting enhanced care management and coordination, these initiatives contributed to the growing practice of advanced primary care and have also provided valuable lessons learned that we are incorporating into our proposals.

Several CMS Innovation Center models address payment for care management services and CTBS. The CPC initiative,[36] the CPC+ model,[37] and the PCF model [38] all included payments for care management services that closely aligned with the care management services included in the PFS. In these initiatives, primary care practices received risk-adjusted, per beneficiary per month (PBPM) payments for care management services furnished to Medicare FFS beneficiaries attributed to their practices. These model payments were designed to offer practices a stable, predictable revenue stream that supported required infrastructure and appropriately compensated practices for the enhanced services they would provide. Practices participating in CPC+ consistently cited these payments as the most useful type of model payment support they received; these stable, prospectively paid payments typically served as the main funding source for compensating care managers, behavioral health providers, and other staff hired to improve care delivery.[39] Because these payments were paid prospectively and could be used to support a range of care management and coordination activities, they provided participants with greater financial stability and flexibility to develop and expand capabilities to meet patients' care needs.[40] Table 19 identifies a number of CMS Innovation Center models and key care delivery methods from each.[41]

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[36] *https://downloads.cms.gov/files/cmmi/CPC-initiative-fourth-annual-report.pdf.*

[37] *https://www.cms.gov/priorities/innovation/data-and-reports/2023/cpc-plus-fifth-annual-eval-report.*

[38] *Evaluation of the Primary Care First Model.* February 2024. *https://www.cms.gov/priorities/innovation/data-and-reports/2024/pcf-second-eval-rpt.*

[39] O'Malley A, Singh P, Fu N, et al. Independent Evaluation of the Comprehensive Primary Care Plus (CPC+): Final Report. Mathematica. December 2023. *https://www.cms.gov/priorities/innovation/data-and-reports/2023/cpc-plus-fifth-annual-eval-report.*

[40] O'Malley A, Singh P, Fu N, et al. Independent Evaluation of the Comprehensive Primary Care Plus (CPC+): Final Report. Mathematica. December 2023. *https://www.cms.gov/priorities/innovation/data-and-reports/2023/cpc-plus-fifth-annual-eval-report.*

[41] For more information on how the Innovation Center is supporting primary care, *https://www.cms.gov/files/document/primary-care-infographic.pdf.*

TABLE 19: Key Care Delivery Methods from Select CMS Innovation Center Models

Model	Key Care Delivery Methods	Citation
ACO Investment Model (AIM)	AIM provided an opportunity for participants to invest in care transformation activities. Specifically, AIM was an opportunity for independent primary care practices in rural communities to hire population health staff, such as care managers or outreach coordinators. Care managers conducted outreach, scheduling, and patient education. Care managers did this through a variety of mechanisms including phone, in the physician office, and via home visits.	Evaluation of the Accountable Care Organization Investment Model, Final Report, September 2020, available at: https://www.cms.gov/priorities/innovation/data-and-reports/2020/aim-final-annrpt
Comprehensive Primary Care (CPC)	CPC practices provided longitudinal and episodic care management services for patients at high or rapidly increasing risk whom the practices believed were most likely to benefit from intensive support. By 2016, CPC practices risk stratified 95% of their empaneled patients, and provided care management to 20% of those patients. CPC practices also greatly increased their use of dedicated care managers over time. By 2016, 89% of practices reported that, "care managers who were members of the [primary care] practice team systematically provided care management services to high-risk patients" – an increase from 20% in 2012. Beneficiaries attributed to CPC practices had slower growth in hospitalizations and emergency department (ED) visits than those being managed by practices not in the model.	Evaluation of the Comprehensive Primary Care Initiative, Fourth Annual Report, May 2018, available at: *https://downloads.cms.gov/files/cmmi/CPC-initiative-fourth-annual-report.pdfhttps://downloads.cms.gov/files/cmmi/CPC-initiative-fourth-annual-report.pdf* Long-Term Effects of the Comprehensive Primary Care Model on Health Care Spending and Utilization. May 2022. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9130381/.*
Comprehensive Primary Care Plus (CPC+)	CPC+ practices used data and team-based care to proactively identify the needs of their patients and efficiently manage their care. Additionally, by the final year of the model, about 97% of physicians in CPC+ and comparison practices reported the use of scheduled phone, video, or e-visits for at least some of their patients. Finally, CPC+ had small favorable effects on some claims-based, quality-of-care measures of planned care and population health and patient and caregiver engagement.	Independent Evaluation of Comprehensive Primary Care Plus. Final Report, December 2023, available at: *https://www.cms.gov/priorities/innovation/data-and-reports/2023/cpc-plus-fifth-annual-eval-report.*

Model	Key Care Delivery Methods	Citation
Primary Care First (PCF)	All PCF practices provide 24/7 access to a care team practitioner with real-time access to an electronic health record (EHR). Practices also provide risk-stratified care management for all empaneled patients and ensure beneficiaries receive timely follow-up contact from the practice after ED visits and hospitalizations. Practices commonly report expanding their practice care team by hiring additional clinical and non-clinical staff to bolster longitudinal care management services.	Evaluation of the Primary Care First Model, Second Annual Report, February 2024, available at: *https://www.cms.gov/priorities/innovation/data-and-reports/2024/pcf-second-eval-rpt.*

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b. Proposed HCPCS G-Codes for Advanced Primary Care Management (APCM)

We are proposing to establish coding and make payment under the PFS for a newly defined set of APCM services described and defined by three new HCPCS G-codes. To recognize the resource costs associated with furnishing APCM services to Medicare beneficiaries, we are proposing to establish and pay for three new G-codes that describe a set of care management services and CTBS furnished under a broader application of advanced primary care. This new coding and payment would reflect the recognized effectiveness and growing adoption of the advanced primary care approach to care.[42] It would also encompass a broader range of services and simplify the billing and documentation requirements, as compared to existing care management and CTBS codes, for clinicians who care for their patients using an advanced primary care model. We recognize that there are primary care physicians, practitioners, and practices beyond those that have participated in CMS Innovation Center primary care models (such as those discussed in section II.G.2.a.(1) in this proposed rule), that may incur resource costs associated with their treatment of patients based on the advanced primary care delivery model. Providing care using an advanced primary care delivery model involves resource costs associated with maintaining certain practice capabilities and continuous readiness and monitoring activities to support a team-based approach to care, where significant resources are used on virtual, asynchronous patient interactions, collaboration across clinical disciplines, and real-time management of patients with acute and complex concerns, that are not fully recognized or paid for by the existing care management codes. We have observed medical practice trends in primary care for several years. We note that in prior rulemaking, for example, in the CY 2013 PFS final rule, we stated, ''we further consider[ed] how advanced primary care practices can fit within a fee-for-service model'' (77 FR 68987), and in the CY 2015 PFS final rule, we stated our commitment ''to supporting advanced primary care, including the recognition of care management as one of the critical components of primary care that contributes to better health for individuals and reduced expenditure growth'' (79 FR 67715). In the CY 2017 PFS final rule, we discussed changes to retain elements of the CCM service that are ''most characteristic of the changes in medical practice toward advanced primary care'' (81 FR 80251). As the delivery of primary care has evolved to embrace advanced primary care more fully, we believe that it is prudent to now adopt specific coding and payment policy to better recognize the resources involved in care management under an advanced primary care delivery model.

Below, we explain the proposed new codes and their descriptors. In the next section, we propose to define the elements of the scope of service for APCM that would be required for a practitioner to bill Medicare for the APCM service, and we explain the proposed standards for practices that furnish APCM services to ensure that the physicians and practitioners who bill for these services have the capability to fully furnish advanced primary care, including APCM services (see section II.G.2.c. of this proposed rule). At this time, we are proposing to identify specific care management and CTBS services that are a part of advanced primary care delivery and would be bundled into the PFS payment for the APCM services. As such, we will identify the services that we are proposing would overlap substantially with the new codes and which would not be separately billable with the APCM codes under our proposal (see section II.G.2.d. of this proposed rule). Finally, we propose to establish relative values for these codes for purposes of payment under the PFS (see section II.G.2.e. of this proposed rule).

We are proposing to establish the following G-codes and descriptors for APCM services, and as explained in the next section, due to the similar scope of APCM and other care management and CTBS services, we are proposing to include some of the same language from the CCM and PCM service elements in the APCM code descriptors, as well as emphasize that certain practice capabilities and requirements are inherent in these elements and must be met in order to bill for APCM services:

HCPCS code GPCM1 (*Advanced primary care management services provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar*

[42] National Academies of Sciences, Engineering, and Medicine (NASEM). 2021. Implementing high-quality primary care: Rebuilding the foundation of health care. Washington, DC: The National Academies Press. *https://doi.org/10.17226/25983.;* Maeng DD et al. Reducing long-term cost by transforming primary care: evidence from Geisinger's medical home model. Am J Manag Care. 2012 Mar;18(3):149–55. PMID: 22435908. Available here: *https://pubmed.ncbi.nlm.nih.gov/22435908.;*/ Jones C et al. Vermont's Community-Oriented All-Payer Medical Home Model Reduces Expenditures and Utilization While Delivering High-Quality Care. Popul Health Manag. 2016;19(3):196–205. Available here: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4913508/.*

month, with the following elements, as appropriate:

- *Consent;*

++ Inform the patient of the availability of the service; that only one practitioner can furnish and be paid for the service during a calendar month; of the right to stop the services at any time (effective at the end of the calendar month); and that cost sharing may apply.

++ Document in patient's medical record that consent was obtained.

- *Initiation during a qualifying visit for new patients or patients not seen within 3 years;*
- *Provide 24/7 access for urgent needs to care team/practitioner, including providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent needs regardless of the time of day or day of week;*
- *Continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments;*
- *Deliver care in alternative ways to traditional office visits to best meet the patient's needs, such as home visits and/or expanded hours;*
- *Overall comprehensive care management;*

++ Systematic needs assessment (medical and psychosocial).

++ System-based approaches to ensure receipt of preventive services.

++ Medication reconciliation, management and oversight of self-management.

- Development, implementation, revision, and maintenance of an electronic patient-centered comprehensive care plan;

++ Care plan is available timely within and outside the billing practice as appropriate to individuals involved in the beneficiary's care, can be routinely accessed and updated by care team/practitioner, and copy of care plan to patient/caregiver;

- *Coordination of care transitions between and among health care providers and settings, including referrals to other clinicians and follow-up after an emergency department visit and discharges from hospitals, skilled nursing facilities or other health care facilities as applicable;*

++ Ensure timely exchange of electronic health information with other practitioners and providers to support continuity of care.

++ Ensure timely follow-up communication (direct contact, telephone, electronic) with the patient and/or caregiver after an emergency department visit and discharges from hospitals, skilled nursing facilities, or other health care facilities, within 7 calendar days of discharge, as clinically indicated.

- *Ongoing communication and coordinating receipt of needed services from practitioners, home- and community-based service providers, community-based social service providers, hospitals, and skilled nursing facilities (or other health care facilities), and document communication regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors, in the patient's medical record;*
- *Enhanced opportunities for the beneficiary and any caregiver to communicate with the care team/practitioner regarding the beneficiary's care through the use of asynchronous non-face-to-face consultation methods other than telephone, such as secure messaging, email, internet, or patient portal, and other communication-technology based services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with patients, as appropriate;*

++ Ensure access to patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits).

- *Analyze patient population data to identify gaps in care and offer additional interventions, as appropriate;*
- *Risk stratify the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients;*
- *Be assessed through performance measurement of primary care quality, total cost of care, and meaningful use of Certified EHR Technology.*).

HCPCS code GPCM2 (*Advanced primary care management services for a patient with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the elements included in GPCM1, as appropriate*) and HCPCS code GPCM3 (*Advanced primary care management services for a patient that is a Qualified Medicare Beneficiary with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the elements included in GPCM1, as appropriate*).

HCPCS codes GPCM1 through GPCM3 would describe APCM services furnished per calendar month, following the initial qualifying visit (see section II.G.2.c.(1) for more on the initiating visit). Physicians and NPPs, including nurse practitioners (NPs), physician assistants (PAs), certified nurse midwives (CNMs) and clinical nurse specialists (CNSs), could bill for APCM services. As we will describe in more detail in section II.G.2.c., within the code descriptors for GPCM1, GPCM2, and GPCM3, we are including the elements of the scope of service for APCM as well as the practice capabilities and requirements that we believe to be inherent to care delivery by the care team/practitioner who is billing under a practice using an advanced primary care delivery model, and necessary to fully furnish and, therefore, bill for APCM services.

As described in more detail below, within the code descriptors for GPCM1, GPCM2, and GPCM3, we are proposing that the practitioner who bills for APCM services intends to be responsible for the patient's primary care and serves as the continuing focal point for all needed health care services. We anticipate that most practitioners furnishing APCM services will be managing all the patient's health care services over the month and have either already been providing ongoing care for the beneficiary or have the intention of being responsible for the patient's primary care and serving as the continuing focal point for all the patient's health care services. We anticipate that these codes will mostly be used by the primary care specialties, such as general medicine, geriatric medicine, family medicine, internal medicine, and pediatrics, but we are also aware that, in some instances, certain specialists function as primary care practitioners—for example, an OB/GYN or a cardiologist. In contrast to situations where the patient's overall, ongoing care is being managed, monitored, and/or observed by a practitioner, we believe that there are situations when care is provided by a practitioner who would not serve as

''the continuing focal point for all needed health care services.''

Similarly, there are some time- or condition-limited practitioner-patient relationships that are clearly not indicative of the ongoing care that we anticipate practitioners would be responsible for when furnishing APCM services. As we stated in the CY 2021 PFS proposed rule and CY 2024 PFS final rule in the context of our policies for the O/O E/M visit complexity add-on code (HCPCS code G2211), a practitioner whose ''relationship with the patient is of a discrete, routine, or time-limited nature; such as, but not limited to, a mole removal or referral to a physician for removal of a mole; for treatment of a simple virus, for counseling related to seasonal allergies, initial onset of gastroesophageal reflux disease; treatment for a fracture; and where comorbidities are either not present or not addressed, and/or when the billing practitioner has not taken responsibility for ongoing medical care for that particular patient with consistency and continuity over time, or does not plan to take responsibility for subsequent, ongoing medical care for that particular patient with consistency and continuity over time'' (85 FR 84570 and 84571, 88 FR 78971). For example, a patient who spends one month of the year in another location could require physicians' services in that location if they experience exacerbation of one of their chronic conditions, but the practitioner who treats them would not intend to manage or monitor that patient's overall, ongoing care. Finally, HCPCS code G2211 can also be billed when medical services are ''part of ongoing care related to a patient's single, serious condition or complex condition,'' but this is different from the APCM requirement. A practitioner's management of one or more serious conditions (as is often the case with specialty care), without more, does not mean that the practitioner is also responsible for all primary care services and the focal point for all needed care (the requirement for APCM), and thus would not necessarily mean that the practitioner could bill for APCM.

As is our current policy for other care management services, and consistent with both CPT guidance and Medicare rules for CPT codes 99487, 99489, 99490, we are proposing that HCPCS codes GPCM1, GPCM2, and GPCM3 may only be reported once per service period (calendar month) and only by the single practitioner who assumes the care management role with a particular beneficiary for the service period. That is, based on a patient's status, a physician or practitioner would identify the patient to receive Level 1, Level 2, or Level 3 APCM services during a given service period (calendar month), and we would make payment for only one claim for APCM services for that service period. At this time, we do not see the need or value of proposing restrictions or complex operational mechanisms to identify a single physician or NPP who may bill for APCM services for a specific beneficiary. However, we recognize that other initiatives, such as the Medicare Shared Savings program, have operational mechanisms in place to attribute patients to certain ACOs (§ 425.400). While a similar approach could be used to attribute patients for APCM services, we are reluctant to introduce unnecessary complexity for these services. As we continue to develop our policies in this area, we are seeking feedback from interested parties on methodologies that could allow for identification of the beneficiary's primary care practitioner. We are also seeking comment on whether there should be additional requirements to prevent potential care fragmentation or service duplication.

We anticipate that APCM services would ordinarily be provided by clinical staff incident to the professional services of the billing practitioner in accordance with our regulation at § 410.26. We are proposing that APCM services would be considered a ''designated care management service'' under § 410.26(b)(5) and, as such, could be provided by auxiliary personnel under the general supervision of the billing practitioner.

Unlike the current coding to describe care management services, we are further proposing that the code descriptors for GPCM1, GPCM2, and GPCM3 would not be time-based. Based on feedback from the physician and practitioner community, we understand that ongoing care management and coordination services are standard parts of advanced primary care, even in months when documented clinical staff or billing professional minutes may not reach the required thresholds for billing or the patient's condition does not meet the clinical conditions for care management services under the existing code set. In consideration of the extensive feedback from interested parties, we have learned that practitioners who currently furnish monthly care management services may already be providing APCM services in a variety of clinical circumstances, documenting all necessary aspects of the patient-centered care furnished monthly to the patient without meeting the requirements to bill for care management services, such as satisfying the administrative requirement to count clinical staff minutes to reach specific time-based thresholds. As we stated in the CY 2024 PFS final rule in the context of the O/O E/M visit complexity add-on code (HCPCS code G2211), primary care physicians may diagnose and treat a condition in an O/O E/M visit that is not expected to last as long as three months or would not reasonably be expected to result in a risk of hospitalization, and the practitioner's clinical staff may provide significant care management and coordination services relating to that condition. For example, COVID–19 cases are clinical circumstances that generally do not last three months but may require significant acute management, care coordination, and follow-up within a given month, particularly for patients with comorbidities (88 FR 78973). Practitioners may also provide care management and coordination services to a patient whose condition meets the criteria in one or more care management codes, but the documented minutes of service may not reach the minimum time threshold to bill for a care management service. For example, the practitioner might provide care coordination for a month that includes 20 minutes of consulting with the patient's other healthcare providers and modifying medications to address an acute exacerbation of hypertension, but would not meet the requirements for billing the PCM service. We also note that, unlike the current coding to describe certain CTBS services, we are proposing that the code descriptors for GPCM1, GPCM2, and GPCM3 would not include the timeframe restrictions for billing certain CTBS (for example, the restriction for virtual check-in services that there is not a related E/M service provided within the previous 7 days or an E/M service or procedure within the next 24 hours or the soonest available appointment). As addressed in the CY2019 Final Rule, we have heard from interested parties that the timeframe restrictions for billing certain CTBS are administratively burdensome (83 FR 59686).

We are also proposing that not all elements included in the code descriptors for APCM services must be furnished during any given calendar month for which the service is billed. APCM services are largely designed to be person-centered and focused on the individual patient, such that the elements that are provided depend on medical necessity and individual patient need. Therefore, we anticipate that all the APCM scope of service

elements (for example, comprehensive care management and care coordination) will be routinely provided, as deemed appropriate for each patient, acknowledging that not all elements may be necessary for every patient during each month (for example, the beneficiary may have no hospital admissions that month, so there is no management of a care transition after hospital discharge). We also anticipate that there may be some months where it may be appropriate for some service elements to be performed more than once for the patient. For example, in one month a patient with heart failure and chronic kidney disease receiving APCM Level 2 services (GPCM2) may be on a stable medication regimen, receive communication about their care plan, but no virtual check-ins. The next month, the patient may experience a heart failure exacerbation requiring inpatient admission, and then receive as part of their APCM service timely communication and follow-up with new labs ordered, multiple virtual check-ins ensuring that the patient understands their new medications, a phone call to help the patient understand the lab results, and an interprofessional consultation with the patient's cardiologist to help decide if the patient's diuretic dosage should be changed.

However, even if not all elements of the APCM service are furnished each month for which APCM is billed, we propose that billing practitioners and auxiliary personnel must have the ability to furnish every service element and furnish these elements as is appropriate for any individual patient during any calendar month. As described in more detail in section II.G.2.c. of this proposed rule, we believe that maintaining certain advanced primary care practice capabilities and requirements is inherent in these elements and must be met to fully furnish and bill APCM. For example, if in our previous example, the patient with heart failure and chronic kidney disease receiving Level 2 APCM experiences swollen legs, the patient should be able to submit a photo or video to the practitioner via a secure communications system, and the practitioner must be able to interpret and communicate remotely with the patient about those images.

While we are proposing that specific minutes spent furnishing APCM services for purposes of billing HCPCS codes GPCM1–GPCM3 need not be documented in the patient's medical record, we would expect that any actions or communications that fall within the APCM elements of service would be described in the medical record and, as appropriate, its relationship to the clinical problem(s) they are intended to resolve and the treatment plan, just as all clinical care is documented in the medical record.

We are seeking feedback on these service descriptions, and on whether there are elements of other care management services that should be removed or altered for purposes of APCM services.

Finally, while the service descriptors above are consistent across all three APCM levels because the scope of service elements are consistent across all levels of APCM and the elements that are provided depend on medical necessity and individual patient need, we are proposing that the APCM codes would be stratified into three levels based on certain patient characteristics that are broadly indicative of patient complexity and the consequent resource intensity involved in the provision of these services in the context of advanced primary care. We are proposing that the new APCM coding schema would be stratified based on APCM services being furnished using the advanced primary care model to patients with one or fewer chronic conditions (''Level 1''); patients with two or more chronic conditions (''Level 2''); and Qualified Medicare Beneficiaries (QMBs) [43] with two or more chronic conditions (''Level 3'') (see Table 20 for the three APCM code levels). This stratification of APCM into three levels allows us to distinguish among different levels of patient complexity and more accurately reflect the resources required to furnish APCM services for certain categories of beneficiaries. We anticipate that a practitioner using the advanced primary care model would bill for APCM services for all or nearly all the patients for whom they intend to assume responsibility for primary care.

Furthermore, we recognize the ways in which this new APCM coding intersects with current care management codes around number of chronic conditions. We note that the current care management codes are generally stratified in a similar, though more granular way, by the degree of complexity of care based on the presence of chronic conditions and complexity of medical decision making, who directly performs the service, and the time spent furnishing the service. In establishing separate payment for CCM services in the CY 2014 PFS final rule, we recognized that the resources involved in furnishing comprehensive, coordinated care management services to patients with multiple (two or more) chronic conditions were greater than those included in a typical non-face-to-face care management service, which we continued to consider as bundled into the payment for face-to-face E/M visits (78 FR 43337). In the CY 2017 PFS final rule, based on robust feedback from interested parties indicating that the new CCM codes did not fully capture the service time required to furnish care to beneficiaries with more complex conditions, we finalized new codes for patients with complex care management needs. In the CY 2016 PFS final rule, in considering how to improve the accuracy of our payments for care coordination, particularly for patients requiring more extensive care management, we stated that we believe the care coordination and management for Medicare beneficiaries with multiple chronic conditions, a particularly complicated disease or acute condition, or certain behavioral health conditions often requires extensive discussion, information-sharing, and planning between a primary care physician and a specialist (for example, with a neurologist for a patient with Alzheimer's disease plus other chronic diseases) (80 FR 70919).

[43] See 42 CFR 435.123. The proposal includes both individuals in the QMB eligibility group who also have full scope Medicaid coverage (''QMB-plus'') and individuals in the QMB eligibility group who do not have Medicaid eligibility under any other Medicaid coverage group (''QMB-only''). However, this proposal would not include those QMBs who are in the Medicare Part B Immunosuppressive Drug benefit, which provides coverage of immunosuppressive drugs based on eligibility requirements described in § 407.55, because such individuals would not qualify for Medicare coverage of the services described in this rulemaking. See 42 CFR 435.123(c)(2).

TABLE 20: Patient-Centered Risk Stratification for Billing APCM Codes

Level 1 [GPCM1]	Level 2 [GPCM2]	Level 3 [GPCM3]
Patients with one or fewer chronic conditions.	Patients with two or more chronic conditions.	Patients with two or more chronic conditions and who are Qualified Medicare Beneficiaries.

(1) Level 1 APCM

We are proposing the Level 1 APCM code for patients with one or fewer chronic conditions because of the increased import and use of non-face-to-face interactions in advanced primary care even for patients with relatively fewer health needs, which has increased over time for several observable reasons, including broad evolution in information and communication technology in everyday life, diffusion of practices first adopted for higher-acuity patients, and continuing practices widely adopted during the COVID–19 pandemic that reduce reliance on in-person interactions. We believe APCM services for a patient diagnosed with one or fewer chronic conditions will require significantly less time and resources than one with two or more chronic conditions since, in general, there would be fewer ongoing health needs and other health care resources to coordinate, a lower risk of drug interactions, and less complicated physiology. Based on CY 2010 Medicare claims data, the difference in annual expenditures per beneficiary between patients with one or fewer chronic conditions and those with two or three chronic conditions was $3,673.[44] Our current care management coding similarly delineates patient complexity between patients with a single serious chronic condition (PCM codes) and those with two or more serious chronic conditions (CCM codes). We anticipate that practitioners who would furnish APCM services may have already had experience with care management services coding and payment for much of this population. The Level 1 APCM code would also address the current gap in coding and payment for care management services furnished using an advanced primary care model for patients without multiple chronic conditions.

(2) Level 2 APCM

We are proposing the Level 2 APCM code for patients with two or more chronic conditions because of the frequency of chronic conditions in the Medicare population. In fact, nearly four in five Medicare beneficiaries have two or more chronic conditions.[45] Furthermore, as noted previously, our current care management coding delineates patient complexity for the CCM codes for patients with two or more serious chronic conditions, and we anticipate that practitioners who would furnish APCM services may have already had experience with care management services coding and payment for much of this population.

For example, someone with chronic kidney disease and heart failure requires regular check-ins, coordination with specialty care, follow-up after hospital admissions for heart failure exacerbations, regular modifications of the care plan, and more. These services are typically described by the existing CCM services. The patient may also typically need to reach out more often to their primary care practitioner with questions or new symptoms via the patient portal. For instance, the person sends a message through the patient portal to ask whether or not they should come into the primary care office after gaining ten pounds in the last week—which could be a sign of increased fluid retention and the need for increased diuretic dosages to avoid pleural edema (an accumulation of fluid in the lungs). The primary care team books the patient for a same-day urgent care appointment to assess for signs of swelling and pleural edema. Again, this on-demand access to their primary care team can help treat the patient's chronic conditions in a patient-centered way and avoid unnecessary complications.

(3) Level 3 APCM

We are proposing the Level 3 APCM code for patients with QMB status and two or more chronic conditions based on our understanding that people with both multiple chronic conditions and social risk factors generally require even more time and resources from primary care practitioners and their teams to ensure that the patient's chronic conditions are managed appropriately and effectively. We are proposing to use a patient's QMB status as a method to identify beneficiaries with social risk factors that generally necessitate relatively greater resource requirements to effectively furnish advanced primary care than people without such risk factors. There is significant evidence that such dually eligible beneficiaries, on average, are more medically complex and have higher healthcare needs;[46] for example, dually eligible beneficiaries are more likely to have poor functional status[47] and recent expenditure data found that the difference in Medicare spending on a per person per year basis between dually eligible and non-dually eligible Medicare beneficiaries was $13,198 in CY 2021.[48]

QMBs are the largest eligibility group within the Medicare-Medicaid dually eligible enrollee population, comprising of 66 percent of the 12.8 million individuals per the most recent available data.[49] For the approximately 8.5 million dually eligible beneficiaries who are QMBs, Medicaid provides assistance for patients to meet Medicare's cost-sharing requirements. The QMB eligibility group helps to ensure full access to the Medicare benefit for the lowest income enrollees by covering these costs. Individuals can qualify for QMB status if their income is below 100 percent of the Federal Poverty Level ($15,300/year in 2024) and assets are no more than $9,430/$14,130 (one person/married couple in 2024), although states can request CMS approval to disregard certain income and assets.[50] Beneficiaries apply for this

[44] Centers for Medicare and Medicaid Services. Chronic Conditions among Medicare Beneficiaries, Chartbook, 2012 Edition. Baltimore, MD. 2012. *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/chronic-conditions/downloads/2012chartbook.pdf.*

[45] Lochner, K., Goodman, R., Posner, S., & Parekh, A. (n.d.). *Multiple Chronic Conditions Among Medicare Beneficiaries.* CMS. *https://www.cms.gov/mmrr/Downloads/MMRR2013_003_03_b02.pdf.*

[46] *Kaiser Family Foundation. (n.d.). A primer on Medicare: What is the role of Medicare for dual-eligible beneficiaries?* Retrieved June 24, 2024, from *https://www.kff.org/report-section/a-primer-on-medicare-what-is-the-role-of-medicare-for-dual-eligible-beneficiaries/#:~:text=A%20larger%20share%20of%20dual,beneficiaries%3B%20and%20more%20than%20half%20*(.

[47] *ASPE. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. December 2016. https://aspe.hhs.gov/reports/report-congress-social-risk-factors-performance-under-medicares-value-based-purchasing-programs.*

[48] *https://www.macpac.gov/wp-content/uploads/2024/01/Jan24_MedPAC_MACPAC_DualsDataBook-508.pdf.*

[49] *Beneficiaries Dually Eligible for Medicare and Medicaid. Data from CY 2021.* (January 2024). Medpac and Macpac. *https://www.macpac.gov/wp-content/uploads/2024/01/Jan24_MedPAC_MACPAC_DualsDataBook-508.pdf.*

[50] *Access to Care Issues Among Qualified Medicare Beneficiaries (QMB).* (2015). Centers for

benefit with their State's Medicaid program and must be redetermined eligible at least annually.

There is growing recognition that social risk factors—such as income, education, access to food and housing, and employment status—play a major role in health,[51] such that social risk factors may affect a person's ability to reach their health goals, as well as the diagnosis and treatment of their medical problems. A report submitted to Congress by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) in response to the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 (Pub. L. 113–185) found that dual Medicare-Medicaid enrollment as a marker for low income was typically the most powerful predictor of poor outcomes on quality measures among social risk factors examined.[52] Beneficiaries with social risk factors may have worse health outcomes due to a host of factors, including higher levels of medical risk, worse living environments (for example, availability of community services, pollution, safety), greater challenges in adherence to medication regimens and medical recommendations (for example, diet/lifestyle), and/or bias or discrimination. Evidence suggests that many health outcomes are related more to social, environmental, and economic factors (which may be beyond practitioners' control) than to clinical interventions.[53] Dual enrollees, and more specifically, QMBs, are therefore a category of Medicare beneficiaries who we believe to be the most socially at-risk of poorer clinical outcomes. As stated in the ASPE report, ''Some of the observed relationship between social risk factors and outcomes may be the result of underlying differences in medical complexity, frailty, disability, and/or functional status. For example, dually-enrolled beneficiaries are more likely to have poor functional status, and therefore, may be more likely to be readmitted after a hospitalization.'' As another example, a patient with diabetes, heart failure, and QMB status may experience food, transportation, or housing insecurity that contributes to difficulty maintaining blood glucose control which can contribute to medical complications including potentially preventable heart failure exacerbations. The primary care practitioner's team may need to check-in regularly to ensure, for example, that the patient gets needed specialty care such as an ophthalmologic examination to avoid the ocular manifestations of diabetes; and consider the availability of transportation vouchers so the patient can attend the ophthalmology appointment. We are proposing the Level 3 APCM code to recognize the unique characteristics of QMBs as beneficiaries with social risk factors for whom significantly more resources are involved in comprehensive care management by practitioners that furnish advanced primary care services to them.

Additionally, we note that patients with QMB status are not responsible for the Medicare cost-sharing associated with covered Medicare Part A or B services, including for any APCM services. Generally, States cover such cost-sharing on behalf of QMBs, although many states use a ''lesser-of'' policy through which states pay less than the full cost sharing amounts.[54] We solicit comments from States on how they would cover cost sharing for the proposed APCM bundle, considering lesser-of policies.

We are also seeking feedback on the use of QMB status and multiple (two or more) chronic conditions as the basis to bill for APCM Level 3 (GPCM3), whether QMB status is an appropriate indicator to identify beneficiaries with added social risk, and whether there is an equivalent marker of social deprivation for use in commercial markets that might be a possible alternative identifier.

c. APCM Service Elements and Practice-Level Capabilities

All the elements within the scope of APCM services are included in the service descriptors for GPCM1, GPCM2, and GPCM3, listed in Table 22, and described in this section. As described above, we are proposing that APCM services would include nearly the same scope of service elements and conditions we established for CCM and PCM services (including elements of 24/7 access and care continuity, care management and care plan, care coordination, management of care transitions, and enhanced communication). We believe this is appropriate because care management is a key component of care delivery using an advanced primary care model. The proposed phrasing in the code descriptors for APCM services generally tracks the code descriptors for CCM and PCM services, except for references to ''time spent'' or ''minutes'' of service.

We are seeking to ensure that the APCM codes would fully and appropriately capture the care management and CTBS services that are characteristic of the changes in medical practice toward advanced primary care, as demonstrated in select CMS Innovation Center models. As we do for CCM and PCM services, we propose to require for APCM services that the practitioner provide an initiating visit and obtain beneficiary consent (see section II.G.2.c.(1) and II.G.2.c.(2) of this proposed rule). As described in more detail below, we are proposing to incorporate as elements of APCM services ''Management of Care Transitions'' and ''Enhanced Communications Opportunities.'' For the ''Management of Care Transitions'' APCM service element, we are proposing to specify timely follow-up during care transitions (see section II.G.2.c.(6) of this proposed rule). For the ''Enhanced Communications Opportunities'' APCM service element, we are proposing to incorporate access to CTBS services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with the patient, as well as access to patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits) (see section II.G.2.c.(8) of this proposed rule).

We are also proposing to specify for APCM services the practice-level characteristics and capabilities that are

Medicare & Medicaid Services. *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Access_to_Care_Issues_Among_Qualified_Medicare_Beneficiaries.pdf*.

[51] Long P, Abrams M, Milstein A, Anderson G, Apton KL, Dahlberg M, Whicher D. Effective care for high-need patients. Washington, DC: National Academy of Medicine. 2017. *https://nam.edu/wp-content/uploads/2017/06/Effective-Care-for-High-Need-Patients.pdf*; Schroeder, S. (2007, September 20). We Can Do Better—Improving the Health of the American People. New England Journal of Medicine, 357(12), 1221–1228. *https://www.nejm.org/doi/full/10.1056/NEJMsa073350*.

[52] ASPE. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. December 2016. *https://aspe.hhs.gov/reports/report-congress-social-risk-factors-performance-under-medicares-value-based-purchasing-programs*.

[53] World Health Organization. (2018). Health Impact Assessment (HIA): The determinants of health. *http://www.who.int/hia/evidence/doh/en/*.

[54] Under the ''lesser of'' policy, a State caps its payment of Medicare cost-sharing at the Medicaid rate for a particular service. For example, if the Medicare rate for a service is $100, of which $20 is beneficiary coinsurance, and the Medicaid rate for the service is $90, the state would only pay $10. If the Medicaid rate is $80 or lower, the state would make no payment.

inherent to, and necessarily present when a practitioner is providing covered services using an advanced primary care delivery model. As described in more detail below, included in the service descriptors for GPCM1, GPCM2, and GPCM3, and listed in Table 22, our proposed practice-level capabilities that reflect care delivery using an advanced primary care model are focused around 24/7 access and continuity of care (see section II.G.2.c.(3) of this proposed rule), patient population-level management (see section II.G.2.c.(9) of this proposed rule), and performance measurement (see section II.G.2.c.(10) of this proposed rule). These practice capabilities are indicative of, and necessary to, care delivery using an advanced primary care model. Further, APCM services, as we propose to define them, could not be fully performed in the absence of these practice capabilities; and, in such cases, APCM services should not be billed.

We are proposing that practitioners participating in the ACO REACH model, the Making Care Primary model, and the Primary Care First model would satisfy the proposed initiating visit, patient population-level management, and performance measurement APCM service elements and practice-level capabilities by virtue of their model participation. These CMS Innovation Center models promote advanced primary care delivery consistent with the proposed APCM service elements and practice-level capabilities described in Table 21. The models all utilize attribution methods that review the most recently available two years of Medicare claims to identify whether a model participant is responsible for a Medicare beneficiary's primary care, aligning with the initiating visit requirements for APCM services. Additionally, these three models also include risk stratification and quality and cost performance metrics that are aligned or overlap with the Value in Primary Care MVP.[55] Around-the-clock access and continuity of care, patient population-level management, and performance measurement are indicative of, and necessary to, care delivery using an advanced primary care model. We are also considering whether certain practitioners in other types of CMS Innovation Center models also satisfy the proposed service elements and requirements and seek comments on this question.

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[55] See, *e.g.,* ACO Realizing Equity, Access, and Community Health (REACH) Model Request for Applications. Available at *https://www.cms.gov/priorities/innovation/media/document/aco-reach-rfa,* ACO Realizing Equity, Access, and Community Health (REACH) Model PY 2024 Quality Measurement Methodology. Available at *https://www.cms.gov/files/document/aco-reach-quality-msr-meth-py24.pdf;* Making Care Primary Payment and Attribution Methodologies. Available at *https://www.cms.gov/files/document/mcp-pymt-att-methodologies.pdf,* Primary Care First Payment and Attribution Methodologies PY 2024. Available at *https://www.cms.gov/files/document/pcf-py24-payment-meth.pdf.*

TABLE 21: APCM Service Elements* and Practice-Level Capabilities

Consent • Inform the patient of the availability of APCM services; that only one practitioner can furnish and be paid for these services during a calendar month; of the right to stop services at any time (effective at the end of the calendar month); and that cost sharing may apply* (may be covered by supplemental health coverage) • Document in patient's medical record that consent was obtained
Initiating Visit for New Patients (separately paid) • Initiation during a qualifying visit for new patients • An initiating visit is not needed: (1) if the beneficiary is not a new patient (has been seen by the practitioner or another practitioner in the same practice within the past three years) or (2) if the beneficiary received another care management service (APCM, CCM, or PCM) within the previous year with the practitioner or another practitioner in the same practice.
24/7 Access to Care and Care Continuity • Provide 24/7 access for urgent needs to care team/practitioner with real-time access to patient's medical information, including providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent needs regardless of the time of day or day of week • Continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments • Deliver care in alternative ways to traditional office visits to best meet the patient's needs, such as home visits and/or expanded hours, as appropriate
Comprehensive Care Management • Overall comprehensive care management may include, as applicable • Systematic needs assessment (medical and psychosocial) • System-based approaches to ensure receipt of preventive services • Medication reconciliation, management and oversight of self-management
Patient-Centered Comprehensive Care Plan • Development, implementation, revision, and maintenance of an electronic patient-centered comprehensive care plan which is available timely within and outside the billing practice as appropriate to individuals involved in the beneficiary's care, can be routinely accessed and updated by care team/practitioner, and copy of care plan to patient/caregiver
Management of Care Transitions (for example, discharges, ED visit follow-up, referrals, as applicable) • Coordination of care transitions between and among health care providers and settings, including transitions involving referrals to other clinicians, follow-up after an emergency department visit, or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities, as applicable • Ensure timely exchange of electronic health information with other practitioners and providers to support continuity of care. • Ensure timely follow-up communication (direct contact, telephone, electronic) with the patient and/or caregiver after ED visits and discharges from hospitals, skilled nursing facilities, or other health care facilities, within 7 calendar days of discharge, as clinically indicated
Practitioner, Home-, and Community-Based Care Coordination • Ongoing communication and coordinating receipt of needed services from practitioners, home- and community-based service providers, community-based social service providers, hospitals, and skilled nursing facilities (or other health care facilities), as applicable, and document communication regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors in the patient's medical record

Enhanced Communication Opportunities • Enhanced opportunities for the beneficiary and any caregiver to communicate with the care team/practitioner regarding the beneficiary's care through the use of asynchronous non-face-to-face consultation methods other than telephone, such as secure messaging, email, internet, or patient portal, and other communication technology-based services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with patients, as appropriate • Ensure access to patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits)
Patient Population-Level Management • Analyze patient population data to identify gaps in care and offer additional interventions, as appropriate • Risk stratify the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients • A practitioners who is participating in a Shared Savings Program ACO, REACH ACO, Making Care Primary, or Primary Care First satisfies this requirement
Performance Measurement Be assessed on primary care quality, total cost of care, and meaningful use of CEHRT, which can be met in several ways: • For MIPS-eligible clinicians, by registering for and reporting the Value in Primary Care MVP** • A practitioner who is part of a TIN participating in a Shared Savings Program ACO satisfies this requirement through the ACO's reporting of the APM Performance Pathway • A practitioner who is participating in a Shared Savings Program ACO, REACH ACO, Making Care Primary, or Primary Care First satisfies this requirement through the quality reporting, assessment and performance requirement and other program and model requirements.

* Medicare beneficiaries who are enrolled in the QMB eligibility group do not have any Medicare cost-sharing responsibility for copays, deductibles, and coinsurance.

** See discussion in section II.G.2.c.(10) of this proposed rule for a description of the timeline of MIPS reporting. For APCM services billed in 2025, practitioners would register to report the MVP in 2025, and report the MVP in 2026 for the 2025 performance year/2027 MIPS payment year. For more details, see the 2024 MIPS Quick Start Guide, available at *https://qpp.cms.gov/mips/reporting-options-overview*.

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We are seeking comment on whether the proposed elements and requirements are appropriately reflective of care management services for advanced primary care, and whether there are proposed elements of APCM services or proposed practice capabilities that should be modified or removed. We are also seeking feedback on ways to align the APCM services with other Medicare programs and initiatives, such as the Shared Savings Program, ACO REACH, and advanced primary care models, and the Quality Payment Program, including MIPS and Advanced Alternative Payment Models (Advanced APMs). We seek to create a low burden way for practitioners to furnish APCM services by appropriately recognizing ways in which they may meet APCM billing requirements as part of these programs and initiatives. We note that under the Quality Payment Program, practitioners who are MIPS eligible clinicians would report measures and activities as specified by CMS under the four MIPS performance categories: quality, cost, improvement activities, and Promoting Interoperability (PI). To report to MIPS for a performance period (§ 414.1320(i)) for the PI performance category, a MIPS eligible clinician must use Certified EHR Technology (CEHRT), as defined at paragraph (2) under CEHRT at § 414.1305, report on the objectives and associated measures as specified by CMS, and submit required attestations as specified in § 414.1375(b)(3) (§ 414.1375(b)). Eligible clinicians who participate in Advanced APMs under the Quality Payment Program are required under the terms of those APMs to use CEHRT as specified in § 414.1415(a)(1)(iii); and are paid under the terms of those APMs based on MIPS-comparable quality measures as specified in § 414.1415(b).

As described in the sections below, we are proposing that a billing practitioner who is part of a Shared Saving Program ACO, or CMS Innovation Center ACO or participating in Making Care Primary or Primary Care First would already satisfy the proposed practice-level requirements for patient population-level management (see section II.G.2.c.(9) of this proposed rule), and performance measurement (see section II.G.2.c.(10) of this proposed rule) by meeting separately applicable participation requirements within the Shared Savings Programs and models. As noted previously, we are considering whether practitioners in other types of CMS Innovation Center models also satisfy certain proposed service elements and practice-level requirements through their participation in the models, and seek comments on this question.

(1) Beneficiary Consent

Consistent with other care management services, we are proposing that the beneficiary's consent to receive APCM services must be documented in the medical record as a condition of payment for APCM services, as not all Medicare beneficiaries for whom APCM services would be medically necessary may want to receive these services. As we do for CCM and PCM services, we are proposing to require billing practitioners to inform the beneficiary of the availability of APCM services, and ensure the beneficiary is aware that Medicare cost-sharing usually applies (though these costs may be covered through supplemental health coverage). The practitioner should also inform the beneficiary that, by providing APCM services, they intend to assume responsibility for all of the patient's primary care services and serve as the continuing focal point for all needed health care services; and that only one

practitioner can furnish and be paid for APCM services during a calendar month, but that their consent to receive APCM services does not limit their option to receive Medicare covered health care services from other practitioners. The practitioner should inform the beneficiary that APCM is an ongoing, monthly service and of their right to stop APCM services at any time (effective at the end of the calendar month), and that they only need to provide consent once to receive APCM services from the practitioner. We are proposing that the practitioner would document in the beneficiary's medical record that this information was explained and note whether the beneficiary accepted or declined APCM services. We note that practitioners can still elect to obtain written consent rather than verbal consent.

Practitioners have informed us that beneficiary cost sharing is a significant barrier to provision of similar care management services, such as CCM services. The proposed patient consent requirement is intended to ensure that patients do not incur unexpected expenses for care that is largely, or in significant part, non-face-to-face in nature. The proposed requirement for patient consent would also help to avoid duplicative practitioner billing, as the patient would understand that the practitioner intends to serve as the focal point for all their care, and that only one practitioner can furnish and be paid for APCM services in any particular month.

We seek feedback on these proposed requirements, including how best to effectively educate both practitioners and beneficiaries on the benefits of APCM, especially as it reflects a new bundle of services that may have previously been separately billed, and whether a CMS-provided template to facilitate patient consent would be helpful. We also seek feedback on whether CMS should require practitioners to revisit consent for APCM services on an ongoing basis with patients.

(2) Initiating Visit

Consistent with CCM services (CPT codes 99437, 99439, 99487, and 99489–99491) and PCM services (CPT codes 99424–99427), we are proposing to require an initiating visit for APCM services only for new patients instead of for all beneficiaries receiving APCM services. Consistent with the definition of ''new patient'' as described in the CPT® 2024 Professional Edition Code Book on page 4, we are proposing to define a ''new patient'' as a person who did not receive any professional services from the physician or other qualified health care professional or another practitioner in the same group practice within the previous 3 years.[56] The initiating visit furnished in advance of APCM services establishes the beneficiary's relationship with the billing practitioner, ensures the billing practitioner assesses the beneficiary prior to initiating APCM services, facilitates collection of comprehensive health information to inform the care plan, and provides an opportunity to obtain beneficiary consent (although beneficiary consent can be obtained outside of the initiating visit). We are proposing that the same services that can serve as the initiating visit for CCM services could serve as the initiating visit for APCM, including a Level 2 through 5 E/M visit, initial preventive physician exam (IPPE), or TCM service, and we propose that the initiating visit could be provided in person or as a Medicare telehealth service.

We are proposing that an initiating visit would not be required for ''established patients'' based on certain circumstances that we believe demonstrate an established patient-practitioner relationship in advance of furnishing APCM services: (1) if the beneficiary is not a new patient (has been seen by the practitioner or another practitioner in the same practice within the past three years) or (2) if the beneficiary received another care management service (including an APCM service, non-complex or complex CCM service (CPT codes 99487, 99489, 99490, 99491, 99439, 99437), or PCM service (CPT codes 99424, 99425, 99426, 99427)) within the previous year with the practitioner or another practitioner in the same practice. We do not believe there necessarily is a need for an initiating visit for APCM services for patients with whom the practitioner (or another in the same practice) has an established relationship; and we would not want to require an initiating visit under circumstances where a visit may not be medically necessary. The proposed policy not to require an initiating visit for beneficiaries who have received any professional service from the physician or other qualified health care professional or another practitioner in the same group practice within the previous 3 years is consistent with CPT's definition of the term ''established patient,'' such that we believe this captures patients who have been seen relatively recently and who have an existing relationship with the practice. In the case of beneficiaries who have received care management services from a practitioner within the practice in the past year, we believe this indicates that the patient is also an ''established patient'' in that the patient has an existing relationship with the practice, and the patient previously has consented to the receipt of care management services, which have overlapping service elements with APCM services.

We note that these standards would be consistent with applicable Shared Savings Program and CMS Innovation Center patient attribution standards in ACO REACH, Making Care Primary, and Primary Care First. Any beneficiary eligible to be assigned to an ACO because of an established care relationship between the beneficiary and a billing practitioner who would be billing for APCM services under the ACO participant's TIN, including beneficiaries who voluntarily aligned to a practitioner in the ACO, would not be considered a new patient and would not require an initiating visit. Medicare rules governing patient attribution to an ACO on the basis of care provided by an ACO-participating clinician similarly establishes where an existing care relationship exists. Similarly, beneficiaries eligible to be assigned to a REACH ACO, or a Making Care Primary or Primary Care First practice because of an established care relationship between the beneficiary and a billing practitioner who would be billing for APCM services under the model participant's TIN, including beneficiaries who voluntarily aligned to a practitioner participating in one of these three models would not be considered a new patient and would not require an initiating visit. While we are proposing certain exceptions to the initiating visit requirement for APCM services, we note that an initiating visit may still be needed even when not required, and the billing practitioner can always furnish and bill for medically necessary visits, including before initiating APCM services.

We seek feedback on these proposed requirements, including whether additional services could serve as the initiating visit and whether a different period of time (for example, patients not seen within one or two years) would be more appropriate.

(3) 24/7 Access and Continuity of Care

Access and continuity build on the patient-practitioner relationship to ensure patients receive the right care at the right time from the right care team member. We are proposing to include for APCM services the same scope of service elements we established for CCM and PCM services for 24/7 Access

[56] American Medical Association. CPT Professional 2024. American Medical Association, 2023.

and Continuity of Care with some modifications. For 24/7 Access to Care, the scope of the service element we propose for APCM services would be to provide 24/7 access for urgent needs to the care team/practitioner with real-time access to patient's medical records, including providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent needs regardless of the time of day or day of week.

As described in the CY 2017 PFS final rule, this accurately reflects the potential role of clinical staff or call-sharing services in addressing after-hours care needs, and that after-hours services typically would and should address any urgent needs and not only those explicitly related to the beneficiary's chronic conditions (79 FR 67722). In advanced primary care models of care, primary care practices should be at the center of that care—providing an effective ''first contact'' for patients, supporting patients in their management of care, and coordinating across different settings of care. Achieving this level of access to primary care requires timeliness and an effective relationship with those in the practice who are providing that care. True access is fully informed by knowledge about the patient and their care, which is only possible through real-time access to the patient's electronic health information. Access to primary care, informed by health information technology (IT), makes the right care at the right time possible, potentially avoiding costly urgent and emergent care. Practices can achieve 24/7 access to care informed by health IT through call coverage by a practitioner with health IT system access. This can be a practitioner from the practice or a covering practitioner who has system access. Many practices and systems use nurse call lines or answering services working with standard protocols to provide the initial point of contact after hours and effectively address common problems. In this situation, an escalation protocol will engage a practitioner with system access when needed for decision making. Other successful practices expand hours, add urgent care services or partner with other practices to provide these services, or contract with existing urgent care providers to manage and coordinate care after regular office hours.

For Continuity of Care, the scope of service element would be to provide continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments. Continuity of care refers to the ability of patients to receive care from practitioners who know them and are known by them. This continuity builds and reinforces a relationship based in trust and shared experience that is highly valued by both practitioners and patients. Practice focus on continuity of care can translate to improved preventive and chronic care, patient and practitioner satisfaction, lower hospital utilization, and lower costs.[57] Depending on the type and setting of care, there are three components of continuity that improve patient outcomes and experience: [58] relational continuity (defined as the ''ongoing therapeutic relationship between a patient (and often their family/caregiver)'' which is foundational in advanced primary care), informational continuity (where practitioners have access to information on patients' past events and personal circumstances to inform current care decisions); and longitudinal continuity (which refers to ongoing patterns of healthcare visits that occur with the same practice over time). A key strategy to optimize continuity is ensuring that all practitioners and/or the care team have access to the same patient information to guide care within health IT, and successful practices start with a review and discussion of the practice-level data developed through measurement of continuity.[59] Practices can develop the capability to measure continuity of care between the patient and the practitioner/care team using health IT, practice management software, or other tracking mechanisms, allowing them to track improvements over time.

As included in the APCM code descriptors, we are proposing to specify for the ''24/7 Access to Care'' APCM service element that the practice would maintain the capability to deliver care in alternative ways to traditional office visits to best meet the patient population's needs, such as e-visits, phone visits, home visits, and/or expanded hours. This proposed standard for alternatives to office visits is similar to several requirements tested in CMS Innovation Center models (such as the CPC+ model's requirement that participating practices regularly offer at least one alternative to traditional office visits [60]), and reflects the understanding that providing alternatives to traditional office visits is an essential element of the delivery of care under an advanced primary care model of care. Moving care out of traditional office visits can reduce demand and open supply for prioritized visits. By changing where and how care is delivered, practices may have increased availability for patients with complex needs who may be better served by more time-intensive visits in the office, at home, or in a nursing home. We are not proposing that a practice would need to regularly deliver care in all these alternative ways—for example, a practice may routinely offer e-visits and phone visits, but not regularly furnish home visits, and still demonstrate this primary care practice capability. Another practice might offer extended hours on certain days to help patients who may find it hard to take off work to see their clinician, and this would satisfy this practice requirement.

We seek feedback on these proposed requirements.

(4) Comprehensive Care Management

We are proposing for APCM services the ''Comprehensive Care Management'' service element we established for CCM and PCM services with some modifications. Rather than ''care management for chronic conditions,'' the APCM service element would be ''overall comprehensive care management'' which, like the element for CCM and PCM services, may include, as applicable, ''systematic assessment of the patient's medical, functional, and psychosocial needs;

[57] Hussey, P.S., Schneider, E.C., Rudin, R.S., Fox, D.S., Lai, J., & Pollack, C.E. (2014). Continuity and the costs of care for chronic disease. JAMA Internal Medicine, 174(5), 742–748; Bayliss, E.A., Ellis, J.L., Shoup, J.A., Zeng, C., McQuillan, D.B., & Steiner, J.F. (2015). Effect of continuity of care on hospital utilization for seniors with multiple medical conditions in an integrated health care system. The Annals of Family Medicine, 13(2), 123–129; Nyweide, D.J., Anthony, D.L., Bynum, J.P., Strawderman, R.L., Weeks, W.B., Casalino, L.P., & Fisher E.S. (2013). Continuity of care and the risk of preventable hospitalization in older adults. JAMA Internal Medicine, 173(20), 1879–1885; Haggerty, J.L., Reid, R.J., Freeman, G.K., Starfield, B.H., & Adair, C.E. (2003). Continuity of care: a multidisciplinary review. BMJ, 327, 1219. *doi:10.1136/bmj.327.7425.1219;* Gupta, R., & Bodenheimer, T. (2013). How primary care practices can improve continuity of care. JAMA Internal Medicine, 173(20), 1885–1886. doi:10.1001/jamainternmed.2013.7341; Willard R., & Bodenheimer T. (2012, April). The building blocks of high-performing primary care: Lessons from the field. California Healthcare Foundation. *http://www.chcf.org/publications/2012/04/building-blocks-primary-care.*

[58] Haggerty, J.L., Reid, R.J., Freeman, G.K., Starfield, B.H., & Adair, C.E. (2003). Continuity of care: a multidisciplinary review. *BMJ, 327,* 1219. *doi:10.1136/bmj.327.7425.1219.*

[59] Gupta, R., & Bodenheimer, T. (2013). How primary care practices can improve continuity of care. *JAMA Internal Medicine, 173*(20), 1885–1886. doi:10.1001/jamainternmed.2013.7341; Willard R., & Bodenheimer T. (2012, April). *The building blocks of high-performing primary care: Lessons from the field.* California Healthcare Foundation. *http://www.chcf.org/publications/2012/04/building-blocks-primary-care.*

[60] *https://www.cms.gov/priorities/innovation/innovation-models/comprehensive-primary-care-plus.*

system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of patient self-management of medications.'' This care management standard is similar to several requirements tested in CMS Innovation Center models (such as the CPC+ model's requirement that participating practices provide targeted, proactive, relationship-based care management to all patients identified as at increased risk and likely to benefit from intensive care management and provide short-term care management, including medication reconciliation, to patients following hospital admission/discharge/transfer, including observation stays, and, as appropriate, following an ED discharge)[61] and is an essential element of the delivery of care under an advanced primary care model of care. Care management is a resource-intensive process of working with patients, generally outside of face-to-face office visits, to help them understand and manage their health, navigate the health system, and meet their health goals. Practices working with patients who have complex care needs have found care management to be an effective and necessary strategy for mitigating risk and improving health outcomes. Practices have found it valuable to think in terms of two broad types of patients who might benefit from different approaches to care management: patients with some combination of multiple comorbidities, complex treatment regimens, frailty and functional impairment, behavioral and social risks, and serious mental illness who would often benefit from long-term, proactive, and relationship-based longitudinal care management; and patients who are otherwise stable and will benefit from short-term, goal-oriented episodic care management during periods of increased risk like transitions of care; diagnosis of a new, serious illness or injury involving complex treatment regimens; or newly unstable chronic illness.

Successful practices use on-site, non-physician, practice-based, or integrated shared care managers to provide longitudinal care management for the highest risk cohort of patients, with assistance from other practice staff, as needed. Multiple team members may engage in care management, but each patient identified as eligible should have a clinically trained individual in the practice who is accountable for active, ongoing care management that goes beyond office-based clinical diagnosis and treatment.[62] Longitudinal care management is captured in health IT and includes providing proactive care that moves beyond traditional office visits or crisis-driven care (for example, ED care or hospitalization) and is not primarily visit-based. Although office visits are opportunities to define goals, plan patient care, engage in shared decision making, and build a trusting relationship, most care management activities take place by phone, patient portal, email, mail, or home visits (and through visits to skilled nursing facilities or hospitals to support transitional care).

Practices use the concept of episodic care management to identify patients who have acute or urgent needs using ''triggering events'' (for example, hospital discharge, new diagnoses, medical crisis, major life event, decompensation in otherwise controlled chronic condition) for short-term, problem-focused care management services. Episodic care management is generally time-limited and problem focused and most often includes coordination of services and follow-up, patient education and support for self-management, and medication reconciliation.

We seek feedback on these proposed requirements.

(5) Patient-Centered Comprehensive Care Plan

We are proposing for APCM services the ''Comprehensive Electronic Care Plan'' service element we established for CCM and PCM services with some modifications. As included in the APCM code descriptors, we are proposing to specify that the care plan is ''patient-centered'' which, as for CCM and PCM services, ''is available timely within and outside the billing practice'' as appropriate to individuals involved in the beneficiary's care, can be routinely accessed and updated by care team/practitioner, and ''copy of care plan to patient/caregiver.''

Providing longitudinal care management, which is an essential element of the delivery of care under an advanced primary care model of care, includes the process of personalized care planning. The personalized care planning process helps practices engage and collaborate with patients to ensure that their care aligns with patient preferences, goals, and values.[63] A care plan is a mutually agreed-upon document that outlines the patient's health goals, needs, and self-management activities and is accessible to all team members providing care for the patient. The care plan should be patient-friendly, accessible to the patient, and should limit use of unfamiliar medical jargon and acronyms. The care plan should also be structured and standardized, documented in health IT to enable sharing among patient, caregivers, and care team members. All high-risk patients receiving longitudinal care management should have a personalized care plan developed in a joint, open-ended conversation between the patient and care team. Personalized care planning is a dynamic process; therefore, the care plan document should be updated at regularly defined intervals by the care team and patient. In addition, when patients' health status, preferences, goals, and values change, their plans of care should, too.

As described in the CY 2020 final rule, we proposed language to describe the ''typical'' care plan elements which do not comprise a set of strict requirements that must be included in a care plan for purpose of billing but are intended to reflect those that are typically included in a care plan as medically appropriate for a particular beneficiary. The comprehensive care plan for all health issues typically includes, but is not limited to, the following elements: problem list; expected outcome and prognosis; measurable treatment goals; cognitive and functional assessment; symptom management; planned interventions; medical management; environmental evaluation; caregiver assessment; interaction and coordination with outside resources and practitioners and providers; requirements for periodic review; and when applicable, revision of the care plan.

We seek feedback on these proposed requirements.

(6) Management of Care Transitions

We are proposing to adopt for APCM services the ''Management of Care Transitions'' service element we established for CCM and PCM services with some modifications. Rather than

[61] *https://www.cms.gov/priorities/innovation/innovation-models/comprehensive-primary-care-plus.*

[62] Taylor, E.F., Machta, R.M., Meyers, D.S., Genevro, J., & Peikes, D.N. (2013). Enhancing the primary care team to provide redesigned care: The roles of practice facilitators and care managers. *Annals of Family Medicine, 11*(1), 80–83. *doi:10.1370/afm.1462.*

[63] Coulter A., Entwistle, V.A., Eccles, A., Ryan, S., Shepperd, S., & Perera, R. (2015). Personalised care planning for adults with chronic or long-term health conditions. *Cochrane Database System Review, 3,* CD010523; Edwards, S.T., Dorr, D.A., & Landon, B.E. (2017). Can personalized care planning improve primary care? *JAMA, 318*(1), 25–26.

requiring that the practice must facilitate communication of relevant patient information through electronic exchange of continuity of care documents with other health care providers regarding these transitions, we are proposing more simply to require the billing practitioner to ''ensure timely exchange of electronic health information'' with other practitioners and providers. As included in the APCM code descriptors, we are also proposing to specify for the ''Management of Care Transitions'' APCM service element that the care team/practitioner would follow up with the patient and/or caregiver within 7 days after each ED visit and hospital discharge. This proposed timely follow-up standard is similar to several requirements tested in CMS Innovation Center models (such as the CPC+ model's requirement that participating practices ensure patients with ED visits received a follow-up interaction within one week of discharge [64] and the MCP model's requirement that participating practices implement episodic care management to provide timely follow-ups for high-risk patients post ED visit and hospitalization [65]), and we patterned the timely follow-up element after our policy for TCM services which requires, for example, ''communication (direct contact, telephone, electronic) with the patient and/or caregiver with 2 business days of discharge'' and a ''face-to-face visit within 7 calendar days of discharge.'' Providing timely follow-ups for patients is an essential element of the delivery of care under an advanced primary care model of care, and we believe this will help achieve timely, seamless care across settings especially after discharge from a facility. Key aspects of follow-up after ED visits and hospitalizations include identifying and partnering with target hospitals and EDs where the majority of a practice's patients receive services to achieve timely notification and transfer of information following hospital discharge and ED visits.[66] When developing a standardized process for data exchange and timely follow-up, successful practices include the following processes: information and data exchange about patients seen in an ED or admitted to/discharged from a hospital (for example, via HIE, hospital portal, hospital-generated report, EHR, or additional health IT system); definition for ''timely'' follow-up after discharge (for example, no later than within 2 days of discharge from hospital admission or observation stay and within 1 week of discharge from the ED); protocols for when follow-up will be done (for example, before discharge or following a standardized follow-up protocol); process of incorporating into the patient's medical record so the information is available at the time of the follow-up visit or other patient contact; and standardized processes and protocols for data exchange and formalized partnerships to develop an efficient workflow to ensure timely follow-up and facilitate efficient and safe transitions of care.

Practices use a variety of scheduling strategies to prioritize same-day or next-day access for acutely ill patients and to provide timely follow-up for patients experiencing care transitions. Successful practices are those that can strike the right balance between timely access to visits and the offering patients a provider of their choice (Continuity of Care). Establishing standardized protocols and pathways to improve and ensure responsiveness and timely callbacks to patients is an effective way to impact patient–practitioner/care team communication and to ensure a safeguard for addressing emergent and urgent patient phone calls. Successful practices routinely evaluate the degree to which patients' phone calls are answered promptly or returned within a practices' established guidelines (for example, non-urgent, emergent, urgent) and routed to the appropriate practitioner or care team member, incorporating patients' clinical needs and preferences.[67] Such strategies are paramount for practices whose patients may be contacting the practice with care needs that require care team prioritization and urgent reply.

We seek feedback on these proposed requirements.

(7) Practitioner, Home-, and Community-Based Care Coordination

We are proposing to adopt for APCM services the ''Home- and Community-Based Care Coordination'' service element we established for CCM and PCM services with some modifications. As included in the APCM code descriptors, we are proposing to specify that the ''ongoing communication and coordinating receipt of needed services'' is with not only with home- and community-based service providers, but also with ''practitioners,'' ''community-based social service providers, hospitals, and skilled nursing facilities (or other health care facilities), as applicable.'' We are also proposing to add more detail about the communication documented in the patient's medical record in that it would include ''the patient's psychosocial strengths and needs, and functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.''

Coordinated referral management with specialty groups and other community or healthcare organizations ensures referrals are properly managed, coordinated, and communicated. These efforts help practices achieve goals of enhancing the quality of patient care, improving the patient's care experience, and lowering cost, particularly for practices serving high-risk patient populations. Evidence suggests that the development of formal relationships (for example, collaborative care agreements) between the primary care practice and referred groups/organizations that define shared goals and responsibilities, facilitate the coordinated referral management process.[68] The foundation of successful coordinated referral management with specialty groups and other community or healthcare organizations is the development of processes and procedures to ensure high-value referrals, such as collaborative care agreements and electronic consultations (e-Consults). Establishing clear and agreed-upon expectations regarding communication and clinical responsibilities with specialty practices and other care organizations, through a collaborative care agreement, improves the process. Collaborative care agreements often

[64] *https://www.cms.gov/priorities/innovation/files/x/cpcplus-practicecaredlvreqs.pdf.*

[65] *https://www.cms.gov/priorities/innovation/innovation-models/making-care-primary.*

[66] Carrier, E., Yee, T., & Holzwart, R.A. (2011). Coordination Between Emergency and Primary Care Physicians (NIHCR Research Brief No. 3). National Institute for Health Care Reform. *http://nihcr.org/analysis/improving-care-delivery/prevention-improving-health/ed-coordination/;* Ventura, T., Brown, D., Archibald, T., et al. (2010, January–February). Improving care transitions and reducing hospital readmissions: establishing the evidence for community-based implementation strategies through the care transitions theme. *http://www.communitysolutions.com/assets/2012_Institute_Presentations/caretransitioninterventions051812.pdf.*

[67] Hempel, S., Stockdale, S., Danz, M., Rose, D.E., Kirsh, S., Curtis, I., & Rubenstein, L.V. (2018). Access management in primary care: Perspectives from an expert panel (Research Report No. RR–2536–DVA). Rand Corporation. *https://www.rand.org/content/dam/rand/pubs/research_reports/RR2500/RR2536/RAND_RR2536.pdf*; O'Brien, L.K., Drobnick, P., Gehman, M., Hollenbeak, C., Iantosca, M.R., Luchs, S., Manning, M., Palm, S.K., Potochny, J., Ritzman, A., Tetro-Viozzi, J., Trauger, M., & Armstrong, A.D. (2017). Improving responsiveness to patient phone calls: A pilot study. Journal of Patient Experience, 4(3), 101–107. *doi:10.1177/2374373517706611.*

[68] Medicare Payment Advisory Commission (MedPAC). (2012, June). Report to the Congress: Medicare and the Health Care Delivery System. *http://medpac.gov/docs/default-source/reports/jun18_medpacreporttocongress_sec.pdf?sfvrsn=0.*

include the following elements: defining the types of referrals, consultation, and co-management arrangements available; specifying who is accountable for which processes and outcomes for care within the referral, consultation, or co-management arrangement; and specifying what clinical and other information should be provided, how the information is transferred, and timeliness expectations. The electronic e-Consults process is typically conducted through a system-wide EHR or a secure, web-based system by which a practice receives guidance from a specialty provider or other care organization.[69] In this process, a practitioner sends a clinical question and relevant clinical information to the specialist (or other care organization), who responds by providing a clinical opinion and guidance and/or confirms the need for a face-to-face appointment with the patient. This tool and process has the potential to streamline consultations, reduce cost and burden for patients, and improve access to specialty care for high-value referrals. As part of the CY 2019 PFS final rule, we finalized interprofessional consultation services codes, which support payment both to the treating, requesting (primary care) practitioner (CPT code 99452) and the receiving, consultative specialist (CPT codes 99446–99449 and 99451) who engage in e-Consults, and so some practitioners have already become accustomed to providing and billing for these services.

Strategies for addressing common health-related social needs (HRSNs) for a practice's high-risk patients include conducting needs assessments at regular intervals, creating a resource inventory for the most pressing needs of the patient population, and establishing relationships with key community organizations. Practices can focus on developing relationships with community-based organizations that support patients' most significant HRSNs. Practices can also seek to find common ground with community and social service organizations, focus on the structure and process of referrals, and develop a bidirectional flow of information. Successful practices work with their patients to ensure there is a shared understanding of the purpose of the referral and aim to understand bottlenecks and barriers to meeting their needs through the process. Many practices identify a care team member to be a community referral resource for their patients. Successful referrals can help practices determine the most useful and available resources in their community.

We seek feedback on these proposed requirements.

(8) Enhanced Communications Opportunities

We are proposing to include for APCM services the element of ''Enhanced Communications Opportunities'' we established for CCM and PCM services with some modifications. Specifically, we would add ''internet and patient portal'' as examples of asynchronous non-face-to-face consultation methods and specify that the practitioner would provide ''other communication technology-based services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with patients, as appropriate'' as well as specify ''access to patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits).'' Providing asynchronous non-face-to-face consultation methods and other CTBS services is an essential element of the delivery of care under an advanced primary care model of care, and we believe this will allow patients to access their usual source of care more conveniently (see section II.G.2.c.(3) of this proposed rule). There is growing consensus that incorporating telehealth into primary care will allow patients to access their usual source of care more conveniently.[70] Patients using telehealth visits have reported high satisfaction, identifying convenience and perceived high quality of care as contributors,[71] such that these may be a good alternative and, in some cases, preferable to in-person communication.[72] Expansion of telehealth to address episodic and chronic conditions has been a significant trend in the evolution of telehealth applications, and there is some evidence that video visits may enable more timely communication of test results than in-person appointments.

As noted in section II.G.2.b. of this proposed rule, we are not proposing timeframe restrictions for this proposed element, which includes access to certain CTBS (for example, the restriction for virtual check-in services that there is not a related E/M service provided within the previous 7 days or an E/M service or procedure within the next 24 hours or the soonest available appointment).

We seek feedback on these proposed requirements.

(9) Patient Population-Level Management

As specified in the proposed APCM code descriptors, we are proposing to establish an APCM service element for Patient Population-Level Management that would include practice capabilities for population-based, data-driven approaches to manage preventive and chronic care for their patient population and to plan and implement strategies to improve care and outcomes. We are proposing that all practices would use data to develop clear improvement strategies and analytic processes to proactively manage population health, including analyzing patient population data to identify gaps in care and risk-stratifying the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients (such as those at risk for poor health outcomes), and then would offer additional interventions, as appropriate.

These proposed patient population-level management standards are similar to several requirements tested in CMS Innovation Center models, including CPC+, which found that model participants used data to identify and resolve gaps in care. We have modeled the proposed patient population-level management standards on the CPC+ care delivery requirements. In the CPC+ Model, participating practices were required, for example, to ''use a two-step risk stratification process for all empaneled patients, addressing medical need, behavioral diagnoses, and health-related social needs'' and ''define at least one subpopulation of patients with specific complex needs, develop capabilities necessary to better address

[69] Vimalananda, V., Gupte, G., Seraj, S., Orlander, J., Berlowitz, D., Fincke, B., & Simon, S. (2015, September). Electronic consultations (e-consults) to improve access to specialty care: A systematic review and narrative synthesis. Journal of Telemedicine and Telecare 21(6), 323–330. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4561452/.*

[70] Levine DM, Linder JA. Retail Clinics Shine a Harsh Light on the Failure of Primary Care Access. J Gen Intern Med. 2016;31(3):260–262.; Dorsey ER, Topol EJ. State of Telehealth. N Engl J Med. 2016;375(2): 154–161.; Powell, Rhea E., et al. ''Patient perceptions of telehealth primary care video visits.'' The Annals of Family Medicine 15.3 (2017): 225–229.

[71] Polinski JM, Barker T, Gagliano N, Sussman A, Brennan TA, Shrank WH. Patients' Satisfaction with and Preference for Telehealth Visits. J Gen Intern Med. 2016;31(3):269–275.

[72] Krishnan N, Fagerlin A, Skolarus TA. Rethinking Patient-Physician Communication of Biopsy Results—The Waiting Game. JAMA Oncol. 2015;1(8):1025–1026.; Cusack CM, Pan E, Hook JM, Vincent A, Kaelber DC, Middleton B. The value proposition in the widespread use of telehealth. J Telemed Telecare. 2008;14(4):167–168.

those needs, and measure and improve the quality of care and utilization of this subpopulation.'' [73] Central to the delivery of advanced primary care is the organization of the practice into care teams that have the data they need to manage their patient populations and that have time allocated to plan and implement practice improvement strategies.[74] Using evidence-based protocols, registries, and the registry functionality of the EHR, reminders and outreach help practices deliver appropriate preventive care and consistent evidence-based management of chronic conditions for the entire patient population.[75] Measurement of clinically relevant data at the practice-level guides testing and implementing strategies to improve care and outcomes. Patient population-level management capabilities are essential to the delivery of care under an advanced primary care model of care and enable practices to meet the preventive and chronic care needs of their entire patient population. Regular use of data to identify populations or groups of patients with similar needs allows practices and care teams to use streamlined strategies, including setting goals with measurable outcomes, to positively impact their patient populations. Evidence shows that primary care teams supported with real-time, population-level clinical outcomes data effectively manage population health and address care gaps which eliminates external costs to close gaps in care.[76] More specifically, risk stratification allows practitioners to identify beneficiaries for longitudinal care management, track beneficiaries with higher levels of need and manage their conditions, and prevent beneficiaries from falling through the cracks, while developing strategies to address those patients who are at increased and rising risk and most likely to benefit from targeted, proactive, relationship-based care management and other strategies essential to APCM.[77] Empanelment, which assigns each active patient to a practitioner and/or care team with consideration of patient and caregiver preferences, allows practices to build responsive care teams to optimize patient care and to address the preventive, chronic, and acute needs of all patients, and provides a way for practices to identify care gaps and proactively reach out to patients who have not been seen or contacted in a while.[78] For example, we believe these elements of advanced primary care management could increase screening rates and ultimately improve care of chronic conditions, such as hypertension and diabetes.

We note that this Patient Population-Level Management requirement of the APCM services would be met for practitioners billing for APCM services through a TIN that is participating in an ACO in the Shared Savings Program by virtue of the practitioner's participation in the ACO which must meet eligibility requirements for population management, care coordination and quality improvement, including required processes and patient-centeredness criteria in § 425.112. We note that ACOs in the Shared Savings Program and their practitioners are already engaged in analyzing the patient population for care gaps, risk-stratifying patients to further identify those at risk for poor health outcomes, and identifying patients for whom additional interventions are appropriate. Similarly, the ACO REACH, Making Care Primary, and Primary Care First CMS Innovation Center Models all require their participants to deploy population health strategies to identify and offer interventions to mitigate health risks.[79] Participants in these models and their practitioners are already engaged in population health management as described in Table 21.

We seek feedback on these proposed requirements.

(10) Performance Measurement

We are proposing for the APCM services a practice-level requirement of performance measurement of primary care quality, total cost of care, and meaningful use of CEHRT. Performance measurement is a critical element of care management services delivered in the context of advanced primary care, and it forms the basis for practice improvement efforts by enabling practices to identify key measures for improvement activities (for example, cost and utilization data, clinical quality measures, patient experience of care data). Quality measurement improves care delivery, including prevention of heart attacks, increasing vaccination rates, and improving patient safety,[80] and quality measures are also effective tools to ensure that high-quality advanced primary care, including care management, is being delivered. Several performance measurement requirements were tested in CMS Innovation Center models (such as the CPC+ model's requirement that participating practices use data at both the practice- and panel-level to set goals to improve population health management and to continuously improve patients' health, experience, and quality of care, and decrease cost). Using data resources and developing workflows and analytics to guide practice changes can help practices achieve reductions in total utilization and cost of care, and improvements in patient experience and quality of care. Improving upon key outcome measures requires engaged clinical and administrative leadership and a commitment to continuous, data-driven improvement.[81] In the context of the PFS, performance management through quality measurement as a practice-level requirement also ensures integrity to the provision of advanced primary care because it holds billing practitioners accountable to factors that are affected by several service elements of APCM coding. For example, effective patient-population level management can mean the practices close care gaps in diabetes management, and the billing practitioner would perform better on diabetes quality measures that assess for a patient's control of hemoglobin A1c.

[73] CPC+ Care Delivery Resource. January 2019.

[74] *CPC+ Care Delivery Resource. January 2019.*

[75] O'Malley AS, Draper K, Gourevitch R, Cross DA, Scholle SH. Electronic health records and support for primary care teamwork. J Am Med Inform Assoc. 2015 Mar;22(2):426–34. doi: 10.1093/jamia/ocu029. Epub 2015 Jan 27. PMID: 25627278; PMCID: PMC4394968.

[76] *https://www.cms.gov/priorities/innovation/files/x/cpcplus-practicecaredlvreqs.pdf.*

[77] *Hayes, S.L., & McCarthy, D. (2016, December 7). Care Management Plus: Strengthening Primary Care for Patients with Multiple Chronic Conditions. The Commonwealth Fund. http://www.commonwealthfund.org/publications/case-studies/2016/dec/care-management-plus; Hong, C.S., Siegel, A.L., & Ferris, T.G. (2014, August). Caring for High-Need, High-Cost Patients: What Makes for a Successful Care Management Program? The Commonwealth Fund http://www.commonwealthfund.org/~/media/files/publications/issue-brief/2014/aug/1764_hong_caring_for_high_need_high_cost_patients_ccm_ib.pdf; Lakin, J.R., Robinson, M.G., Obermeyer, Z., Powers, B.W., Block, S.D., Cunningham, R., Tumblin, J. M.m Vogeli, c., & Bernacki, R.E. (2019). Prioritizing primary care patients for a communication intervention using the ''Surprise Question'': A prospective cohort study. Journal of General Internal Medicine, 8.*

[78] Grumbach, K., & Olayiwola, N.J. (2015). Patient empanelment: The importance of understanding who is at home in the medical home. Journal of the American Board of Family Medicine, 28(2), 170–272.; Altschuler, J., Margolius, D., Bodenheimer, T., & Grumbach, K. (2012). Estimating a reasonable patient panel size for primary care physicians with team-based task delegation. Annals of Family Medicine, 10(5), 396–400. *doi:10.1370/afm.1400.*

[79] ACO Realizing Equity, Access, and Community Health (REACH) Model Request for Applications. Available a: *https://www.cms.gov/priorities/innovation/media/document/aco-reach-rfa,* Making Care Primary Request for Applications. Available at *https://www.cms.gov/files/document/mcp-rfa.pdf,* Primary Care First Request for Applications Cohort 2. Available at *https://www.cms.gov/priorities/innovation/media/document/pcf-cohort2-rfa.*

[80] *https://www.ahrq.gov/patient-safety/quality-measures/21st-century/challenges.html.*

[81] *https://www.cms.gov/priorities/innovation/innovation-models/comprehensive-primary-care-plus.*

We are proposing that this performance measurement practice-level requirement can be met in several ways. For MIPS-eligible clinicians, the requirement would be met by registering for and reporting the ''Value in Primary Care'' MIPS Value Pathway (MVP). A practitioner who is part of a TIN that is participating as a Shared Savings Program ACO or a REACH ACO, or a Primary Care First or Making Care Primary practice would meet these requirements by virtue of the Shared Savings Program and CMS Innovation Center quality reporting, assessment of quality performance, accountability for total cost of care, and other program and model requirements.

In the CY 2024 PFS final rule (88 FR 80042 through 80047), we finalized ''The Value in Primary Care'' Merit-based Incentive Payment System (MIPS) Value Pathway (MVP), which focuses on the clinical theme of promoting quality care for patients in order to reduce the risk of diseases, disabilities, and death; and it includes cost measures, Promoting Interoperability (PI) measures, improvement activities, and quality measures for common chronic conditions (for example, hypertension, diabetes, depression).[82] The Value in Primary Care MVP contains the Adult Universal Foundation quality measure set, which is consistent with the National Quality Strategy goal of using the Universal Foundation measures across as many programs as is feasible.[83] This MVP is especially well-suited to reflect the delivery of care using the advanced primary care model as it was developed to include quality metrics that reflect clinical actions that should be considered the foundations of primary care. The quality measures include key elements such as cancer screening, immunization, blood pressure management, behavioral health, care coordination, person-centered care, and screening for social drivers of health. The improvement activities include engaging community resources to address drivers of health, implementing changes in the practice's patient portal to improve communication and patient engagement, reviewing practices in place on targeted patient population needs, and chronic care and preventive care management for empaneled patients, aspects of advanced primary care already discussed in this proposal. The cost measures include costs for common chronic conditions, such as asthma/chronic obstructive pulmonary disease (COPD), diabetes, depression, and heart failure, as well as the Total Per Capita Cost (TPCC) measure, which assesses the overall cost of care delivered to a patient with a focus on the primary care they receive from their provider(s) and captures the broader healthcare costs influenced by primary care.[84] The Value in Primary Care MVP serves to demonstrate performance measurement that is reflective of the care furnished using advanced primary care delivery. To ensure performance measurement consistent with the delivery of advanced primary care services, we are proposing as an element of the APCM services that a practitioner who is a MIPS eligible clinician as defined in § 414.1305 can satisfy the performance measurement requirement by registering for and reporting the Value in Primary Care MVP for the performance year in which they bill for APCM services. A MIPS eligible clinician can report to MIPS as an individual, subgroup, group, APM Entity, or in any combination of these four participation options, and can participate in multiple ways to report MVPs.[85]

MIPS-eligible clinicians who report the MVP are also required to report the PI performance category measures and attestations throughout the performance period in which they bill for APCM services,[86] as required under § 414.1375(b) (§ 414.1365(c)(4)(i)) (see section IV of this proposed rule for details on reporting the objectives and measures for the MIPS PI performance category for CY 2025 performance period/2027 MIPS payment year). The measures in the MIPS PI performance category include measures such as electronic referral loops, receiving and reconciling health information, and providing patients with electronic access to their health information, all of which are reflective of important communication and coordination channels between primary care, other specialist practitioners caring for the patient, and the patient themselves. In addition, as set forth in 42 CFR 414.1375(b)(3), the MIPS PI performance category also requires submission of affirmative attestations: (1) regarding their cooperation in good faith with ONC direct review of their CEHRT; and (2) that they did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of CEHRT.[87]

For CCM services (CPT codes 99437, 99439, 99487, and 99489–99491) and PCM services (CPT codes 99424–99427), we established that practitioners must use CEHRT to record certain patient health information in a structured format, provide patients with access to their health information, and exchange all relevant patient health information, including in providing the ''Management of Care Transitions'' element of CCM services. For the APCM services, which are furnished as part of a practitioner's care delivery using the advanced primary care model, we are proposing for practitioners who are MIPS eligible clinicians a practice-level requirement to register for and report the MVP, including but not limited to the PI performance category measures which focus on meaningful use of CEHRT, ensuring that patients/caregivers and physicians or other qualified practitioners or clinical staff have real-time access to patient's medical information. We believe that comprehensive CEHRT use is a critical element of care management services delivered in the context of advanced primary care.

As we stated in adopting the CEHRT use element for CCM and PCM services, we believe that the meaningful use of CEHRT is vital to ensure that practitioners are capable of providing the full scope of services, such as timely care coordination and continuity of care (see our prior discussion of this issue at 79 FR 67723 and 84 FR 62696), and we believe that flexibility in how practices can provide the requisite 24/7 access to care, continuity of care, and management of care transitions, can facilitate appropriate access to these services for Medicare beneficiaries. The meaningful use of CEHRT helps ensure that members of the care team have timely access to the patient's most updated health information and offer an integrated view of a patient's clinical history from different points of care, supporting continuing, quality, and integrated healthcare while avoiding duplication of efforts and costs, such as

[82] *Value in Primary Care.* Quality Payment Program. *https://qpp.cms.gov/mips/explore-mips-value-pathways/2024/M0005.*

[83] *https://www.cms.gov/medicare/quality/cms-national-quality-strategy/aligning-quality-measures-across-cms-universal-foundation.*

[84] *https://qpp.cms.gov/docs/cost_specifications/2023-12-13-mif-tpcc.pdf.*

[85] *https://qpp.cms.gov/mips/mvps/learn-about-mvp-reporting-option?option=Group.*

[86] The MIPS PI performance period is a minimum of 180 consecutive days in the calendar year that occurs 2 years prior to the MIPS payment year (see 42 CFR 414.1320(i)).

[87] Note that, under the Quality Payment Program, CMS may reweight the MIPS PI performance category to zero percent of the MIPS final score, and not require an individual, group, or virtual group to use CEHRT and demonstrate whether they are a meaningful user of CEHRT, by granting a significant hardship exception or other type of exception based on certain circumstances as set forth in 42 CFR 414.1380(c)(2)(i)(C).

repeated exams.[88] For example, practices use EHRs to identify high-risk patients with chronic conditions to better coordinate care and can supplement the practice's EHR data with data from external sources (for example, State-level quality organizations) to obtain a more comprehensive view of patients. Practices can also integrate clinical data from EHRs, health plan claims data, and county-level social services data to evaluate population needs, stratify by risk, and assess what programs would be most effective for supporting at-risk patients.[89] Standardized communication methods, enabled by CEHRT, are a significant part of the advanced primary care delivery model. Health IT systems that include remote access to the care plan or the full EHR after hours, or a feedback loop that communicates back to the primary care physician and others involved in the beneficiary's care regarding after-hours care or advice provided, are extremely helpful.[90] They help ensure that the beneficiary receives necessary follow up, particularly if the patient is referred to the ED, and follow up after an ED visit is required under the element of ''Management of Care Transitions.'' Accordingly, we believe the use of CEHRT or remote access to the care plan is fundamental to providing the APCM service elements of 24/7 Access to Care, Continuity of Care, and Management of Care Transitions under an advanced primary care delivery model. Requiring performance of the requirements in these measures and attestations to the meaningful use of CEHRT is similar to several requirements tested in CMS Innovation Center models (such as the PCF model's requirement that participating practices adopt and maintain CEHRT for electronic clinical quality measure reporting, support data exchange with other providers and health systems, and connect to their regional health information exchange (HIE),[91] and the MCP model's requirement that participating practices use EHR technology that has been certified under the ONC Health IT Certification Program [92]). Furthermore, the Shared Savings Program requires practitioners (that is, MIPS eligible clinicians, QPs and Partial QPs) in all ACOs to demonstrate meaningful CEHRT use through the reporting of the MIPS Promoting Interoperability annually beginning in 2025.

We recognize that many practitioners who are not MIPS eligible clinicians for a year would be excluded from MIPS by achieving Qualifying APM Participant (QP) status based on their levels of participation in an Advanced APM. Based on the characteristics of Advanced APMs detailed in § 414.1415, including the requirement that payment is based on MIPS or MIPS-comparable quality measures, practitioners who with QP status are necessarily engaging in performance measurement through the Advanced APMs in which they participate in a way that is consistent with advanced primary care. We also recognize there are other practitioners who are not MIPS eligible clinicians for other reasons, such as practitioners who are newly enrolled in Medicare or bill a low volume of Medicare services. These practitioners technically could bill for APCM services. However, newly enrolled practitioners are only excluded from MIPS for one year, after which the practitioner would either be a MIPS eligible clinician who would need to report the MVP in order to bill for APCM services, or excluded from MIPS on another basis such as QP status. In the case of practitioners with low Medicare volume, we anticipate that they would be unlikely to bill for APCM services since the delivery of advanced primary care generally involves time and resources to establish practice-level infrastructure, and the economies of scale usually make this a more likely investment if the infrastructure can be utilized across a larger patient panel.

We are also proposing that the performance measurement element of the APCM services would be satisfied for practitioners billing for APCM services through a TIN that is participating in a Shared Savings Program ACO for a performance year in which they furnish APCM services. ACOs are currently required to report the APP quality measure set on behalf of their practitioners, and would be required to report the APP Plus quality measure set as proposed in Section III.G. of this proposed rule. Practitioners in ACOs are also already being held accountable for reporting and performance and outcomes on many of the Universal Foundation measures already, which are used in the Value in Primary Care MVP, and the APP Plus quality measure set would fully align the Shared Savings Program's quality performance standard with the Universal Foundation measures upon the complete implementation of the APP Plus measure set.

We propose to include the performance measurement requirement as an element of APCM services furnished by practitioners. MIPS eligible clinicians who intend to report on the Value in Primary Care MVP for the CY 2025 must register to report the Value in Primary Care MVP as described under § 414.1365(b), a MIPS eligible clinician must register for an MVP during between April 1 and November 30 of the applicable CY performance period to report the MVP. MIPS eligible clinicians submit data on measures and activities in the first quarter of the year following (CY 2026) the MIPS performance period. Under this proposal, a MIPS eligible clinician billing for APCM services furnished in 2025 and who is satisfying the performance measurement requirement through reporting the Value in Primary Care MVP, would need to register for the MVP between April and November of 2025 and report data between January and March 2026 on measures and activities in the Value in Primary Care MVP relating to services furnished in 2025. A MIPS eligible clinician billing for APCM services furnished in 2026 and who is satisfying the performance measurement requirement through reporting the Value in Primary Care MVP, would need to register for the Value in Primary Care MVP between April and November of 2026, and report data between January and March of 2027 on measures and activities in the Value in Primary Care MVP relating to services furnished in 2026, and so on in subsequent years.

As described above, we are seeking feedback on ways to align the APCM services with other Medicare programs and initiatives, such as the Shared Savings Program and the Quality Payment Program, including MIPS and Advanced APMs. We seek to create a low burden way for practitioners to furnish APCM services by appropriately recognizing ways in which they may meet APCM billing requirements as part of these programs and initiatives, including other ways that practitioners may be fulfilling these performance measurement requirements. We are seeking feedback on whether there are areas of duplication within the APCM service elements and practice capabilities that we should consider addressing. We are also seeking comment on how to appropriately align

[88] McDonald, C.J., Tang, P.C., Hripcsak, G. and In: (eds) Biomedical Informatics. Springer, L. (2014), ''Electronic Health Record Systems,'' in Biomedical Informatics, Shortliffe, E.H. and Cimino, J.J., eds. London: Springer, pp. 391–421.

[89] Harvey, Jillian B., et al. ''Understanding how health systems facilitate primary care redesign.'' Health Services Research 55 (2020): 1144–1154.

[90] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3475839/#CR25.*

[91] *https://www.cms.gov/priorities/innovation/innovation-models/primary-care-first-model-options.*

[92] *https://www.cms.gov/priorities/innovation/innovation-models/making-care-primary.*

the time period for which the practitioner bills the monthly APCM code with the calendar year reporting period covered by the MVP, and how we would verify and enforce the performance measurement requirement of the APCM service.

We seek feedback on these proposed requirements.

d. Duplicative Services and Concurrent Billing Restrictions

In this section, we identify the services that would overlap substantially with APCM services based on the proposed elements of the scope of service for APCM which we have built into the service descriptors for GPCM1, GPCM2, and GPCM3 (see sections II.G.2.b. and II.G.2.c. of this proposed rule). As such, we are proposing that APCM services could not be billed by the same practitioner or another practitioner within the same practice for the same patient concurrent with these other services: CCM, PCM, TCM, interprofessional consultation, remote evaluation of patient videos/images, virtual check-in, and e-visits. Given that we have intentionally designed the proposed elements of APCM services to track closely with the elements of several other care management service and CTBS codes, these services are substantially duplicative of APCM services. Further, these specific services (shown in Table 19) are duplicative with APCM services because there is significant overlap in the patient populations included in the code descriptors for these services and APCM services, such as patients who have chronic conditions, high-risk conditions, or both complex and chronic conditions.

BILLING CODE P

TABLE 22: Care Management and CTBS which CMS Proposes are Substantially Duplicative of APCM Services

Service	Description
Care Management Services (12 CPT Codes)	
Chronic Care Management (CCM) (CPT Codes 99487, 99489, 99490, 99491, 99439, 99437)	Management of all care for patients with two or more serious chronic conditions, timed, per month
Principal Care Management (PCM) (CPT Codes 99424, 99425, 99426, 99427)	Management of all care for patients with one serious chronic condition, timed, per month
Transitional Care Management (TCM) (CPT Codes 99495, 99496)	Management of transition from acute care or certain outpatient stays to a community setting, with face-to-face visit (bundled into payment for the code), once per patient within 30 days post-discharge
Communication Technology-Based Services (15 CPT Codes)	
Interprofessional Internet Consultation (IPC) (CPT Codes 99446, 99447, 99448, 99449, 99451, 99452)	Consultations between or among certain kinds of medical practitioners.
Remote Evaluation of Patient Videos/Images (HCPCS code G2250)	Remote evaluation of recorded video and/or images submitted by patient
Virtual Check-In (HCPCS codes G2251, G2252)	Virtual check-in service to decide whether an office visit or other service is needed
Online Digital E/M (e-Visit) (CPT codes 98970, 98971, 98972, 99421, 99422, 99423)	Communication between patient and their provider through an online patient portal

BILLING CODE C

As we have described in the sections above, comprehensive care management services are essential to providing advanced primary care in the context of this proposal, and many of the service elements for CCM/PCM/TCM shown in Table 19 are substantially the same as the elements we are proposing for APCM services.

Also described above, providing CTBS is an essential element of the delivery of care under an advanced primary care model of care. Recognizing this, we designed the proposed APCM service elements to substantially overlap with the elements of the CTBS (for example, interprofessional consultation and e-Visits) shown in Table 22. CTBS are used in delivery of advanced primary care to maintain ongoing communication with patients and enable interprofessional care teams to provide comprehensive support to manage chronic conditions over time, which we believe will allow patients to access their usual source of care more

conveniently.[93] We also believe that interprofessional consultation can help promote integration of behavioral health and primary care.[94]

We also considered whether other care management services (such as Behavioral Health Integration (BHI)), services addressing HRSNs (Community Health Integration (CHI), Social Determinants of Health Risk Assessment, and Principal Illness Navigation (PIN)), and/or other CTBS (Remote Physiologic Monitoring (RPM) and Remote Therapeutic Monitoring (RTM)) would be duplicative of the proposed APCM services. We believe that these services, when appropriate, may complement APCM services rather than substantially overlap or duplicate services, and that these other services are sufficiently different from the APCM services in the nature and extent of the interventions and the qualifications of individuals providing the services, to allow concurrent billing for services when appropriate. While these may be services that a practitioner using the advanced primary care model would be likely to furnish, when appropriate, they are not part of the core, routinely and universally essential elements of the advanced primary care model. We also believe that several of these other services (such as BHI, CHI, SDOH Risk Assessment, and PIN) could be supplemental to APCM for patients that have very specific identified health care needs.

We are seeking more information from interested parties through our Advanced Primary Care RFI about whether to consider incorporating additional service elements into the APCM service elements and valuation for APCM codes; and whether and, if so, how to best incorporate E/M services into future coding (see section II.G.3. of this proposed rule). We note that, for BHI services, there is an established evidence base for approaches to caring for beneficiaries with behavioral health conditions which involve integration in the primary care setting, are typically provided by a primary care team, and include structured care management with regular assessments of clinical status and modification of treatment. BHI is a term that refers broadly to collaborative care that integrates behavioral health services with primary care. BHI is a team-based approach to care that focuses on integrative treatment of patients with medical and mental or behavioral health conditions. For BHI in particular, including CPT codes 99492, 99493, 99494, and 99484 and HCPCS code G0323, we are also seeking information regarding how evolving changes in practice may warrant reconsideration of payment and coding policies.

We propose that the care management and CTBS codes that are identified in Table 19 could not be separately billed with the APCM codes for the same beneficiary by the same practitioner, or a different one within the same practice, for the same service period. This would prevent duplicative payments for substantially similar services and is consistent with how we have paid for potentially overlapping care management services in the past.

As we refine our APCM policies, we note that we are not currently proposing to make changes to the coding and payment policies for the existing care management and CTBS services, other than to prohibit concurrent billing for the same patient during the same month by the same practitioner or another in the same practice. For CY 2025, those codes would still be available for practitioners who do not furnish care using the advanced primary care model or who may prefer to document the existing care management and CTBS codes rather than use the new proposed APCM codes.

We are also seeking comment on potential overlap between APCM services and other services currently paid under the PFS, including but not limited to care management and care coordination and other CTBS. If interested parties identify overlaps between APCM and other services, we are seeking comment on whether the degree of overlap would warrant a policy to restrict the services from being billed concurrently with APCM. We also seek comment on whether any overlap would depend upon whether the same or a different practitioner reports the services.

As we test new CMS Innovation Center models that include payments for the services defined above, including CCM, PCM, TCM, interprofessional consultation, remote evaluation of patient videos/images, virtual check-in, and e-visits, or as changes in the advanced primary care model of care or more general changes to Medicare payment policy take place that affect existing CMS Innovation Center models, consistent with existing policy, we will address potential overlaps between payments made to model participants with our proposed payment for APCM, elements of the proposed APCM service, and these duplicative services, and seek to implement appropriate payment policies.

e. Valuation of APCM Services—GPCM1, GPCM2, and GPCM3

To improve the accuracy of payment for the kinds of services furnished as part of advanced primary care and reduce the administrative burden associated with current coding and billing rules, we are proposing to create three HCPCS codes to use for reporting the proposed APCM service (GPCM1, GPCM2, and GPCM3) (sections II.G.2.b. and II.G.2.c. of this proposed rule). Although these codes are unique in that they would be created to differentially pay for advanced primary care management, the proposed APCM services incorporate elements of existing services with the understanding that some patients will require more resources and some fewer based on variability in patient complexity and needs (see section II.G.2.b of this proposed rule). As we ordinarily do, we are proposing to base the PFS valuation for APCM codes on the resources involved in furnishing the typical case of the service which may not necessarily reflect the actual resources involved in furnishing every individual service.

In this section, we detail our proposed methods to identify a typical case and set of resources involved in furnishing APCM, and the proposed valuation of these codes. To value APCM, we compared the service elements described by the proposed APCM codes to the values we have established for the specific care management and CTBS codes on which we modeled the proposed the service elements of the APCM codes and which we built into the service descriptors for GPCM1, GPCM2, and GPCM3 (see Table 19 and sections II.G.2.b. through II.G.2.d. of this proposed rule). As stated above, we believe that the proposed elements of APCM services reflect the comprehensive approach to care management involved in care delivery using the advanced primary care model. This is a model of primary care that is being integrated into current medical practice. As such, we believe that it would be appropriate to use the current valuation and uptake of the codes on which we modeled the APCM codes to inform our valuation of APCM services. Using Medicare FFS claims data and evidence from our primary care models, we sought to understand how these

[93] Levine DM, Linder JA. Retail Clinics Shine a Harsh Light on the Failure of Primary Care Access. J Gen Intern Med. 2016;31(3):260–262.; Dorsey ER, Topol EJ. State of Telehealth. N Engl J Med. 2016;375(2):154–161.; Powell, Rhea E., et al. ''Patient perceptions of telehealth primary care video visits.'' The Annals of Family Medicine 15.3 (2017): 225–229.

[94] We are planning a separate proposal on expanding who can bill for IPC, including clinical psychologists, LCSWs, marriage and family therapists (MFTs), and MHCs; see further discussion in section II.I of this proposed rule.

different services have been used historically and relate that information to the way we are thinking about the service elements for APCM and the valuation of the three APCM code levels. We know that for Medicare beneficiaries who receive care management services during a year, the non-complex CCM base code is billed on average for five months and with three add-on codes during those five months. We also know that initial information from practitioner interviews conducted as part of our CCM evaluation efforts indicates that practitioners overwhelmingly meet and exceed the 20-minute threshold time for billing the non-complex CCM base code; typically, these practitioners reported spending between 45 minutes and an hour per month on CCM services for each patient, with times ranging between 20 minutes and several hours per month (81 FR 80244). However, this does not account for the care management services that are provided beyond one time-based billing interval and without reaching the next; nor does it account for the resources involved in maintaining certain advanced primary care practice capabilities and continuous readiness and monitoring activities, including patient population monitoring and care needs assessment, to fully furnish and bill APCM services as is medically reasonable and necessary for any individual patient during any calendar month. Finally, this does not account for changes to utilization of APCM that may occur as a result of the billing and documentation requirements for APCM services when compared to the current coding and payment for care management and CTBS services. While our aim is to value APCM services based on refined assumptions that we believe better recognize likely utilization of the new proposed codes and the work required to furnish APCM services, this is challenging without more information. We welcome comments on ideas for other sources of data that would help us to assess APCM services valuation.

We considered various alternatives for valuing the APCM services and how these may impact the broader health care landscape given that primary care is of such import across the country. We are proposing to set baseline APCM code values for this first year based on historical utilization of the care management services we have drawn upon in designing the APCM codes. We note that utilization of the care management services has been significantly higher than CTBS, and we found that CTBS are not typically billed for a patient in the same month as care management services. It is unclear whether the kinds of services described by the CTBS are not typically provided during these months or whether they are being provided but not separately reported. We will continue to seek information, including from public comments on this proposed rule, to help us identify the best approach to reflecting the proposed CTBS elements incorporated into the APCM monthly bundle, and we are particularly interested in data that could illuminate differences between what services are furnished and what is being reported separately. We will continue to consider refinements to the valuation of APCM codes to reflect available information about changes in the volume and mix of care management and communication activities being furnished as part of APCM services in the delivery of advanced primary care.

For APCM Level 1, we assumed the typical case would involve fewer resources than the current care management services based upon the proposed GPCM1 code descriptor and a broad eligible population that would require limited monthly APCM services; however, it would also involve certain resources inherent to maintaining advanced primary care practice capabilities and continuous readiness and monitoring activities, including patient population monitoring and care needs assessment, to fully furnish and bill APCM. As described in sections II.G.2.b. and II.G.2.c. above, certain elements of the APCM service require resources to maintain continuous readiness and monitoring activities to furnish covered services consistent with the advanced primary care model of care. We concluded that the APCM Level 1 services would be similar in work to that of two billing units of the non-complex code for CCM services (CPT code 99490 (*CCM services provided by clinical staff per calendar month*)) over the course of a year, and therefore based the proposed inputs on CPT code 99490 multiplied by 1/6 (or 2 units over 12 months). Specifically, we proposed a work RVU for GPCM1 of 0.17, which is the work RVU for CPT code 99490 multiplied by 1/6. The resulting proposed PE and MP RVUs are proportionately similar to those for CPT code 99490 and are available in Addendum B (see *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates*).[95] Table 23 displays payment amount estimates using the 2024 PFS Conversion Factor.

For APCM Level 2, which describes APCM services to patients with two or more chronic conditions we assumed the typical, higher intensity work associated with managing a patient with multiple chronic conditions would involve significantly more resources and require more, and more frequent, APCM service elements. We concluded that the APCM Level 2 services would be similar to current utilization assumptions of five billing units of the non-complex CCM code (CPT codes 99490) (*CCM services provided by clinical staff per calendar month*) and three billing units of add-on codes annually, given that, for Medicare beneficiaries who receive these CCM services during a year, the non-complex CCM base code is billed on average for five months and with three add-on codes during those 5 months. Additionally, we are proposing to account for what we believe to be continued underutilization of CCM services in this patient population by adding one billing unit of the complex CCM code (CPT code 99490 (*CCM services provided by clinical staff per calendar month*) annually. As we noted in the CY 2020 PFS final rule, ''utilization [of CCM services] has reached approximately 75 percent of the level we initially assumed under the PFS when we began paying for CCM services separately under the PFS; while these are positive results, we believe that CCM services (especially complex CCM services) continue to be underutilized'', 81 FR 80244 and 84 FR 62688, considering the number of eligible Medicare beneficiaries. In 2019, approximately 22.6 million FFS beneficiaries were identified as being potentially eligible for CCM (or 63.4 percent of the 35.6 million Medicare FFS beneficiaries); however, the use of CCM services was low among potentially eligible beneficiaries, such that just 4.0 percent of beneficiaries potentially eligible for CCM received any CCM services.[96] Therefore, we based the proposed inputs on CPT code 99490 multiplied by 5/12 (or, five units

[95] *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices?DLSort=2&DLEntries=10&DLPage=1&DLSortDir=descending.*

[96] *The determination of potential eligibility for CCM was based on presence of two or more Chronic Condition Warehouse (CCW) chronic condition flags, one of which was hypertension, hyperlipidemia, or diabetes. Beneficiaries on Medicare Advantage, with end stage renal disease (ESRD) or using the hospice benefit were excluded. ASPE. Analysis of 2019 Medicare Fee-for-Service (FFS) Claims for Chronic Care Management (CCM) and Transitional Care Management (TCM) Services. March 2022. https://aspe.hhs.gov/sites/default/files/documents/31b7d0eeb7decf52f95d569ada0733b4/CCM-TCM-Descriptive-Analysis.pdf.*

over 12 months), plus CPT add-on code 99439 (*CCM services each additional 30 minutes by clinical staff directed by a physician or other qualified health care professional, per calendar month*) multiplied by ⅙ (or two units), plus CPT add-on code 99489 (*Complex CCM services each additional 30 minutes by clinical staff directed by a physician or other qualified health care professional, per calendar month*) multiplied by 1/12 (one unit), plus CPT code 99487 (*Complex CCM services provided by clinical staff directed by a physician or other qualified health care professional, per calendar month*) multiplied by 1/12 (one unit). Specifically, we proposed a work RVU for GPCM2 of 0.77, which is the sum of the work RVU for CPT codes 99490, 99439, 99489, and 99487 multiplied by their respective proportions above. The resulting proposed PE and MP RVUs are proportionately similar and are available in Addendum B (see *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates*).[97] Table 23 displays payment amount estimates using the 2024 PFS Conversion Factor.

For APCM Level 3 (HCPCS code GPCM3), which describes APCM services to patients with QMB status and two or more chronic conditions, we are proposing to value the service as a relative increase to the valuation of APCM Level 2 based on recent Medicare expenditure data for dually eligible Medicare beneficiaries. In CY 2021, per person per year spending on dually eligible beneficiaries was $24,370 and for non-dually eligible beneficiaries was $11,172. The difference between these two amounts is 218 percent. We have considered the likely resource demands and intensity of the practitioner-patient interaction for this patient population, consistent with our coding and valuation policies that reflect variations in resource cost and patient-centered care delivery policies.[98] By taking into consideration the difference in Medicare spending on a per person per year basis between dually eligible and non-dually eligible Medicare beneficiaries, we believe that we can capture the increased resources involved in furnishing APCM services to patients with QMB status and multiple chronic conditions. Therefore, we based the proposed inputs for the APCM Level 3 code on the APCM Level 2 inputs multiplied by 218 percent. Specifically, we proposed a work RVU for GPCM3 of 1.67, which is the proposed work RVU for GPCM2 multiplied by 218 percent. The resulting proposed PE and MP RVUs are proportionately similar to those and are available in Addendum B (see *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates*).[99] Table 23 displays payment amount estimates using the 2024 PFS Conversion Factor.

Table 23 includes the proposed placeholder codes (which, if finalized, will be replaced with numeric G-codes announced in the final rule), short descriptors, crosswalk codes, proposed RVUs (work, PE, and MP), and approximate payment rate. For illustration purposes, we multiplied the proposed APCM relative values for work, practice expense (PE), and malpractice (MP), without geographic adjustment, by the CY 2024 conversion factor (CF) ($32.7442) to convert the proposed relative value units (RVUs) into approximate national payment rates.

TABLE 23: Proposed APCM Bundled Codes and Valuation

Code	Short Descriptor	Crosswalk Codes	CMS Proposed Work RVU	CMS Proposed PE RVU	CMS Proposed MP RVU	CMS Proposed Full RVU	Approximate National Payment Rate
GPCM1	APCM for patients with up to one chronic condition	99490	0.17	0.14	0.01	0.31	$10
GPCM2	APCM for patients with multiple (two or more) chronic conditions	99490, 99439, 99487, 99489	0.77	0.72	0.05	1.54	$50
GPCM3	APCM for QMBs enrollees with multiple chronic conditions	Calculated as a relative increase from GPCM2	1.67	1.57	0.12	3.36	$110

We are seeking feedback on whether these proposed values appropriately reflect the resource costs involved in furnishing these services, or whether adjustments to the proposed values or additional coding may be needed. We are broadly interested in public comments and input from interested parties on potential refinements in code and service definitions, including how we might refine our utilization assumptions for these codes, and other important information involving coding and payment for APCM services to better reflect the current practice of advanced primary care, including elements of CTBS and care management services. We are interested in developing a better understanding of the resource costs involved in furnishing comprehensive care management as part of advanced primary care to various patient populations, including specifically QMBs.

We intend to engage in further discussions with the public over the next several years to potentially refine our policies for 2025 and future years, and we expect that having APCM utilization data, once the proposed codes are established, would inform future refinement of the valuations for these codes.

Finally, as described in the Advanced Primary Care RFI that follows, we note that there is potential for the valuation of these codes and future related codes to change and/or scale into larger units if we expand them to incorporate more

[97] *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices?DLSort=2&DLEntries=10&DLPage=1&DLSortDir=descending.*

[98] *https://www.macpac.gov/wp-content/uploads/2024/01/Jan24_MedPAC_MACPAC_DualsDataBook-508.pdf.*

[99] *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices?DLSort=2&DLEntries=10&DLPage=1&DLSortDir=descending.*

service elements (see section II.G.3. of this proposed rule). As we receive more information about how these codes are being used and implemented in medical practice, we anticipate that these codes and future related codes will be refined over time. We note that the development of payment and coding policies for these and other kinds of services under the PFS is typically an iterative process that responds to changes in medical practice and may be best refined over several years through annual rulemaking for the PFS, and through the development of CPT codes by the AMA's CPT Editorial Committee.

As described in the next section, we believe that this new proposed APCM code set could serve as a chassis to incorporate primary care model learnings over time under the PFS and an additional pathway to accountable care for primary care practitioners.

3. Request for Information: Advanced Primary Care Hybrid Payment

a. Background

Recent evidence reviews show that while primary care is the only part of the health system in which investments routinely result in not only improved outcomes but also increased equity,[100] the practice and sustainability of the primary care sector is under significant strain.[101] The NASEM found that many of these challenges relate to a primary care payment system that principally rewards visit volume versus creation and maintenance of longitudinal [102] care relationships over time.[103] We have set a goal of having 100 percent of traditional Medicare beneficiaries and the vast majority of Medicaid beneficiaries in accountable care relationships by 2030. Accountable care occurs when a person-centered care team takes responsibility for improving quality of care, care coordination and health outcomes for a defined group of individuals, to reduce care fragmentation and avoid unnecessary costs for individuals and the health system.[104] Advanced primary care is a core mechanism for achieving this goal. With this goal, we acknowledge the need to increase the capability of primary care clinicians to engage, maintain, and promote longitudinal and accountable relationships with beneficiaries through incentives and flexibilities to manage quality and total cost of care.

Over the past 11 years, the CMS Innovation Center has tested a number of primary care models: CPC, CPC+, Maryland Primary Care Program, PCF, as well as the upcoming MCP and ACO Primary Care Flex. Each of these primary care models has focused on testing what happens when we pay for primary care services with hybrid payments (a mix of fee-for-service and population-based payments), as described earlier. While these models have not met the criteria for expansion to date, the findings suggest advanced primary care may reduce unnecessary utilization and improve diabetes care and cancer screening rates.

In addition to testing new approaches to improve care for beneficiaries by supporting primary care, we have focused on approaches to incorporating these innovations into Medicare programs. For example, lessons learned from the CMS Innovation Center's ACO models may be incorporated into the Shared Savings Program. As such, part of the intent of our proposal to create new APCM payment and coding is that we would have a similar foundation to scale advanced primary care model learnings over time.

Previous Innovation Center primary care model tests have helped us learn lessons to inform our current and future work. For example, participants in primary care models have indicated difficulty investing in and maintaining primary care redesign activities due to a range of challenges. First, additional non-visit-based primary care payments have been generally layered upon base payments still predominantly FFS in structure. As such, the incentives and abilities of practices to focus on proactive, population-based non-visit activities may be limited if the funding stream for these activities is limited in scope and duration.[105] [106] (Examples of non-visit-based activities include, but are not limited to: activities to improve care coordination, implement data-driven quality improvement, or enhance targeted care management for beneficiaries identified as high-risk.) Further, model funding for the clinical and administrative staff needed to accomplish advanced primary care coordination and population health functions is contingent on continued participation in these models.[107] Once the models end, practices are left without the funding that they received under the models for the clinical and administrative staff that had supported population health functions under the model. Moreover, because these models involve additional payments tied to performance rather than changes to base primary care payment, practices report that the funding they use to support non-visit activities is sometimes received well after the non-visit services have occurred, leading to further challenges sustaining these efforts fiscally. Solving these challenges is a key goal of future Innovation Center model work.[108]

To strengthen the primary care infrastructure within FFS Medicare, we are exploring opportunities to create new sustainable pathways to support advanced primary care, equitable access to high-quality primary care, and continued transformation among a wide variety of practices. One potential strategy to increase access to advanced primary care and prepare practitioners in traditional Medicare to engage in more accountable care is through the creation and ongoing refinement of specific billing and coding under the PFS that better recognizes advanced primary care and incorporates the resources involved in furnishing longitudinal care and maintaining relationships with patients over time. In section II.G.2. of this proposed rule, we are proposing a set of APCM services that make use of lessons learned from the CMS Innovation Center's primary care models, grouping existing care management and CTBS service elements into a bundle for use starting in CY 2025.

We are seeking feedback regarding potential further evolution in coding and payment policies to better recognize advanced primary care. Through this Advanced Primary Care RFI, we are committed to collaborating with

[100] National Academies of Sciences, Engineering, and Medicine (NASEM); Implementing High-Quality Primary Care (*https://nap.nationalacademies.org/read/25983*).

[101] Milbank Memorial Fund, The Health of US Primary Care: 2024 Scorecard (*https://www.milbank.org/wp-content/uploads/2024/02/Milbank-Scorecard-2024-ACCESS_v06.pdf*).

[102] Longitudinal care management is long-term, proactive, relationship-based care management that augments routine and acute visits with intentional, proactive outreach, especially during times of illness and transitions of care.

[103] NASEM, Implementing High-Quality Primary Care (*https://nap.nationalacademies.org/read/25983*).

[104] *https://www.cms.gov/priorities/innovation/key-concepts/accountable-care-and-accountable-care-organizations.*

[105] Independent Evaluation of Comprehensive Primary Care Plus (CPC+): Final Report. *https://www.cms.gov/priorities/innovation/data-and-reports/2023/cpc-plus-fifth-annual-eval-report.*

[106] Schurrer J, Timmins L, Gruszczynski M, et al. Evaluation of the Primary Care First Model: Second Annual Report. Mathematica. February 2024. *https://www.cms.gov/priorities/innovation/data-and-reports/2024/pcf-second-eval-rpt.*

[107] CMS defines population health as health behaviors and outcomes of a broad group of individuals, including the distribution of such outcomes affected by the contextual factors within the group.

[108] *https://www.cms.gov/about-cms/what-we-do/cms-strategic-plan.*

interested parties to lay the path for a more transparent movement to value-based care. Specifically, we are requesting input on a broader set of questions related to care delivery and incentive structure alignment and five foundational components:

- Streamlined Value-Based Care Opportunities
- Billing Requirements
- Person-Centered Care
- Health Equity, Clinical, and Social Risk
- Quality Improvement and Accountability

We encourage input on the questions below from diverse voices, including beneficiaries and advocates, community-based organizations, providers, clinicians, researchers, unions, and all other interested parties.

b. Solicitation of Public Comments

We are seeking feedback regarding potential changes to coding and payment policies for advanced primary care services to be incorporated in traditional Medicare. For example, in the future, coding for APCM services (proposed in section II.G.2. of this proposed rule) could be revised to include additional service elements, including traditional E/M services. This Advanced Primary Care RFI is designed to solicit feedback on how we can further the goals of reducing administrative burden to refocus time on patient care; better recognizing the relative resources involved in furnishing care; recognizing interdisciplinary, team-based primary care; and supporting primary care sustainability and stability (especially for underserved communities). Whenever possible, respondents are requested to draw their responses from objective, empirical, and actionable evidence and to cite this evidence within their responses. We anticipate potential changes to primary care coding and payment policies, such as use of coding that recognizes groups of services furnished over a fixed time period, that would offer a new opportunity within the PFS for primary care clinicians to move to payment structures that are not fully dependent on billing for each discrete component of overall care and act as a step toward accountability for the cost and quality of patient care. Therefore, we are seeking feedback on building advanced primary care payment mechanisms that create pathways to recognize how primary care practice has moved away from an encounter-based orientation toward population-based care. This Advanced Primary Care RFI is the first step in ensuring ample opportunity for public input, followed by notice and comment rulemaking in subsequent years.

(1) Streamlined Value-Based Care Opportunities

We are seeking to create a steppingstone for primary care clinicians, including those new to value-based care, to move away from either encounters or other discrete components of overall care as the dominant method of primary care payment and toward payments in larger units that are better tied to the relative resource costs involved in population-based, longitudinal care. Feedback from interested parties has been helpful when considering how to scale the availability of payments into larger units, and incorporate population-based variability in resources, all while driving toward accountability, and person-centered care. Ultimately, to create more opportunities for beneficiaries to receive high-quality, accountable primary care, we are focused on creating multiple pathways to recognize delivery of integrated care across settings, and engagement in comprehensive, team-based, longitudinal care.

When considering the evolution of a hybrid payment system within the PFS, we seek input on the following questions:

- How can CMS better support primary care clinicians and practices who may be new to population-based and longitudinal care management?
- What are the primary barriers to providing particular strategies or supports needed for pediatric clinicians and practices?
- How can CMS ensure that potential future advanced primary care payment will not induce clinicians to leave effective accountable care relationships and clinician networks that already produce positive results? Additionally, how can CMS support growth over time in existing effective accountable care relationships and clinician networks?
- Should CMS evolve the proposed APCM services into an advanced primary care payment that includes E/M and other relevant services, or maintain a separate code set for APCM?
- If E/M services are bundled together for advanced primary care payments, how can CMS ensure that there is not a disincentive for primary care clinicians to continue to provide E/M visits, or increase accountability to E/M visits as warranted?
- As many codes depend on E/M visits (for example, as the base code for an add-on code, or to initiate specific care management activities), how should CMS consider the downstream impacts of incorporating E/M visits into advanced primary care payments?
- Should CMS consider incorporating other CTBS services into advanced primary care hybrid payments, such as Remote Physiologic Monitoring and/or Remote Therapeutic Monitoring?
- Should CMS consider incorporating other services that involve comprehensive care management and care coordination, such as Behavioral Health Integration, End-Stage Renal Disease Monthly Capitation Payment (ESRD MCP), Assessment/Care Planning for Cognitive Impairment, and/or Advance Care Planning?
- Should CMS consider incorporating other services while the patient is under care of home health agencies or hospices, such as Care Plan Oversight?
- Newly finalized HCPCS codes are eligible for use by other payers, including commercial insurers, state Medicaid agencies, and others. We note that value-based alignment is a key goal of CMS. If the APCM codes are finalized, they would be eligible for use by these other payers as well. To what extent are other payers interested in adopting the APCM codes? Are there any other changes that would be necessary for other payers to adopt the codes?
- CMS has historically used information presented by the Relative Value Scale Update Committee to determine PFS payment rates. Are there other sources of data on the relative value of primary care services that CMS should consider when setting hybrid payment rates?

(2) Billing Requirements

Previous CMS Innovation Center primary care models have provided key lessons learned about how to increase comfort with population-based payments, the importance of reducing the administrative burden of billing, and how to begin addressing gaps in equitable access to population-based payments.[109] Specifically, we have learned through Innovation Center initiatives that retrospective reconciliation or adjustment of payments for services rendered can be especially frustrating for practitioners, as it reduces the predictability and stability of payments.[110]

[109] Independent Evaluation of Comprehensive Primary Care Plus (CPC+): Final Report. *https://www.cms.gov/priorities/innovation/data-and-reports/2023/cpc-plus-fifth-annual-eval-report;* Independent Evaluation of Primary Care First: Second Annual Report. *https://www.cms.gov/priorities/innovation/data-and-reports/2024/pcf-second-eval-rpt.*

[110] Independent Evaluation of Primary Care First: Second Annual Report. *https://www.cms.gov/*

Continued

For these reasons, we are seeking to understand how advanced primary care hybrid payments can balance program integrity, high-quality care, payment stability, and clinician burden.

We seek input on the following questions:

- How can CMS reduce the potential burden of billing for population-based and longitudinal care services?
- Are there particular types of items or services that should be excluded from the advanced primary care bundle?
- Are there particular services paid under the PFS today that should be included in the advanced primary care bundle?
- Care management activities are currently billed monthly. What episode lengths should CMS consider when thinking about an advanced primary care bundle of services for hybrid payment? Include evidence to support the proposed episode length.
- Should CMS attribute the advanced primary care clinical episode to a single clinician, or consider weighted attribution and payment for multiple entities or clinicians? How could weighted attribution and payment work? What rules or processes should CMS consider to attribute the episode?
- Care management coding and payment have historically required an initiating visit prior to starting monthly billing, to ensure that the services are medically reasonable and necessary and consistent with the plan of care. Are there other ways that CMS could ensure the clinician billing APCM is responsible for the primary care of the Medicare beneficiary?
- Care management coding and payment require beneficiary cost sharing. Has beneficiary cost sharing been a barrier to practitioners providing such services?
- Consistent with the initiating visit requirement in the APCM proposal, should CMS require the billing of specific qualifying services for billing of an advanced primary care bundle that is larger in scale and scope than APCM?
- Are there Health IT functions beyond what is proposed for APCM services that clinicians should be required to have to bill for an advanced primary care bundle? What should CMS consider in the design of the advanced primary care bundle to effectively incorporate Health IT standards and functionality, to support interoperability and the aims of advanced primary care?
- Should CMS limit the types of non-physician clinicians that can bill for an advanced primary care bundle that is larger in scale and scope than APCM? If so, include evidence to support the restriction.
- How should CMS reconcile instances where an advanced primary care bundle is billed, but primary care services are then billed for and provided by separate entities?

(3) Person-Centered Care

Person-centered care integrates individuals' clinical needs across providers and settings, while addressing their social needs.[111] We strive for better, more affordable care and improved health outcomes. Key to this mission are care innovations that empower beneficiaries and clinicians, while reducing the administrative burden of providing episode-based and longitudinal care management. We are seeking comment on how an advanced primary care code(s) could be structured to both increase efficiency and promote the use of high-value services.

We seek input on the following questions:

- What activities that support the delivery of care that is coordinated across clinicians, support systems, and time should be considered for payment in an advanced primary care bundle that are not currently captured in the PFS?
- How can CMS structure advanced primary care hybrid payments to improve patient experience and outcomes?
- How can CMS structure advanced primary care hybrid payments to ensure appropriate access to telephonic and messaging primary care services?
- What is the best reporting structure to ensure that targeted services are delivered without causing undue or excessive documentation?
- How can CMS facilitate coordination between primary care clinicians that bill for advanced primary care bundles and specialists to reduce costs and improve patient outcomes?

(4) Health Equity, Social and Clinical Risk

We define health equity as, ''the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.'' [112] The CMS Framework for Health Equity lays out how we are working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our beneficiaries need to thrive.[113] For advanced primary care hybrid payments, this may mean incorporating different types of social and clinical risk into the payment than have typically been considered in traditional E/M or care management codes.

Recent models such as ACO REACH [114] and Making Care Primary [115] have incorporated risk adjustment for social risk factors, such as Part D Low Income Subsidy enrollment status and Area Deprivation Index, to better capture factors relevant to care of the patient. We seek input on how advanced primary care billing and payment policy could be used to reduce health disparities and social risk. Furthermore, we are seeking to balance a simple payment structure that encourages the uptake of advanced primary care services, while ensuring that the risk adjustment method used to develop the payment rates incentivizes the appropriate coding of patient conditions and needs, including those that have previously been under-documented, such as dementia and patient frailty.[116]

We seek input on the following questions:

- What non-claims-based indicators could be used to improve payment accuracy and reduce health disparities, and how can CMS ensure that they are collected uniformly and documented consistently without unduly increasing administrative burden?
- What risk factors, including clinical or social, should be considered in developing payment for advanced primary care services?

priorities/innovation/data-and-reports/2024/pcf-second-eval-rpt.

[111] CMS White Paper on CMS Innovation Center's Strategy: Driving Health System Transformation—A Strategy for the CMS Innovation Center's Second Decade (*https://www.cms.gov/priorities/innovation/strategic-direction-whitepaper*).

[112] *https://www.cms.gov/pillar/health-equity.*

[113] Centers for Medicare & Medicaid Services, The CMS Framework for Health Equity (2022–2032). April 2022. *https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.*

[114] *https://www.cms.gov/priorities/innovation/innovation-models/aco-reach.*

[115] *https://www.cms.gov/priorities/innovation/innovation-models/making-care-primary.*

[116] National Academies of Sciences, Engineering, and Medicine (NASEM); Committee on the Decadal Survey of Behavioral and Social Science Research on Alzheimer's Disease and Alzheimer's Disease-Related Dementias. Reducing the Impact of Dementia in America: A Decadal Survey of the Behavioral and Social Sciences. National Academies Press. July 26, 2021. *https://nap.nationalacademies.org/catalog/26175/reducing-the-impact-of-dementia-in-america-a-decadal-survey.*

• How can CMS account for apparent changes in risk that are due to changes in coding patterns rather than changes in health status?

• What risk adjustments should be made to proposed payments to account for higher costs of traditionally underserved populations?

• What indicators are used to capture added social risk in commercial insurance? Should CMS consider using these?

• What metrics should be used or monitored to adjust payment to ensure that health disparities are not worsened as an unintended consequence?

• How can CMS ensure that advanced primary care hybrid payment increases access to health care services for patients without a usual source of primary care?

• Are there steps CMS can take to ensure advanced primary care billing and coding is utilized for dually eligible beneficiaries, and by safety net providers?

• Should CMS incorporate Community Health Integration and/or Principal Illness Navigation services and payment into an advanced primary care bundle?

(5) Quality Improvement and Accountability

We are committed to affordable quality health care for all people with Medicare. We seek feedback regarding how we can continue to strengthen beneficiary access to high-quality health services within FFS Medicare. One goal of the CMS Innovation Center Strategy Refresh is to increase the capability of practitioners furnishing advanced primary care to engage in accountable care relationships with beneficiaries through incentives and flexibilities to manage clinical quality, outcomes, patient experience, and total cost of care. As such, part of the intent of evolving and creating over time advanced primary care hybrid payments is that the practitioners who bill for these services are engaged in a relationship where they are responsible for the quality and cost of care for the beneficiary, counting toward the overall 2030 goal of every person with Traditional Medicare being in an accountable care relationship. This Advanced Primary Care RFI seeks input from beneficiaries and their caregivers, primary care and other clinicians, and health plans on how advanced primary care bundles could support that goal.

We seek input on the following questions:

• How can CMS ensure clinicians will remain engaged and accountable for their contributions to managing the beneficiary's care?

• What are key patient-centered measures of quality, outcomes and experience that would help ensure that hybrid payment enhances outcome and experience for patients?

• How could measures of quality, outcomes, and experience guard against and decrement in access or quality?

• As described in the APCM proposal, reporting of the ''Value in Primary Care'' MVP would be an APCM service element for MIPS eligible clinicians beginning in 2026. Since this MVP contains measures focused on both the total cost and quality of care, would its inclusion as an APCM service element be sufficient to count as ''accountable care?'' If not, what other service delivery or quality reporting would be expected in ''accountable care?''

• What should CMS consider so that that advanced primary care bundles could be used to promote accountable care across payers, both commercial and Medicaid?

• What quality measures are other payers using to drive improvements in primary care?

• What utilization measures are other payers using to drive improvements in primary care?

• What patient experience measures are other payers using to drive improvements in primary care?

• Should CMS consider flexibilities for smaller practices to bill the advanced primary care bundle? Should CMS consider flexibilities for entities exempt from MIPS to bill the advanced primary care bundle?

• Would clinicians be willing to take on more accountability to further reduce the frequency and/or administrative burden of billing?

• For APCM services, are there other key practice-level elements of the service that should be considered for advanced primary care practices to bill for advanced primary care?

4. Cardiovascular Risk Assessment and Risk Management

a. Background

Cardiovascular disease (CVD) is a leading cause of death, disability, and health care expenditures in the U.S.[117] The burden of CVD is unequal, with black Americans experiencing higher rates of CVD-related morbidity than white Americans.[118] Atherosclerotic CVD[119] is also distinct among leading causes of death for Americans in the proportion of CVD attributable to behavioral causes,[120] making improvement in modifiable CVD risk factors (for example, diet, exercise, smoking cessation) is a key treatment target to reduce the burden of CVD across populations.[121]

The CMS Innovation Center's Million Hearts® Cardiovascular Disease (CVD) Risk Reduction model[122] (hereafter referred to as Million Hearts® model) was launched in 2017 as part of the ongoing HHS Million Hearts® Initiative.[123] The model's goals were to decrease the incidence of first-time heart attacks and strokes among medium and high-risk Medicare beneficiaries over five years and reduce Medicare spending on cardiovascular events. The model was implemented as a randomized design where participant organizations in the intervention group agreed to (1) calculate traditional Medicare beneficiaries' risk of having a heart attack or stroke over 10 years, and (2) provide cardiovascular care management services to high-risk patients (defined as a risk of a cardiovascular event in the next decade of greater than thirty percent). The model also identified medium-risk patients (more than fifteen percent risk of an event in the next decade) in its evaluation. In exchange for doing so, CMS paid participant organizations $10 for each eligible traditional Medicare beneficiary for whom the organizations assessed risk, and in the first year of the model, $10 for each high-risk beneficiary during each month when cardiovascular care management services were provided.[124] In

[117] *Heart Disease and Stroke Statistics—2023 Update: A Report from the American Heart Association* Connie W. Tsao, MD, MPH, FAHA et. al. Circulation. 2023;147:e93–e621.

[118] *Cardiovascular Health in African Americans: A Scientific Statement From the American Heart Association* Mercedes R. Carnethon, Ph.D., FAHA et al. Circulation. 2017;136:e393–e423.

[119] What is Atherosclerosis? NIH NHLBI. *https://www.nhlbi.nih.gov/health/atherosclerosis.*

[120] Libby, P., Buring, J.E., Badimon, L. *et al.* Atherosclerosis. *Nat Rev Dis Primers* 5, 56 (2019). *https://doi.org/10.1038/s41572-019-0106-z.*

[121] Ebrahim S, Taylor F, Ward K, Beswick A, Burke M, Davey Smith G. Multiple risk factor interventions for primary prevention of coronary heart disease. *Cochrane Database Syst Rev.* 2011;(1):CD001561 *https://pubmed.ncbi.nlm.nih.gov/21249647/.*

[122] Sanghavi DM, Conway PH. Paying for prevention: a novel test of Medicare value-based payment for cardiovascular risk reduction. *JAMA.* 2015;314(2):123–124. *https://jamanetwork.com/journals/jama/fullarticle/2300705.*

[123] Frieden TR, Berwick DM. The ''Million Hearts'' initiative: preventing heart attacks and strokes. *N Engl J Med.* 2011;365(13):e27. *https://pubmed.ncbi.nlm.nih.gov/21913835/.*

[124] Blue L, Kranker K, Markovitz AR, et al. Effects of the Million Hearts Model on Myocardial Infarctions, Strokes, and Medicare Spending: A Randomized Clinical Trial. *JAMA.* 2023;330(15):1437–1447. *doi:10.1001/jama.2023.19597.*

subsequent years of the model (2018 to 2022) participants were expected to reassess cardiovascular risk and were paid based on cardiovascular risk reduction ($0 to $10 per beneficiary per month) for high-risk beneficiaries.

All CMS Innovation Center models are independently evaluated [125] and the evaluation of the Million Hearts® model found the model reduced the rate of death from any cause for medium and high-risk beneficiaries by four percent, as well as reduced the risk of death from a cardiovascular event (that is, heart attack or stroke) by eleven percent.[126] We consider this to be due to increased rates of cardiovascular risk assessment, discussion of cardiovascular risk by participants' clinicians, and the use of appropriate medications to reduce cardiovascular risk (for example, aspirin and statins).[127]

During the Million Hearts® (MH) model (which was tested from 2017–2022), there was a recently-introduced ASCVD risk assessment tool to incorporate demographic (age, sex, race), clinical (blood pressure, cholesterol, history of diabetes), and risk behavior (smoking status, use of anti-hypertensives, use of statins, use of aspirin) established by the American College of Cardiology (ACC),[128] as well as a longitudinal re-assessment tool used within the model.[129] This tool calculated the 10-year risk of a cardiovascular event for beneficiaries ages 40–79. Subsequently, additional ASCVD risk assessment tools have been developed.[130]

Today in clinical practice, ASCVD risk is generally calculated using a tool combining demographic data, personal history (risk behaviors and medical history), and laboratory data (lipid panel).[131] This information is used to calculate into a 10-year estimate of a patient's ASCVD risk for use in determining treatment advice provided by the treating practitioner. This determination requires both data collection at a visit and laboratory data, which may not be available at an initial visit. This change in clinical practice occurred over time after a series of guidelines from the American Heart Association (AHA) recommended using ASCVD risk in determining treatment decisions for patients without a prior history of CVD.[132] This treatment guideline also includes recommendations for lifestyle modifications for all patients. The CMS Innovation Center Million Hearts® model contributed to this change in clinical practice by demonstrating through a rigorous randomized control trial that the quantitative assessment of 10-year cardiovascular risk improves quality of care, including mortality, compared to prior practice.[133]

In the Million Hearts® model, cardiovascular-focused care management services included an initiating visit where an ASCVD risk assessment is performed, structured recording of patient health information using CEHRT, and a comprehensive care plan focused on cardiovascular risk reduction (including the ABCS focused on in the Million Hearts® model), but did not require 24/7 access to care, management of care transitions, or home and community-based coordination because these services are necessary for the management of complex conditions placing a beneficiary at high risk of death, acute exacerbation/decompensation, or functional decline, and these services are provided to prevent the development of these complex chronic conditions. In the Million Hearts® model, cardiovascular-focused risk management services were provided to beneficiaries at high risk for CVD (more than a thirty percent risk of a cardiovascular event in the next 10 years).

We interpret the findings of the Million Hearts® model to be both reflective of and perhaps augmenting an evolution in clinical practice toward quantitative ASCVD risk assessment. We also do not believe the resources involved in these activities are appropriately reflected in current coding and payment policies. As such, we are proposing to establish codes to describe a separately billable cardiovascular disease risk assessment that is furnished in conjunction with an E/M visit and cardiovascular-focused risk management, when reasonable and necessary due to the presence of increased cardiovascular risk factors identified for the individual patient.

b. ASCVD Risk Assessment

We are proposing a new stand-alone G-code, HCPCS code GCDRA, *Administration of a standardized, evidence-based Atherosclerotic Cardiovascular Disease (ASCVD) Risk Assessment for patients with ASCVD risk factors on the same date as an E/M visit, 5–15 minutes, not more often than every 12 months.* Atherosclerotic Cardiovascular Disease (ASCVD) Risk Assessment refers to a review of the individual's demographic factors, modifiable risk factors for CVD, and risk enhancers for CVD. We are proposing this new code to identify and value the work involved in administering an ASCVD risk assessment when medically reasonable and necessary in relation to an E/M visit.

We further propose that the ASCVD risk assessment must be furnished by the practitioner on the same date they furnish an E/M visit, as the ASCVD risk assessment would be reasonable and necessary when used to inform the patient's diagnosis, and treatment plan established during the visit. ASCVD risk assessment is reasonable and necessary for a patient who has at least one predisposing condition to cardiovascular disease that may put them at increased risk for future ASCVD diagnosis. These conditions could include but are not limited to, obesity, a family history of CVD, a history of high blood pressure, a history of high cholesterol, a history of smoking/

[125] Evaluation of the Million Hearts Cardiovascular Disease Risk Reduction Model. Final Report. August 2023. Mathematica. *https://www.cms.gov/priorities/innovation/data-and-reports/2023/mhcvdrrm-finalannevalrpt.*

[126] Evaluation of the Million Hearts Cardiovascular Disease Risk Reduction Model, p. 43. Final Report. August 2023. Mathematica. *https://www.cms.gov/priorities/innovation/data-and-reports/2023/mhcvdrrm-finalannevalrpt.*

[127] Evaluation of the Million Hearts Cardiovascular Disease Risk Reduction Model, p. 26. Final Report. August 2023. Mathematica. *https://www.cms.gov/priorities/innovation/data-and-reports/2023/mhcvdrrm-finalannevalrpt.*

[128] Grundy SM, Stone NJ, Bailey AL, Beam C, Birtcher KK, Blumenthal RS, Braun LT, de Ferranti S, Faiella-Tommasino J, Forman DE, Goldberg R, Heidenreich PA, Hlatky MA, Jones DW, Lloyd-Jones D, Lopez-Pajares N, Ndumele CE, Orringer CE, Peralta CA, Saseen JJ, Smith SC, Sperling L, Virani SS, Yeboah J. 2018 ACC guideline on the management of blood cholesterol: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. 2018. *https://tools.acc.org/ldl/ascvd_risk_estimator/index.html#!/calulate/estimator/.*

[129] Lloyd-Jones DM, Huffman MD, Karmali KN, Sanghavi DM, Wright JS, Pelser C, Gulati M, Masoudi FA, Goff DC Jr. Estimating Longitudinal Risks and Benefits From Cardiovascular Preventive Therapies Among Medicare Patients: The Million Hearts Longitudinal ASCVD Risk Assessment Tool: A Special Report From the American Heart Association and American College of Cardiology. Circulation. 2017 Mar 28;135(13):e793–e813.

[130] Leading Cardiologists reveal new cardiovascular disease prevention risk calculator. *https://newsroom.heart.org/news/leading-cardiologists-reveal-new-heart-disease-risk-calculator#:~:text=The%20American%20Heart%20Association%20PREVENT,CKM%20syndrome%20into%20CVD%20prevention.*

[131] 2019 ACC/AHA Primary Prevention of Cardiovascular Disease. *https://www.ahajournals.org/doi/pdf/10.1161/CIR.0000000000000678.*

[132] Arnett DK et al. 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2019 Sep 10;140(11):e596–e646. *doi: 10.1161/CIR.0000000000000678.*

[133] Blue L, Kranker K, Markovitz AR, et al. Effects of the Million Hearts Model on Myocardial Infarctions, Strokes, and Medicare Spending: A Randomized Clinical Trial. *JAMA.* 2023;330(15):1437–1447. *doi:10.1001/jama.2023.19597.*

alcohol/drug use, pre-diabetes, or diabetes. We further propose that the ASCVD risk assessment would not be separately billable for patients with a cardiovascular disease diagnosis or those who have history of a heart attack or stroke.

We are not proposing any specific tool that would have to be used for the ASCVD risk assessment, although the assessment tool must be standardized and evidence-based. Proposed elements of the ASCVD risk assessment service would include:

- Current (from the last 12 months) laboratory data (lipid panel) for inputs needed for the risk assessment tool.
- Administration of a standardized, evidence-based ASCVD risk assessment tool that has been tested and validated through research, and includes the following domains:

++ The output of the tool must include a 10-year estimate of the patient's ASCVD risk. This output must be documented in the patient's medical record.

++ Demographic factors (such as age, sex).

++ Modifiable risk factors for CVD (such as blood pressure & cholesterol control, smoking status/history, alcohol and other drug use, physical activity and nutrition, obesity).

++ Possible risk enhancers (such as pre-eclampsia, pre-diabetes, family history of CVD).

++ Billing practitioners may choose to assess for additional domains beyond those listed above if the tool used requires additional domains. Examples of tools include but are not limited to, the ACC ASCVD Risk Estimator [134] and the ACC PREVENT tool.[135] CMS expects that the tool that is used would not introduce discriminatory bias, consistent with Section 1557 final rule.

We are proposing for HCPCS code GCDRA to have a duration of 5–15 minutes for the administration of an ASCVD risk assessment tool, billed no more often than once every 12 months.

We are requesting comments on these proposals, as well as information pertaining to potential clinician education for these proposed codes.

(1) Proposed Valuation for ASCVD Risk Assessment GCDRA

We propose a direct crosswalk to HCPCS Code G0136 (*Administration of a standardized, evidence-based SDOH assessment, 5–15 minutes, not more often than every 6 months*), with a work RVU of 0.18 as we believe this service reflects the resource costs associated when the billing practitioner performs the service described. HCPCS code G0136 has an intra-service time of 15 minutes, and the physician work is of similar intensity to proposed HCPCS code GCDRA. Therefore, we are proposing a work time of 15 minutes for HCPCS code GCDRA based on this same crosswalk to G0136. We are also proposing to use this crosswalk to establish the direct PE inputs for HCPCS code GCDRA.

We are seeking comments on these proposals.

c. Atherosclerotic Cardiovascular Disease Risk Management Services (GCDRM)

Over the past several years, we have worked to develop payment mechanisms under the PFS to improve the accuracy of valuation and payment for the services furnished by physicians and other healthcare professionals, especially in the context of evolving changes in medical practice using evidence-based models of care, such as the Million Hearts® model. We are proposing to establish a G-code to describe ASCVD risk management services that incorporate the ''ABCS'' of CVD risk reduction (aspirin, blood pressure management, cholesterol management, and smoking cessation) for beneficiaries at medium or high risk for ASCVD (>15 percent in the next 10 years) as previously identified through an ASCVD risk assessment. We believe that ASCVD risk management services include continuous care and coordination to reduce or eliminate further elevation of ASCVD risk over time, and potentially prevent the development of future cardiovascular disease diagnoses or first-time heart attacks or strokes.

We are proposing new G-code, GCDRM, *Atherosclerotic Cardiovascular Disease (ASCVD) risk management services with the following required elements: patient is without a current diagnosis of ASCVD, but is determined to be at medium or high risk for CVD (>15 percent in the next 10 years) as previously determined by the ASCVD risk assessment; ASCVD-Specific care plan established, implemented, revised, or monitored that addresses risk factors and risk enhancers and must incorporate shared decision-making between the practitioner and the patient; clinical staff time directed by physician or other qualified health care professional; per calendar month.* Atherosclerotic Cardiovascular Disease (ASCVD) risk management services refer to the development, implementation, and monitoring of individualized care plans for reducing cardiovascular risk, including shared decision-making and the use of the ABCS of cardiovascular risk reduction, as well as counseling and monitoring to improve diet and exercise. We propose that the elements of the Atherosclerotic Cardiovascular Disease (ASCVD) risk management service would include:

- ASCVD Specific Risk Management, which may include:
  - ++ Promoting receipt of preventive services (including tobacco cessation counseling, diabetes screening, diabetes self-management training)
  - ++ Medication management (including aspirin or statins to maintain or decrease risk of CVD)
  - ++ Ongoing communication and care coordination via certified electronic health record (EHR) technology
  - —Synchronous, non-face-to-face communication methods must be offered
- ASCVD-Specific, Individualized, Electronic Care Plan
  - ++ Must address modifiable risk factors and risk enhancers specific to CVD, as applicable, such as:
  - —blood pressure and cholesterol control
  - —smoking, alcohol, and other drug use status, history, and cessation
  - —physical activity and nutrition
  - —obesity
  - ++ Plan must be established, implemented, and monitored and must incorporate shared decision-making between the practitioner and the patient

Although there is no minimum service time requirement for ASCVD risk management services in a month, each of the proposed elements must be addressed to bill for the service, unless a particular element is not medically indicated or necessary at that time for that specific patient. For example, the element of smoking cessation would not be addressed for a patient who does not use tobacco. Documentation of each service element in the patient's medical record is required.

Physicians and non-physician practitioners (NPPs) who can furnish E/M services could bill for ASCVD risk

[134] Lloyd-Jones DM, Huffman MD, Karmali KN, Sanghavi DM, Wright JS, Pelser C, Gulati M, Masoudi FA, Goff DC Jr. Estimating Longitudinal Risks and Benefits From Cardiovascular Preventive Therapies Among Medicare Patients: The Million Hearts Longitudinal ASCVD Risk Assessment Tool: A Special Report From the American Heart Association and American College of Cardiology. Circulation. 2017 Mar 28;135(13):e793 e813.

[135] Leading Cardiologists reveal new cardiovascular disease prevention risk calculator. *https://newsroom.heart.org/news/leading-cardiologists-reveal-new-heart-disease-risk-calculator#:~:text=The%20American%20Heart%20Association%20PREVENT,CKM%20syndrome%20into%20CVD%20prevention.*

management services. We anticipate that ASCVD risk management services would ordinarily be provided by clinical staff incident to the professional services of the billing practitioner in accordance with our regulation at § 410.26. We are proposing that ASCVD risk management services would be considered a ''designated care management service'' under § 410.26(b)(5) and, as such, could be provided by auxiliary personnel under the general supervision of the billing practitioner.

We are proposing that patient consent must be obtained before starting ASCVD risk management services. Like other care management services, ASCVD risk management services would typically be provided by clinical staff outside of face-to-face patient visits. Consent can be written or verbal and must be documented in the medical record. Consent should also include informing the patient about these services, as well as potentially applicable Medicare cost-sharing.

We are proposing that ASCVD risk management services could be billed no more often than once per calendar month, and that payment is limited to one practitioner per beneficiary per month. Patients must be determined to be at medium or high risk for CVD (>15 percent in the next 10 years) as previously determined by the ASCVD risk assessment and must not have a current diagnosis of cardiovascular disease or have a history of heart attack or stroke.

We are seeking comments on each of these proposals.

(1) Proposed Valuation for ASCVD Risk Management Services (GCDRM)

We propose a direct crosswalk to CPT Code 99211 (*Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional*), with a work RVU of 0.18 as we believe this service reflects the resource costs associated when the billing practitioner performs HCPCS code GCDRM. CPT code 99211 has a physician intraservice time of 5 minutes, and the physician work is of similar intensity to our proposed HCPCS code GCDRM. Therefore, we are proposing a work time of 5 minutes for HCPCS code GCDRM based on this same crosswalk to CPT 99211. We are also proposing to use this crosswalk to establish the direct PE inputs for HCPCS code GCDRM, with modifications to reflect non-face-to-face services. These modifications include eliminating PE inputs used in face-to-face services such as preparing and cleaning the room. We are seeking comments on these proposals.

5. Strategies for Improving Global Surgery Payment Accuracy

a. Background

Currently, there are approximately 4,100 physicians' services that are coded and valued under the PFS as global surgical packages (herein ''global packages''). Global packages are single codes that are valued to include all services provided during a specified period of days (0-day, 10-day, or 90-day global packages) by a physician (or another practitioner in the same group practice (as defined at 42 CFR 411.352)) for a specific surgical procedure. The Medicare Physician Fee Schedule (MPFS) look-up tool provides information on each procedure code, including the global surgery indicator. This tool is available at *https://www.cms.gov/medicare/physician-fee-schedule/search/overview*.

The global packages include:

- The surgical procedure itself, including day-of pre-service activities and day-of recovery care;
- Post-operative evaluation and management (E/M) visits and discharge services provided during specified post-operative periods (10- or 90-day periods for most minor and major procedures, respectively; 0-day global packages do not include post-operative visits);
- Pre-operative visits on the day of the procedure (for services with 10- and 90-day periods) and pre-operative visits on the day prior to the procedure (for major procedures with 90-day periods only);
- Services provided during the post-operative period (for services with 10- and 90-day periods) related to the procedure (for example, treatment of complications, pain management).

Any medical care that requires a return to the operating room during the global period is paid separately and starts a new global period. Like other services paid under the PFS, post-operative visits that are part of the global packages can vary by level and site of service. Global packages, including the pre-operative, day-of, and post-operative visits associated with the surgical procedure, are valued using our annual PFS rulemaking process.

As we discussed in the CY 2015 PFS final rule, we have identified and articulated several concerns with the global packages related to the accuracy of valuation and payment under the PFS. Foremost, we have longstanding concerns regarding whether the packages are valued based on estimates consistent with the number and kind of services actually being furnished. Findings from multiple OIG reports suggest that practitioners perform fewer post-operative visits than are expected and accounted for in the valuation of the global packages. We provided a detailed discussion of these concerns in the CY 2015 PFS final rule (79 FR 67582 through 67591). Similarly, we described concerns that global packages as currently constructed may cause potential distortions in valuation among PFS services, and that the structure of the current packages assumes a single model of care delivery (a single practitioner or other practitioners in the same group practice furnishing the surgical procedure and all associated care) and does not appropriately address scenarios where the surgical procedure and follow-up care are provided by different practitioners in different group practices. Taking these findings and concerns into account, we finalized a policy to transition all 10-day and 90-day global packages to 0-day global packages, which would allow any post-operative visits furnished after the day of the procedure to be billed separately as standalone visits by any practitioner who furnishes them. However, in 2015, through amendments made by section 523 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA; Pub. L. 114–10, enacted April 16, 2015), we were prohibited under section 1848(c)(8)(A) of the Act from implementing this finalized policy. Further, under section 1848(c)(8)(B), we were required to collect data beginning in 2017 on the number and level of post-operative visits typically provided to patients during 10- and 90-day global periods and to use this newly collected data and other data beginning in 2019 to improve the accuracy of global package valuation.

In response to these requirements, over the past 9 years, we have:

- Initiated research contracts and implemented a data-collection process to analyze data to understand the extent to which post-operative visits are furnished to patients and improve the accuracy of payment rates for the global surgical packages. This research contract was funded by CMS (HHSM–500–2014–00036I) and carried out within the Payment, Cost, and Coverage Program in RAND Health Care.
- Released three reports (located at *https://www.cms.gov/medicare/payment/fee-schedules/physician/global-surgery-data-collection*) on the number of E/M visits furnished during post-operative periods, the most recent finding that only 4 percent of expected post-operative visits in 10-day global

packages and 38 percent of expected post-operative visits following 90-day global packages were furnished to patients.

- Fielded and released a report on a survey of selected global packages, collecting information related to the level and complexity of medical visits furnished during post-operative periods. This research contract was funded by CMS (HHSM–500–2014–00036I) and carried out within the Payment, Cost, and Coverage Program in RAND Health Care.
- Released two reports on potential approaches for revaluing the global packages based on these findings.
- Analyzed the prevalence of transfer of care modifiers (–54 for surgical care only; –55 for post-operative management only; and –56 pre-operative management only) applied to global packages.

More recently, in the CY 2023 PFS proposed and final rules, we reviewed the prior work and conversations around the accuracy of global package valuations and solicited comments from the public on (1) suggested strategies for revaluing these services, (2) information on how changes to healthcare delivery and payment may be impacting the relevance or accuracy of global package payments, and (3) possible impact of changes to global packages on health care access for beneficiaries (see 87 FR 69432 through 69437). In response to the comment solicitation in the CY 2023 PFS proposed rule, some commenters generally disagreed with our findings that the post-operative visits in the global packages are not performed as frequently as assumed in our valuation of global surgical packages. However, opposition from commenters was based on anecdotal assertions rather than alternative data. Many of these commenters' specific points restated earlier comments submitted in response to our request for feedback in the CY 2020 PFS proposed rule on claims-based reporting of post-operative visits, survey findings on the level of visits, and potential revaluation approaches. Some commenters supported eliminating 10-day global package periods and requested that the AMA RUC review these services. However, these commenters also acknowledged that the AMA RUC review process could take years. In addition to the comments we received in response to the CY 2023 PFS proposed rule, we have received feedback over several years from many interested parties regarding the findings from claims-based reporting of post-operative visits and considered revaluation methodologies presented in our prior reports.

Overall, we have continued exploring ways to improve the accuracy of valuation and payment for global packages to ensure appropriate payments to the practitioners providing pre-operative, surgery, and post-operative care to Medicare beneficiaries while considering feedback from interested parties. In addition, commenters have not proposed specific alternative strategies to revalue global surgical packages.

Separately, we continue to review approaches to better describe physicians' services in the context of the evolving care delivery landscape and to allow practitioners to furnish patient-centered care. Our review work includes considering care delivery models discussed with interested parties (and developed though our CMS Innovation Center work), reviewing our policies and billing requirements, identifying care elements that could serve as the building blocks for describing newer, impactful services, and seeking opportunities to reduce administrative burdens for practitioners while ensuring accurate payment. Through this lens, we have also recently reviewed our billing requirements and payment policies for the global packages, concurrent with continued analysis of the Medicare claims data.

While ongoing, our review highlights opportunities for us to clarify or revise longstanding policy and billing instructions for global packages, using data and experience gathered over the last several years, consistent with our overall objectives to pay more accurately for services and to right-size the valuation of PFS services based on how practitioners currently furnish these services. In this proposed rule, we discuss proposals (1) to revise our transfer of care policy for global packages to address instances where one practitioner furnishes the surgical procedure and another practitioner furnishes related post-operative E/M visits during the global period, and (2) to develop a new add-on code that would account for resources involved in post-operative care provided by a practitioner who did not furnish the surgical procedure. We believe that addressing the use of transfer of care modifiers, and the resources involved when practitioners who do not furnish the surgical procedure provide post-operative care, are essential steps in aligning payment with the way in which surgical procedures are currently furnished as evidenced in our data, and would make meaningful progress toward more accurate payment for these services in particular and improve relative valuation for PFS services overall.

b. Clarifying the Scope of Global Surgical Packages

We have valued global packages to include the surgical procedure and services furnished during the specified global period related to the surgical procedure when furnished by the practitioner who performs the surgery (hereafter in this section, the proceduralist) or by another practitioner in the same group practice as the proceduralist.

Under current Medicare payment policy, certain services furnished during the global period by the proceduralist or by another practitioner in the same group practice may be separately billed with an appropriate modifier:

- Initial decision for surgery: E/M service billed with modifier –57 (Decision for Surgery).
- E/M services unrelated to the procedure: billed with modifier –24 (Unrelated E/M Service During a Global Period).
- Other services unrelated to the procedure (including underlying condition treatment, diagnostic tests, distinct procedures) not including care for complications/returns to the operating room: no modifier required.
- Failure of a less extensive procedure requiring a more extensive procedure: no modifier required.
- Organ transplant immunosuppressive therapy: no modifier required.
- Critical care services unrelated to surgery: billed with modifier –FT if in the post-operative period.

In general, except where a formal transfer of care modifier applies, a practitioner other than the proceduralist or a practitioner in the same group practice as the proceduralist can bill separately for an E/M visit for services they furnish during the global period for a global package, including post-operative E/M visits related to the procedure. We established formal transfer of care modifiers to apply in cases where the work, time, and resources involved in furnishing services included in the global packages are split between the proceduralist (or another practitioner in the same group practice) and other practitioners providing related post-operative visits during the global period. Under our current transfer of care policy, transfer of care modifiers must be reported when a formal transfer of care arrangement is documented by both the proceduralist and another practitioner providing the related post-operative visits. Based on our analysis of Medicare fee-for-service

claims data, these formal transfer of care modifiers are rarely used and, when they are, it is often with respect to certain ophthalmologic procedures (for example, cataract surgery).

Based on our analysis of claims data, we believe that it may be helpful to review our current policy regarding the applicability of transfer of care modifiers for the medical and billing communities. Under our current policy, the scope of the global package extends to services furnished by the entire group practice of the proceduralist, including services furnished by practitioners in the group practice who are a different specialty from the proceduralist. In other words, the PFS payment for post-operative visits and other services furnished during the global period that are related to the surgical procedure and provided by the proceduralist or a practitioner in the same group practice as the proceduralist is bundled into the global package, and those services are not separately billable. If the proceduralist or a practitioner in the same group practice as the proceduralist wants to bill during the global period for a service furnished to the surgical patient, but unrelated to the global package, the correct modifier must be used to indicate that the service is not related to the global package. Without a modifier to indicate otherwise, during the global period for a global package, all E/M services furnished to the patient by the proceduralist or another practitioner in the same group practice as the proceduralist are presumed to be related to, and included in the payment for, the global package. Modifiers for separate payment (such as modifier -24) are required when services unrelated to the global package are billed by the proceduralist or a practitioner in the same group practice as the proceduralist during the global period.

c. Strategies To Address Global Package Valuation

We recognize that we are precluded under section 1848(c)(8)(A) of the Act from revisiting the policy we established in the CY 2015 PFS final rule to revalue all 10-day and 90-day global packages to 0-day global packages (79 FR 67582–67591). Further, we note that transitioning all global packages to 0-day global periods could take several years and require substantial CMS resources (see CY 2014 PFS final rule (77 FR 44737 through 44738) for previous discussion). We have also considered revaluing 10-day and 90-day global packages to reflect the observed number of post-operative visits furnished to patients based on data we have collected over nearly a decade and note that this approach would be quicker to implement, assuming there would be straightforward ways to revalue the services with the data. However, interested parties have continued to express uncertainty about the validity of claims-based counts of post-operative visits. This uncertainty stems primarily from CMS not having complete information surrounding the use of the transfer of care modifiers since they are not currently routinely used. The same interested parties also object conceptually to revaluing the 10-day and 90-day global packages using the ''building block'' framework, where each component of a service, including bundled post-operative visits, contributes to total valuation to align valuation with the number of post-operative visits typically provided to patients. Some interested parties have expressed larger concerns about the redistributive impacts across the PFS among specialties if we were to implement and revalue all global packages.

We acknowledge the practical challenges involved in revaluing 10-day and 90-day global packages, whether they remain as 10-day and 90-day periods with fewer post-operative visits or are transitioned to 0-day global packages, and continue to carefully consider how to best improve global package valuation given access to administrative claims data and other inputs that help us understand the scope of services provided to patients within global packages. Ultimately, we want to ensure payments to practitioners and the relative values assigned to global surgical packages are accurate and, to the extent possible, driven by real-world objective and updatable information regarding the relative resources involved in furnishing the services.

For CY 2025, we are focused on different aspects of our policy objectives for global packages and propose the following policies, which are not mutually exclusive, to obtain information and allow for more accurate payment to reflect time and resources spent on post-operative care associated with the current global packages. We will continue to assess and monitor for potential future opportunities to improve our payment approach for the global packages more broadly.

Additionally, in developing our proposed policies to pay more accurately for the global packages, we also considered whether, when, or how our policies may be affected when services are provided by the proceduralist, versus another practitioner who did not perform the procedure but is providing follow up care. We also recognize that there may be multiple practitioners in the same or different specialties in the same group practice and considered how our policies should apply to practitioners in a range of specialties within the same group practice. We are seeking comment on these considerations in the context of our proposed policies and welcome feedback that may further inform our payment policy for global packages. Additionally, as we continue to better understand what services are being furnished in the global period, by whom, and how the global surgical packages are valued and billed, we are seeking comment on how remote monitoring and other types of new technologies represent new resource costs and/or produce efficiencies and effectiveness of post-operative care. This information could be useful both for purposes of valuation for surgical and post-operative care, as well as for policies regarding when specific PFS codes should be reported during global periods for global packages.

d. Expand Applicability of Transfer of Care Modifiers

We created transfer of care payment modifiers at the inception of the PFS. Under our current policy, these modifiers are required to be appended to the relevant global package code when billing for services that are within the scope of the global package (within the global period and related to the surgical procedure) only when the proceduralist and one or more other practitioners who are not in the same group practice as the proceduralist formally document their agreement to provide distinct portions of the global package.

The following transfer of care modifiers describe the different portions of the global surgical package that could be provided by different practitioners:

- Modifier –54 Surgical Care Only: this modifier is appended to the relevant global package code to indicate that the proceduralist performed only the surgical procedure portion of the global package.
- Modifier –55 Post-operative Management Only: this modifier is appended to the relevant global package code to indicate that the practitioner performed only the post-operative management portion of the global package.
- Modifier –56 Pre-operative Management Only: this modifier is appended to the relevant global package code to indicate that the practitioner performed only the pre-operative portion of the global package.

For each of these modifiers, the payment for the global package is adjusted based on the applicable percentage noted in the PFS Relative Value files (*https://www.cms.gov/medicare/payment/fee-schedules/physician/pfs-relative-value-files*).

As previously noted, we currently require the transfer of care modifiers (–56 pre-operative care, –54 for procedures, and –55 for post-operative care) to be appended in cases where there is a formal documented transfer of care agreement, that is, ''in the form of a letter or an annotation in the discharge summary, hospital record, or Ambulatory Surgical Center (ASC) record'' (CMS Manual System, Pub 100–04 Medicare Claims Processing, Transmittal 11287). In our recent analyses of 2022 Medicare claims data, we identified that these modifiers were rarely used other than for certain ophthalmology global packages. We found over 99 percent of claim lines for 90-day surgical procedures billed with modifier –54 were ophthalmology services (primarily cataract-related procedures). We also identified a difference in the number of claim lines annually for a given 90-day global package with modifier –54 and with modifier –55. In other words, there are sometimes more claim lines billed with modifier –54 than there are corresponding lines with modifier –55 and vice versa during a year. We note that modifier –56 (pre-operative management only) is only very rarely used in practice. These recent observations suggest (1) the overwhelming concentration of reported transfer of care modifiers is in ophthalmology procedures, and (2) a potential mismatch in billing for formal transfer of care cases between proceduralists and other practitioners providing post-operative care.

While we recognize the benefits to continuity of care when the proceduralist also provides pre-operative and follow-up care for the procedure, we also recognize that it is not always feasible, or even perhaps typical practice for the same practitioner to furnish all portions of the global package; for example, in instances when the practitioner furnishing the procedure does not schedule a post-operative visit(s) on the day of the procedure or plans for the patient to follow up with their primary care provider, or when the practitioner performing the surgery arranges alternative follow-up care because it would be difficult for the beneficiary to travel to return for follow-up care. Because our current policies require use of the transfer of care modifiers only where there is a formal documented agreement between practitioners to provide specific portions of the global package, we believe there are many practical and potentially common circumstances under which the transfer of care modifiers would not be required or used.

Beginning for services furnished in 2025, we are proposing to broaden the applicability of the transfer of care modifiers for the 90-day global packages. We are proposing to require the use of the appropriate transfer of care modifier (modifier –54, –55, or –56) for all 90-day global surgical packages in any case when a practitioner plans to furnish only a portion of a global package (including but not limited to when there is a formal, documented transfer of care as under current policy, or an informal, non-documented but expected, transfer of care). Practitioners billing for a global package procedure code with modifier –54 and other practitioners in the same group practice as that practitioner would still be able to bill during the global period for any separately identifiable E/M services they furnish to the patient that are unrelated to the global package procedure. To do so, the practitioner would append modifier –24 to the claim line for the E/M service.

This proposed policy, which would be a first step toward improved valuation and payment while retaining the fundamental structure of the global packages, would provide us with more accurate information on the resources involved in furnishing components of global surgical packages. This proposal would prevent duplicative Medicare payment for post-operative care because the global surgical package payment would be adjusted based on the appended modifier, and payment for post-operative care would not be made both as part of a global surgical package and through separately billed E/M visits. We also anticipate that the proposed policy would provide us with insight into changes in standards of practice and post-operative patient care for services that are not billed with transfer of care modifiers pursuant to our current policy (that is, services other than certain ophthalmology procedures).

We acknowledge the potential challenge associated with anticipating whether other practitioners will furnish portions of the global package and, accordingly, appending the appropriate modifier when billing global package services.

We are interested in understanding and are seeking comment on the circumstances under which practitioners in separate group practices furnish different portions of the care included in global packages, and what that means for reporting the transfer of care modifiers. While we are making proposals related to the 90-day global periods beginning for services furnished in 2025, we are also seeking comment on whether we should consider proposing these changes for the 10-day global packages in future rulemaking.

e. Payment for Global Packages

Under our current policy for global packages where the transfer of care modifiers are used (required only where there is a formal transfer of care arrangement), the total combined PFS payment made for the global package during the global period does not exceed the total global surgical package payment established for the procedure when billed without any transfer of care modifier. In general, we continue to believe this is the appropriate result when more than one practitioner furnishes portions of a global package. Under our proposal, we would require that practitioners performing the surgical procedure but not intending to furnish the post-operative portions of a 90-day global service would appropriately append the –54 modifier that we have previously discussed, which would adjust the portion of payment received to accurately reflect the service furnished.

More specifically, as noted in the discussion above, the transfer of care modifiers correspond to three distinct portions of the global package (pre-operative services, the surgical procedure itself, and post-operative care). We have assigned a proportion of the global package payment to each portion of the service based on longstanding assumptions. Under our current policy, the payment for the entire global package is paid to the billing practitioner unless a transfer of care modifier is included on the claim. Payment is only adjusted if a transfer of care modifier is included on the claim. We are requesting comments, as we further develop our payment policies for global packages, on how best to determine the appropriate payment proportions for the three portions of the global package, which impact payment to the different practitioners who furnish the different portions of the service.

We are continuing to consider approaches to establishing the payment allocations for portions of the global package when the transfer of care modifiers are used, and anticipate revising the allocations through future rulemaking. We are seeking comment on

potential approaches to revise these payment allocations and how they could be established to better reflect current medical practice and conventions for post-operative follow-up care. We seek to identify a procedure-specific, data-driven method for assigning shares to portions of the global package payment to more appropriately reflect the resources involved in each portion. We would appreciate and carefully consider recommendations from interested parties, including the AMA RUC, on what those allocation percentages should be, based on how the global package codes are valued and any other relevant information.

We have contracted with RAND to support data collection and analysis in the past and, as identified in RAND's prior reports and described in detail, we surmise that the policy to apportion and pay for the three portions of the global package based on the presence of transfer of care modifiers does not always work smoothly. In considering RAND's reports, one reason for this is that fewer post-operative visits are provided to patients compared to the number of visits reflected in the valuation of global packages. The global packages reflect a certain number of post operative visits (noted in the Physician Time File) that typically occur during the post-operative global period. However, there is no easy way within a global package to separate the RVUs for the procedure itself from the RVUs for post-operative visits that are not typically provided to patients. If our allocation of the global package payment based on the presence of transfer of care modifiers were to undervalue the surgical procedure portion or the post-operative care portion of the global package, we are concerned that we could unintentionally introduce incentives that influence current medical practice for transfers of care. This gets at RAND's prior recommendation that we revalue global packages to reflect the actual number of post-operative visits provided to patients. After revaluation, separating the procedure and post-operative payments would reflect observed data and mitigate any possible inappropriate incentives in place for practitioners to initiate transfers of care and support use of transfer of care modifiers as medically appropriate. This approach has the advantage of anchoring the valuation of separate –54 and –55 components using real-world information on post-operative visits reported to CMS rather than on historical assumptions or current survey data reflecting estimates of the typical number and level of visits.

In our internal review of the percentages assigned for the pre-operative, surgical care, and post-operative portions of the global package, we found that there are a small number of codes that do not have any assigned percentages in our files even though these codes are identified as global packages. HCPCS codes 77750 (*Infusion or instillation of radioelement solution (includes 3-month follow-up care)*), HCPCS code 77761 (*Intracavitary radiation source applic simple*), HCPCS code 77762 (*Intracavitary radiation source applic intermed*), and HCPCS code 77763 (*Intracavitary radiation source applic complex*) do not have assigned percentages in our RVU files. It is our understanding, however, that the MACs have local edits in place to ensure appropriate payment for these services when billed with the transfer of care modifiers. We are seeking comment on whether we should consider, first, whether these codes are appropriately categorized as 90-day global package codes. If these are appropriately considered to be 90-day global package codes, we are seeking comment on what the assigned percentages should be for the pre-operative, surgical care, and post-operative portions of the service.

f. Post-Operative Care Services Add-On Code

We recognize the importance of continuity in surgical and post-operative care. However, we recognize that there are instances where post-operative care is not furnished by the proceduralist or another practitioner in the same group practice, or even by a practitioner who is in the same specialty as the proceduralist, despite there being no formal transfer of care. We also recognize that there is an extra level of complexity involved when a practitioner sees a patient post-operatively after a surgical procedure performed by another practitioner in those circumstances. The practitioner providing the post-operative care may not be involved in creating the surgical plan, and may not have access to the operative notes to know how the surgery went or be abreast of any particular considerations related to the procedure that may factor in medical care decisions for the post-operative care. As such, we recognize that there are comparatively more resource costs incurred when a practitioner who did not furnish the surgical procedure in a global package provides the follow-up care. We are proposing to address these scenarios, which can occur in a few different ways, by establishing a new add-on code that would account for resources involved in post-operative care for a global package provided by a practitioner who did not furnish the surgical procedure and does not have the benefit of a formal transfer of care. However, we note that when a patient is seen by practitioners in the same group practice or specialty as the surgeon, the same resources are not incurred during follow-up and therefore, the add-on code should not be billed by another practitioner in the same group practice as the practitioner who performed the surgical procedure, or in the same specialty as the practitioner who performed the surgical procedure. In the case of a practitioner providing follow up care who is of a different specialty and not within the same group practice as the proceduralist, researching the procedure to determine expected post-operative course and potential complications may be needed, which would warrant using the add-on code. We also acknowledge that sometimes the proceduralist does not schedule the patient to follow up with them post-operatively and directs the patient to follow up with other practitioners as needed, such as with the patient's primary care provider. The patient may independently choose to follow up with their primary care provider or another practitioner based on other considerations such as convenience of the practice location or ease of scheduling. We understand and acknowledge that the patient can choose to see another practitioner without the knowledge of the practitioner who performed the procedure.

To more appropriately reflect the time and resources involved in these kinds of visits, we are proposing to make payment using a new add-on code to be billed with an office/outpatient E/M visit for post-operative follow-up care during the global period of a global package to capture additional resources associated with practitioners who were not involved in furnishing the surgical procedure. This follow-up care may include, but is not limited to, obtaining and reviewing the surgical notes and surgical history, monitoring for signs and symptoms of infection, taking into account any considerations from the surgical procedure that may affect the medical care, and monitoring for any potential post-operative complications that may arise. It is often difficult in these circumstances for the practitioner who did not perform the surgical procedure to know how the wound looked after the procedure, and so it is more challenging to recognize possible changes that may have occurred since

the time of the procedure (when this is something the operating surgeon would have been able to know). This new code would be billed by the practitioner who furnishes the post-operative office/outpatient E/M visits when that practitioner is not the proceduralist and is not in the same specialty or group practice as the proceduralist. Documentation in the medical record must justify use of the add-on code and that the E/M visit was, as clinically understood by the reporting practitioner, related to a post-operative visit furnished during the 90-day post operative period. As noted earlier, we are proposing to expand the required use of the transfer of care modifiers as a first step toward improving payment for the global packages to promote improved valuation and payment for these services. Instituting an add-on code to capture the time and intensity of post-operative work absent a formal transfer of care, would be an essential step in recognizing how the services are currently furnished and make meaningful progress toward 'right-sizing' the structure of the global packages.

Given the history of the global packages since data collection began, as specified in section 1848(c)(8) of the Act, and in consideration of our policies for post-operative care and our proposal requiring the use of the transfer of care modifiers in a broader set of circumstances, we believe that the timing is appropriate to establish an add-on code and payment for post-operative care provided in the office/outpatient setting by a practitioner other than the proceduralist (or another practitioner in the same specialty) to account for the additional time, intensity, and resources that are involved in post-operative care. We are proposing a new HCPCS code, GPOC1, to capture the additional time and resources spent in providing follow up post-operative care by a practitioner who did not perform the surgical procedure and who has not been involved in a formal transfer of care agreement.

We propose the following code and descriptor for the proposed add-on code: GPOC1 (*Post-operative follow-up visit complexity inherent to evaluation and management services addressing surgical procedure(s), provided by a physician or qualified health care professional who is not the practitioner who performed the procedure (or in the same group practice), and is of a different specialty than the practitioner who performed the procedure, within the 090-day* global period *of the procedure(s), once per 090-day global period, when there has not been a formal transfer of care and requires the following required elements, when possible and applicable:*

- Reading available surgical note to understand the relative success of the procedure, the anatomy that was affected, and potential complications that could have arisen due to the unique circumstances of the patient's operation.
- Research the procedure to determine expected post-operative course and potential complications (in the case of doing a post-op for a procedure outside the specialty).
- Evaluate and physically examine the patient to determine whether the post-operative course is progressing appropriately.
- Communicate with the practitioner who performed the procedure if any questions or concerns arise. (List separately in addition to office/outpatient evaluation and management visit, new or established)).

We are proposing that HCPCS code GPOC1 would be reported by a physician or other practitioner who did not perform the surgical procedure for a global package and provides related post-operative visits during the global period despite the absence of a formal transfer of care. We are proposing that the add-on code (HCPCS code GPOC1) would only be reported with an office or other outpatient E/M visit for the evaluation and management of a new or established patient. We would expect the documentation in the medical record to indicate the relevant surgical procedure, to the extent the billing practitioner can readily identify it, in order to aid in our understanding of the post-operative care being furnished and when there is no transfer of care modifier appended on the claim.

We are proposing that this code could be billed only once during the 90-day global period for the global package because we believe the practitioner would only have additional resource costs upon the first visit following the procedure. We are proposing to assign a ZZZ global period payment indicator for HCPCS code GPOC1, as this allows the add-on code to be billed during the post-operative time frame that applies to payment for each surgical procedure and, under our proposed policy, this code would be reportable with an E/M visit. The ZZZ global period payment indicator would identify this code as a service that is related to another service paid under the PFS and is always included in the global period of the other service.

g. Proposed Valuation for GPOC1 Add-On Code

We note that the proposed valuation of HCPCS code GPOC1 is meant to capture the additional resource costs, including for visit complexity inherent to office/outpatient care associated with a post-operative visit that is not accounted for in the appropriate office/outpatient E/M base code billed by the physician or practitioner. Therefore, we believe that CPT code 90785 (Interactive complexity (List separately in addition to the code for primary procedure)) serves as an appropriate reference for the purposes of valuing HCPCS code GPOC1. CPT code 90785 was created to capture additional work that occurs during diagnostic psychiatric evaluation, psychotherapy, psychotherapy performed with an E/M service and group psychotherapy sessions, and the service refers to specific communication factors that complicate the delivery of a psychiatric/psychotherapy procedure. However, we believe there may be relatively less work involved for GPOC1 when compared to the work of CPT code 90785, considering the amount of time needed to gather the operative history and conduct the elements discussed above. Therefore, we are proposing a work RVU of 0.16, which represents approximately half of the assigned work for minutes of CPT code 90785. Additionally, we are proposing a work time of 5.5 minutes (or half of the 11 minutes established for CPT code 90785), personally performed by the billing practitioner including the elements discussed above during the post-operative E/M visit furnished during the global period, that is, no later than 90-days following a 90-day global code, respectively. CPT code 90785 has no direct PE inputs, and we are proposing the same for HCPCS code GPOC1.

To help inform whether our proposed valuation reflects the typical service, we are seeking comment the typical time and intensity physicians and practitioners spend over and above a separately billed E/M visit when providing post-operative care to a patient when they did not perform the surgical procedure, gathering the surgical history as well as the pre-operative, intra-operative, and post-operative, and on the proposed service elements and the relative intensity compared to similar service elements of other CPT codes. For the individual practitioner, not having an intimate knowledge of the procedure itself and not having a before/after comparison to look at for the wound can all complicate

their E/M visit. The proposed work RVUs are intended to account for the additional relative resource costs in time and intensity in addition to those involved in the E/M visit.

Finally, we recognize that historically, the CPT Editorial Panel has frequently created CPT codes describing services for which we originally established G-codes and adopted them through the CPT Editorial Panel process. We note that we would consider using any newly available CPT coding to describe services similar to those described here in future rulemaking.

For discussion of our expected utilization assumptions for this service, see the discussion in the Regulatory Impact Analysis section of this proposed rule.

H. Supervision of Outpatient Therapy Services in Private Practices, Certification of Therapy Plans of Care With a Physician or NPP Order, and KX Modifier Thresholds

1. Supervision of Outpatient Therapy Services in Private Practices

In the CY 2024 PFS final rule, we finalized our proposal to allow remote therapeutic monitoring (RTM) services to be furnished by occupational therapy assistants (OTAs) and physical therapy assistants (PTAs) under the general supervision of occupational therapists (OTs) and physical therapists (PTs) in private practice, in an effort to align with the general supervision policy for these services for physicians and other practitioners described in the CY 2023 final rule (88 FR 78990). We also noted that we would consider for possible future rulemaking the commenters' responses to our request for information (RFI) on changing the supervision of therapy assistants in the private practice setting to general supervision for all therapy services (88 FR 78990 through 78992).

In the CY 2024 PFS proposed rule, we reviewed the statutory provisions at sections 1861(p) and 1861(g) (by cross-reference to section 1861(p)) of the Act that describe outpatient physical therapy and occupational therapy services furnished to individuals by physical therapists (PTs) and occupational therapists (OTs) meeting licensing and other standards prescribed by the Secretary if the services meet the necessary conditions for health and safety. These statutory provisions refer separately to outpatient therapy services furnished by a provider of services (such as a rehabilitation agency) and those services furnished in the therapist's office or the individual's home, thus distinguishing therapists who work for an institutional provider of therapy services from therapists who furnish and bill independently for these outpatient therapy services (88 FR 52358 through 52359). In regulations, we have addressed these therapists as physical or occupational therapists in private practice (PTPPs and OTPPs) (63 FR 58868 through 58870). The regulations specific to services furnished by occupational or physical therapists in private practice are found at §§ 410.59(c) and 410.60(c), respectively.

We also summarized a history of related regulatory provisions in the CY 2024 PFS proposed rule. In the CY 2005 PFS final rule with comment period (69 FR 66236, 66351 through 66354), we explained that the personnel requirements that are applicable for Home Health Agencies (HHAs) at 42 CFR part 484 for therapists, therapy assistants and speech-language pathologists (SLPs) apply to all outpatient physical therapy, occupational therapy, and speech-language pathology services. In the CY 2005 PFS final rule, we also added a basic rule at §§ 410.59(a) and 410.60(a), respectively, by cross-referencing the qualifications for OTs and their OTAs and PTs and their PTAs for all occupational therapy and physical therapy services, respectively, including those who work in private practices, to 42 CFR part 484. Later, in the CY 2008 PFS final rule (72 FR 66328 through 66332), we updated the qualification standards at 42 CFR part 484 for OTs, OTAs, PTs, PTAs, and SLPs.

In the CY 2024 PFS proposed rule, through our RFI on general supervision of OTAs and PTAs by OTPPs and PTPPs, respectively, we solicited public comment, along with supporting data, for our consideration for possible future rulemaking about the following: (a) the questions and concerns we highlighted related to access, patient safety, and utilization; (b) revising §§ 410.59(a)(3)(ii) and (c)(2) and 410.60(a)(3)(ii) and (c)(2) to permit general supervision of OTAs and PTAs by the OTPP and PTPP, respectively, when furnishing therapy services; and (c) any appropriate exceptions to allowing general supervision in the furnishing of therapy services (88 FR 52358 through 52359).

In the CY 2024 PFS final rule, we reviewed the comments we received in response to the proposed rule (please refer to (88 FR 78990 through 78992)). We noted that we would consider these comments for possible future rulemaking—see our review of comments on the RFI in the CY 2024 PFS final rule (88 FR 78992).

Over the past several years and again more recently, we have heard from interested parties that the direct supervision requirements in the private practice setting are problematic for OTPPs and PTPPs who must remain on-site and immediately available when Medicare patients are treated in order to bill for therapy services furnished by their supervised OTAs and PTAs. As a remedy to this situation, interested parties have requested that we revise our requirement for PTPPs and OTPPs to provide direct supervision of OTAs and PTAs to align with the general supervision policies for OTs and PTs that work in Medicare institutional settings that provide therapy services (for example, rehabilitation agencies, outpatient hospitals, SNFs and comprehensive outpatient rehabilitation facilities (CORFs), etc.), to allow for the general supervision of their therapy assistants. These interested parties tell us that their respective State laws and policies allow general supervision of therapy assistants (most often requiring the OT or PT to be in touch with their therapy assistants via telecommunication) in at least 44 States for PTAs,[136] and all but one State for OTAs.

Some interested parties have reported that allowing for general supervision of OTAs and PTAs by OTPPs and PTPPs, respectively, would allow for patients to have increased access to outpatient therapy services, even with ongoing healthcare workforce shortages. The shortages of OTs [137] and OTAs,[138] PTs,[139] and PTAs,[140] are noted by the United States Bureau of Labor Statistics, which shows thousands of open positions in all of these fields. Interested parties noted that over 22,000 PTs left the workforce in 2021.[141] Additionally,

[136] Federation of State Boards of Physical Therapy Jurisdiction Licensure Reference Guide *https://www.fsbpt.net/lrg/Home/SupervisionRequirementLevelsBySetting.*

[137] Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook,* Occupational Therapists, at *https://www.bls.gov/ooh/healthcare/occupational-therapists.htm* (visited *April 17, 2024*).

[138] Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook,* Occupational Therapy Assistants and Aides, at *https://www.bls.gov/ooh/healthcare/occupational-therapy-assistants-and-aides.htm* (visited *April 17, 2024*).

[139] Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook,* Physical Therapists, at *https://www.bls.gov/ooh/healthcare/physical-therapists.htm* (visited *April 17, 2024*).

[140] Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook,* Physical Therapist Assistants and Aides, at *https://www.bls.gov/ooh/healthcare/physical-therapist-assistants-and-aides.htm* (visited *April 17, 2024*).

[141] See the report by Definitive Healthcare dated October 2022 at *https://www.definitivehc.com/sites/*

these interested parties noted that workforce shortages have greater impact on private practices in rural and underserved areas where hourly wages are lower, and the OTPPs and PTPPs in these areas tend to have small practices. The interested parties stated that Medicare's direct supervision policy, which requires the PTPP and the PTA to both be present when a Medicare patient is treated, does not allow small practices with one PT and one or two PTAs, for example, to work different or overlapping schedules in order to accommodate all patients' availability by allowing the OTA/PTA to work before or after the OTPP/PTPP normal hours. The interested parties also stated that the direct supervision requirement can unfairly delay care for Medicare patients when, for example, a PTPP or OTPP is out sick, the practice does not have alternative coverage, and appointments for Medicare patients must be canceled.

In light of this input, we believe that the direct supervision requirement for OTPPs and PTPPs of OTAs and PTAs, respectively, may have had an unintended consequence of limiting access to needed therapy services. As noted by interested parties, both the OTPP/PTPP and their respective OTA/PTA must be present in the office in order to bill and receive Medicare payment for therapy services furnished by OTAs and PTAs. This means, for example, that an OTPP/PTPP cannot bill and receive payment for therapy services furnished to a Medicare patient in their home when furnished by an OTA/PTA, without the presence of the OTPP/PTPP. The direct supervision requirement for OTAs and PTAs in the private practice setting is more stringent than the supervision requirements for OTAs and PTAs in institutional settings. For example, as we noted in the CY 2024 PFS proposed rule, 42 CFR 485.713 specifies that when an OTA or PTA provides services at a location that is off the premises of a clinic, rehabilitation agency, or public health agency, those services are supervised by a qualified occupational or physical therapist who makes an onsite supervisory visit at least once every 30 days. We also cited Table 4 in our Report to Congress, titled ''Standards for Supervision of PTAs and the Effects of Eliminating the Personal PTA Supervision Requirement on the Financial Caps for Medicare Therapy Services,'' [142] in the CY 2024 PFS proposed rule to demonstrate that the minimum level of supervision by PTs and OTs for services performed by PTAs and OTAs working in institutional settings is a general level of supervision, in accordance with various regulations (88 FR 52359). Therefore, we believe that a change from direct to general supervision would allow OTPPs and PTPPs the flexibility to better accommodate patients' availability and act to ensure access to necessary therapy services. A change from direct to general supervision would also allow OTPPs and PTPPs to bill and receive Medicare payment for therapy services furnished by their OTAs and PTAs when they are not in the office or patient's home at the same time.

We also believe that it is important to better align our supervision policies for OTPPs and PTPPs with the majority of state-established supervision levels for therapy assistants providing occupational therapy and physical therapy services. We note that the majority of states allow OTs and PTs to provide general supervision of their respective OTAs and PTAs when furnishing occupational therapy and physical therapy services. We believe that States are well aware of the health and safety needs for their residents who receive therapy services from OTs and their supervised OTAs, and PTs and their supervised PTAs. Given these beliefs and the input from interested parties, we are proposing to revise our regulations at §§ 410.59(a)(3)(ii) and (c)(2) and 410.60(a)(3)(ii) and (c)(2) to allow for general supervision of OTAs and PTAs by OTPPs and PTPPs, when the OTAs and PTAs are furnishing outpatient occupational and physical therapy services, respectively. We expect that this proposal would both increase access to therapy services and more closely align Medicare policy with the majority of State practice acts for occupational therapy and physical therapy. This will parallel the 44 States that allow general supervision of PTAs and the 49 States that allow general supervision of OTAs (most often described as requiring the PT or OT to be in touch via telecommunication). For the States with more restrictive supervision levels, such as direct supervision, those therapy services are always furnished to the extent that is permitted under State law. We note that while we are proposing to allow for general supervision by OTPPs and PTPPs of their OTAs/PTAs, an OTPP or PTPP would still be required to provide direct supervision to unenrolled OTs and PTs, respectively, in accordance with §§ 410.59(c)(2) and 410.60(c)(2).

We are soliciting comment on our proposals.

2. Certification of Therapy Plans of Care With a Physician or NPP Order

Sections 1861(p), (g), and (ll)(2) of the Act require that an individual outpatient is under the care of a physician and for whom a plan for the physical therapy, occupational therapy, or speech-language pathology services that are to be furnished has been established by a physician or by a qualified PT, OT, or SLP and is periodically reviewed by a physician. Sections 1835(a)(2)(C) and 1835(a)(2)(D) of the Act require that payment for Medicare therapy services may be made for outpatient physical therapy, occupational therapy, and speech-language pathology services only if a physician certifies (and recertifies, where such services are furnished over a period of time) that: (a) the services are or were required because the patient needs or needed therapy services; (b) a plan for furnishing such services was established by a physician or qualified therapist providing such services, and is periodically reviewed by the physician; and (c) the services are or were furnished while the individual was under the care of a physician.

In accordance with the statute and § 424.24(b), Medicare Part B pays for outpatient physical therapy and speech-language pathology services furnished by providers only if a physician certifies the content specified in § 424.24(c)(1) or (4). We recognize that it may not be clear that § 424.24(c) applies to the occupational therapy services furnished by providers, since occupational therapy services are currently only explicitly mentioned in the recertification requirements at § 424.24(c)(4).

We note that there are multiple references to § 424.24(c) in the Medicare Benefit Policy Manual, Pub. 100–02, chapter 15, sections 220.1—Conditions of Coverage and Payment for Outpatient Physical Therapy, Occupational Therapy, or Speech-Language Pathology Services, 220.1.2—Plans of Care for Outpatient Physical Therapy, Occupational Therapy, or Speech-Language Pathology Services, and 220.1.3—Certification and Recertification of Need for Treatment and Therapy Plans of Care, which convey our current policy that all outpatient physical therapy, occupational therapy, and speech-

default/files/resources/pdfs/Addressing-the-healthcare-staffing-shortage.pdf.

[142] See Table 4 of the Report to Congress titled Standards for Supervision of PTAs and the Effects of Eliminating the Personal PTA Supervision Requirement on the Financial Caps for Medicare Therapy Services at *https://www.cms.gov/Medicare/Billing/TherapyServices/Downloads/61004ptartc.pdf.*

language pathology services are subject to requirements for certification and recertification at § 424.24, whether furnished by providers or by suppliers such as therapists in private practice (TPPs). We note that while section 1835 of the Act explicitly refers to services furnished by providers of services, which would include hospitals and other institutional providers as defined in section 1861(u) of the Act, and clinics, rehabilitation agencies, or public health agencies as further described in section 1835(a) of the Act, we have interpreted the requirements of section 1835(a)(2)(C) and 1835(a)(2)(D) as applying to therapy services furnished by both providers and suppliers. See Medicare Benefit Policy Manual, Pub. 100–02, chapter 15, sections 220.1, 220.1.2, and 220.1.3. We believe that this interpretation is based on the certification and recertification requirements under section 1835(a) of the Act as a way to effectuate the requirement in sections 1861(p), (g), and (ll)(2) of the Act that the patient is under the care of a physician, and that the plan of treatment/care for the physical therapy, occupational therapy, or speech-language pathology services has been established by a physician or by a qualified PT, OT, or SLP and is periodically reviewed by a physician. Additionally, we thought it was important to establish conforming policies for these therapy services in both the outpatient provider and private practice settings.

Due to the foregoing concerns, we are proposing to revise the headings of paragraphs (c) introductory text and (c)(1)(i) to include the term ''occupational therapy'' after physical therapy. We propose to replace the term speech pathology with the accepted term speech-language pathology in 42 CFR 424.24(c)(1)(i). We are also proposing to add the term ''occupational therapist'' to 42 CFR 424.24(c)(3)(ii) between physical therapist and speech-language pathologist.

The regulations at 42 CFR 424.24(c) require that a physician, nurse practitioner (NP), physician assistant (PA), or clinical nurse specialist (CNS) who has knowledge of the case sign the initial certification for the patient's plan of treatment. We remind readers that plan of treatment is synonymous with the ''plan of care'' mentioned above. This terminology appears in several sections of Pub. 100–02, chapter 15, and both terms may be used interchangeably. In accordance with § 424.24(c)(2), the initial certification must be obtained as soon as possible after the plan is established by a PT, OT, or SLP. In Pub. 100–02, chapter 15, section 220.1.3 for Certification and Recertification of Need for Treatment and Therapy Plans of Care, we specify that the physician or nonphysician practitioner (NPP) must sign the initial plan of care (POC) with a dated signature or verbal order within 30 days from the first day of treatment, including evaluation (or 14 days if a verbal order), in order for the PT, OT, or SLP to be paid for the services. For this reason, the manual also states that the therapist should forward the treatment plan to the physician/NPP as soon as it is established rather than waiting to do so. The manual allows for a delayed certification when the physician or NPP completes certification and includes a reason for the delay, and delayed certifications are accepted without justification up to 30 days after the due date.

The regulations at § 424.24(c)(4) require recertification at least every 90 days, and the plan or other documentation in the patient's medical record must indicate the continuing need for physical therapy, occupational therapy, or speech-language pathology services. The physician, nurse practitioner, clinical nurse specialist, or physician assistant who reviews the plan must recertify the plan by signing the medical record. Pub. 100–02, chapter 15, section 220.1.4.C clarifies that payment and coverage conditions require that the plan of care be reviewed as often as necessary but at least whenever it is certified or recertified, in order to meet the certification requirements. We explained in the CY 2008 PFS final rule, when changing the plan of care recertification interval from 30 to 90 days, this was done in order to allow more flexibility to the physician/NPP to order the appropriate amount of therapy for each patient's needs (72 FR 66333). Thus, a physician or non-physician practitioner (NPP) may certify or recertify a plan of care at an interval the physician or NPP determines is appropriate, as long as the amount of time between each recertification does not exceed 90 calendar days. As many episodes of therapy treatment are completed in less than 30 calendar days, we expect that physicians and NPPs will continue to certify plans of care that appropriately estimate the duration of needed therapy treatment for a patient, even if the duration is less than 90 days.

Over the past two years, representatives of several therapy-related organizations have requested that CMS reduce the administrative burden involved with attempting to obtain signed plans of treatment from the physician/NPP. They expressed concern that therapists are held accountable for the action or inaction of physicians/NPPs who may be overwhelmed with paperwork. These interested parties report that therapists make exhaustive efforts to obtain the physician/NPP's signature—some reporting that they contact physician offices (via phone, email, or fax, etc.) more than 30 times. Without the required signature, the therapist will not meet the conditions to be paid for the services they deliver. These interested parties recommend that payment for therapy services should be determined by the medical necessity of the service and whether the therapist has met their statutory and regulatory requirements. Some of these interested parties have noted that Pub. 100–02, chapter 15, section 220.1.1, states that the physician/NPP order provides evidence that the patient is under the care of a physician and that the services are medically necessary. Interested parties told us that while CMS allows treatment to begin before the physician's/NPP's signature is obtained, PTs, OTs, and SLPs in private practice do so at their own risk, knowing that they might not be paid for the services if the physician's office does not send back the signed plan of treatment. Accordingly, such interested parties have said that care is delayed while awaiting a physician's signature, which could place the beneficiary's health at risk due to the delay in obtaining outpatient therapy services.

While we do not require an order or referral for a Medicare patient to see a PT, OT, or SLP, we have explained that the presence of a signed order from the treating physician satisfies statutory requirements that therapy is/was medically necessary and the patient is/was under the care of a physician (Pub. 100–02, chapter 15, section 220.1.1). However, with this order documented in the medical record, after the therapist evaluates the patient and establishes the plan of treatment, based on the evaluation's findings, the therapist forwards the patient's plan of treatment back to the referring physician/NPP to obtain a dated signature for the same patient with the same diagnosis to meet coverage and payment conditions to satisfy the initial certification requirement—creating an administrative burden for both the physician/NPP and the therapist. Interested parties have reported to us that most patients seeking outpatient therapy services have written orders from their physician, not to be confused with a written plan of treatment. These interested parties have suggested that we amend the regulation

at § 424.24(c) to permit the presumption of a physician/NPP signature for purposes of certification and recertification in cases where a signed written order or referral from the patient's physician/NPP is on file and there is written documentation in the patient's medical record to substantiate the method and date (such as a fax, email, etc.) that the therapist forwarded the plan of care to the physician/NPP.

Additionally, interested parties representing all therapy disciplines requested that CMS allot time for plan of treatment changes. Interested parties requested that when a physician/NPP orders the therapy services, the physician/NPP be allotted ten business days to modify the plan of treatment by contacting the therapist directly after receiving it from the therapist. For patients without a physician/NPP order, interested parties requested that physician/NPPs be given 30 days after receipt of the plan of treatment to modify the treatment plan.

After reviewing our current regulatory requirements and considering the suggestions of interested parties, we believe it would be appropriate to propose to amend the regulation at § 424.24(c) for those cases when a patient has a signed and dated order/referral from a physician/NPP for outpatient therapy services. Since our policy has been to accept the physician or NPP's signature on the plan of treatment to be their certification of the treatment plan's conditions in the content requirements of § 424.24(c)(1)—that the patient needs or needed physical therapy, occupational therapy or speech-language pathology services, the services were furnished while the individual was under the care of a physician, NP, PA, or CNS, and the services were furnished under a plan of treatment that meets the requirements of § 410.61—we propose that a signed and dated order/referral from a physician/NPP combined with documentation of such order/referral in the patient's medical record along with further evidence in the medical record that the therapy plan of treatment was transmitted/submitted to the ordering/referring physician or NPP is sufficient to demonstrate the physician or NPP's certification of these required conditions. Rather than characterizing this proposal as a ''presumption,'' we are taking the view that when the patient's medical record includes a signed and dated written order or referral indicating the type of therapy needed, CMS (and our contractors) would treat the signature on the order or referral as equivalent to a signature on the plan of treatment. We believe our proposal would be reflective of the intent of the ordering/referring physician/NPP when that order/referral is on file in the patient's medical record. We further believe that this would still be consistent with the initial certification required under section 1835(a) of the Act for providers of therapy services and our current policy for therapy in the private practice setting. When the ordering/referring physician writes the referral for the type of therapy services they determine their patient needs or needed, they also review the treatment plan the therapist established at the time it is forwarded to them, and they verify that the services are or were furnished while the patient is or was under their care. As such, we propose to carve out an exception to the physician signature requirement at § 424.24(c) by adding a new paragraph (c)(5). The proposed policy would be an exception to the physician signature requirement for purposes of an initial certification in cases where a signed and dated order/referral from a physician, NP, PA, or CNS is on file and the therapist has documented evidence that the plan of treatment has been delivered to the physician, NP, PA, or CNS within 30 days of completion of the initial evaluation. However, at this time, we are not proposing and do not intend to establish an exception to the signature requirement for purposes of recertification of the therapy plan of treatment. We believe that physicians and NPPs should still be required to sign a patient's medical record to recertify their therapy treatment plans, in accordance with § 424.24(c)(4), to ensure that a patient does not receive unlimited therapy services without a treatment plan signed and dated by the patient's physician/NPP.

Under our proposal, CMS or its contractors would be able to treat the physician/NPP signature on the order or referral as equivalent to a signature on the plan of treatment for purposes of the initial certification if that physician/NPP has not signed and returned the patient's plan of treatment to the therapist within 30 days of the initial evaluation, but only in cases where the patient's physician/NPP has signed and dated the written order or referral and indicated the type of therapy needed, and that written order or referral is on file in the medical record. This proposed policy would not affect a contractor's ability or authority to determine whether therapy services are reasonable and necessary for a given beneficiary. Lastly, because there is no requirement for a physician/NPP order or referral for patients to obtain outpatient therapy services, we propose to make clear in proposed § 424.24(c)(5) that the references to an order or referral in § 424.24(c)(5) shall not be construed to require an order or referral for outpatient physical therapy, occupational therapy, or speech-language pathology services. We welcome comments on this proposal.

In addition, we are soliciting comments to gather more information about the need for a regulation that would address the amount of time for changes to plans of treatment. Our regulations at 42 CFR 410.61(d), which are further clarified in our manual provisions in Pub. 100–02, chapter 15, section 220.1.2.C, currently allow for changes to the treatment plan by the physician/NPP without time restrictions. Interested parties have suggested that CMS allow physicians/NPPs to have just ten business days from the date of receipt of a plan of care to modify that plan of care (in the case of a patient with an order for the therapy services). Additionally, we are also soliciting comment as to whether there should be a 90 calendar day time limit on the order/referral for outpatient therapy services in cases where the order/referral is intended to be used in relation to the proposed regulatory amendment for the initial certification of the treatment plan at § 424.24(c)(5) discussed above—that 90-day limit would span from the order/referral date until the initial treatment of the patient, including the evaluation furnished by the PT, OT, or SLP. We also seek feedback about whether this limit, or one of a different duration, should be incorporated into the regulatory provision we proposed above for § 424.24(c)(5).

We want to clarify that we are not proposing to amend § 424.27 for CORF physical therapy, occupational therapy, and speech-language pathology treatment plans to align with our proposed amendments at § 424.24 because section 1861(cc) of the Act and regulation at 42 CFR 410.105(c) require these treatment plans to be established by a physician.

We are soliciting comments on these proposals and comment solicitations.

3. KX Modifier Thresholds

The KX modifier thresholds were established through section 50202 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, February 9, 2018) (BBA) and were formerly referred to as the therapy cap amounts. These per-beneficiary amounts under section 1833(g) of the Act (as amended by section 4541 of the Balanced Budget Act of 1997) (Pub. L. 105–33, August 5, 1997) are updated

each year based on the percentage increase in the Medicare Economic Index (MEI). Specifically, these amounts are calculated by updating the previous year's amount by the percentage increase in the MEI for the upcoming calendar year and rounding to the nearest $10.00. Thus, for CY 2025, we propose to increase the CY 2024 KX modifier threshold amount by the most recent forecast of the 2017-based MEI. For CY 2025, the proposed MEI increase is estimated to be 3.6 percent and is based on the expected historical percentage increase of the 2017-based MEI. Multiplying the CY 2024 KX modifier threshold amount of $2,330 by the proposed CY 2025 percentage increase in the MEI of 3.6 percent ($2,330 × 1.036) and rounding to the nearest $10.00 results in a proposed CY 2025 KX modifier threshold amount of $2,410 for physical therapy and speech-language pathology services combined and $2,410 for occupational therapy services. We propose to update the MEI increase for CY 2025 based on historical data through the second quarter of 2024, and we would use such data, if appropriate, to determine the final MEI percentage increase and the CY 2025 KX modifier threshold amounts in the CY 2025 PFS final rule.

Section 1833(g)(7)(B) of the Act describes the targeted medical review (MR) process for services of physical therapy, speech-language pathology, and occupational therapy services. The threshold for targeted MR is $3,000 through CY 2027. Effective beginning with CY 2028, the MR threshold levels would be annually updated by the percentage increase in the MEI, per section 1833(g)(7)(B) of the Act. Consequently, for CY 2025, the MR threshold is $3,000 for physical therapy and speech-language pathology services combined and $3,000 for occupational therapy services. Section 1833(g)(5)(E) of the Act states that CMS shall identify and conduct targeted medical review using factors that may include the following:

(1) The therapy provider has had a high claims denial percentage for therapy services under this part or is less compliant with applicable requirements under this title.

(2) The therapy provider has a billing pattern for therapy services under this part that is aberrant compared to peers or otherwise has questionable billing practices for such services, such as billing medically unlikely units of services in a day.

(3) The therapy provider is newly enrolled under this title or has not previously furnished therapy services under this part.

(4) The services are furnished to treat a type of medical condition.

(5) The therapy provider is part of a group that includes another therapy provider identified using the factors described previously in this section.

We track each beneficiary's incurred expenses for therapy services annually and count them towards the KX modifier and MR thresholds by applying the PFS rate for each service less any applicable MPPR amount for services of CMS-designated ''always therapy'' services (see the CY 2011 PFS final rule at 75 FR 73236). We also track therapy services furnished by critical access hospitals (CAHs), applying the same PFS-rate accrual process, even though they are not paid for their therapy services under the PFS and may be paid on a cost basis (effective January 1, 2014) (see the CY 2014 PFS final rule at 78 FR 74406 through 74410).

When the beneficiary's incurred expenses for the year for outpatient therapy services exceed one or both of the KX modifier thresholds, therapy suppliers and providers use the KX modifier on claims for subsequent medically necessary services. Using the KX modifier, the therapist and therapy provider attest that the services above the KX modifier thresholds are reasonable and necessary and that documentation of the medical necessity for the services is in the beneficiary's medical record. Claims for outpatient therapy services exceeding the KX modifier thresholds without the KX modifier included are denied.

I. Advancing Access to Behavioral Health Services

1. Safety Planning Interventions and Post-Discharge Telephonic Follow-up Contacts

a. Background

In the CY 2024 PFS proposed rule, we sought comment on whether there is a need for potential separate coding and payment for interventions initiated or furnished in the emergency department (ED) or other crisis settings for patients with suicidality or at risk of suicide, such as safety planning interventions and/or telephonic post-discharge follow-up contacts after an emergency department visit or crisis encounter, or whether existing payment mechanisms are sufficient to support furnishing such interventions when indicated. Several commenters encouraged CMS to enable wider implementation under Medicare of the Safety Planning Intervention (SPI) and the Post-Discharge Telephonic Follow-up Contacts Intervention (FCI) and expressed that the current payment mechanisms are not sufficient, noting that the lack of adequate payment mechanisms and suitable billing codes for these interventions are barriers that are essential to address. The commenters noted that EDs are not the only care setting where there is need and opportunity to enhance suicide prevention, but that elevated suicide risk is particularly prevalent among ED patients. One commenter noted that a designated code for SPI would make it significantly easier to document that SPI was furnished, including in quality reporting and value-based payment programs.

More than 49,000 people died by suicide in 2022 and death by suicide is growing significantly in older adults, who comprise most of the Medicare population. We recognize data showing that suicide by intentional overdose is a growing concern, particularly among young people, older people, and Black women, although researchers acknowledge the complexities of distinguishing intentional from unintentional death.[143]

b. Safety Planning Interventions (SPI)

Safety planning interventions involve a patient working with a clinician to develop a personalized list of coping strategies and sources of support that the person can use in the event of experiencing thoughts of harm to themselves or others. This is not a suicide risk assessment, but rather, an intervention provided to people determined to have elevated risk. Safety planning interventions have also been used to reduce the risk of overdose. The basic components of a safety plan include the following: (1) recognizing warning signs of an impending suicidal crisis or actions that increase the risk of suicide; (2) employing internal coping strategies; (3) utilizing social contacts and social settings as a means of distraction from suicidal thoughts and/or taking steps to reduce the risk of suicide; (4) utilizing family members, significant others, caregivers, and/or friends to help resolve the crisis; (5) contacting mental health professionals, crisis services, or agencies; and (6) making the environment safe, including restricting access to lethal means, as applicable.[144] One important aspect of making an environment safe could be,

[143] *https://www.nih.gov/news-events/news-releases/suicides-drug-overdose-increased-among-young-people-elderly-people-black-women-despite-overall-downward-tren.*

[144] Barbara Stanley, Gregory K. Brown, Safety Planning Intervention: A Brief Intervention to Mitigate Suicide Risk, Cognitive and Behavioral Practice, Volume 19, Issue 2, 2012, Pages 256–264, ISSN 1077–7229, *https://doi.org/10.1016/j.cbpra.2011.01.001.*

for example, addressing a person's access to lethal means, such as firearms.

We understand that safety planning is consistent with current practice standards and that many hospitals and clinicians in other settings are already providing some or all of these services to the people who need them, including through the Department of Veterans Affairs (VA).[145] [146] However, in one survey of EDs, only 15.3 percent could confirm routinely implementing safety planning with all of the structured elements mentioned above. Provision of individual safety planning elements ranged from 24.8 percent (n = 492) to 79.2 percent (n = 1710), with 2 of 6 elements being routinely provided more than 50 percent of the time: lists of professionals or agencies to contact in a crisis (1710 [79.2 percent]) and helping patients to recognize warning signs of suicide (1075 [52.2 percent]).[147] Suicide risk among people with substance use disorders who also are at high risk for or may have experienced an intentional overdose is not well recognized.[148]

Therefore, we are proposing to establish separate coding and payment under the PFS describing safety planning interventions. Specifically, we are proposing to create an add-on G-code that would be billed along with an E/M visit or psychotherapy when safety planning interventions are personally performed by the billing practitioner in a variety of settings. We recognize that training and expertise are needed to perform these interventions safely and appropriately and are seeking comment regarding whether clinical staff who meet the definition of auxiliary personnel defined at 42 CFR 410.26(a)(1) or who are employed by a hospital could participate in furnishing this service under the supervision of the billing practitioner in certain settings with the relevant training needed to perform the service as well as what sort of training would be needed.

The proposed G-code is HCPCS code GSPI1: *Safety planning interventions, including assisting the patient in the identification of the following personalized elements of a safety plan: recognizing warning signs of an impending suicidal crisis; employing internal coping strategies; utilizing social contacts and social settings as a means of distraction from suicidal thoughts; utilizing family members, significant others, caregivers, and/or friends to help resolve the crisis; contacting mental health professionals or agencies; and making the environment safe; (List separately in addition to an E/M visit or psychotherapy).* We welcome comments on the proposed elements of the safety planning code.

We are proposing to value HCPCS code GSPI1 based on the valuation for CPT code 90839 (*Psychotherapy for crisis*), which describes 60 minutes, and which we believe describes a similar level of intensity as HCPCS code GSPI1. For HCPCS code GSPI1, we are assuming a typical time of 20 minutes, resulting in a proposed work RVU of 1.09 (based on one third of the work value currently assigned to CPT code 90839, which is 3.28). We welcome comments on whether 20 minutes accurately captures the typical amount of time spent with a patient on safety planning interventions, including all six elements enumerated in this section. Additionally, we welcome comments on whether these interventions typically occur in the context of an encounter, such as an E/M visit or psychotherapy, or whether there may be times when they may be furnished as a standalone service and whether we should consider allowing this code to be billed on its own. We also welcome comments regarding which clinician types might be most likely to bill such a code on its own.

c. Post-Discharge Telephonic Follow-Up Contacts Intervention (FCI)

Some research suggests that patients seen in the ED with deliberate self-harm, intentional overdose, and/or suicidal ideation have been associated with substantially increased risk of suicide and other mortality during the year following their visit to the ED.[149] FCI is a specific protocol of services for individuals with suicide risk involving a series of telephone contacts between a provider and patient in the weeks and sometimes months following discharge from the emergency department and other relevant care settings, that occurs when the person is in the community and is designed to reduce the risk for subsequent adverse outcomes. FCI calls are typically 10–20 minutes in duration and aim to encourage use of the Safety Plan (as needed in a crisis) and updating it to optimize effectiveness, expressing psychosocial support, and helping to facilitate engagement in any indicated follow-up care and services. We note that this service would not be within the scope of Medicare telehealth services and not subject to the restrictions described in Section 1834(m) because these services are specifically structured to be delivered via audio-only phone calls and are not a substitute for an in-person service.

In a recent study led by the Joint Commission, which surveyed a national sample of hospitals to assess the prevalence of SPI and several other recommended suicide prevention services, fewer than half of responding hospitals reported furnishing any post-discharge follow-up contacts. Of these, only 33 percent (16 percent of responding hospitals overall) reported reaching discharged patients ''most of the time.'' Further, among hospitals that furnish follow-up contacts, fewer than half reported covering any of the main aims of FCI, for example, 41 percent review the Safety Plan, 49 percent provide psychosocial support, and 38 percent facilitate outpatient care.[150]

However, some studies have demonstrated that SPI and other services may be able to reduce suicidal behaviors. For example, in the ED–SAFE trial for emergency department (ED) patients identified with elevated suicide risk, the intervention included SPI and up to seven post-discharge follow-up calls with the patient ''focused on identifying suicide risk factors, clarifying values and goals, safety and future planning, facilitating treatment engagement/adherence, and facilitating patient-significant other problem-solving.'' [151] In the SAFE VET study [152] of ED patients identified with elevated suicide risk, the intervention included SPI and at least two follow-up calls with patients ''to monitor suicide risk, review and revise the SPI, and

[145] *https://www.mentalhealth.va.gov/docs/vasafetyplancolor.pdf.*

[146] *https://www.mirecc.va.gov/visn19/research/our-research/implementation.asp.*

[147] Bridge JA, Olfson M, Caterino JM, Cullen SW, Diana A, Frankel M, Marcus SC. Emergency Department Management of Deliberate Self-harm: A National Survey. JAMA Psychiatry. 2019 Jun 1;76(6):652–654. *doi: 10.1001/jamapsychiatry.2019.0063.* PMID: 30865243; PMCID: PMC6552299.

[148] Ries RK, Livengood AL, Huh D, et al. Effectiveness of a Suicide Prevention Module for Adults in Substance Use Disorder Treatment: A Stepped-Wedge Cluster-Randomized Clinical Trial. *JAMA Netw Open.* 2022;5(4):e222945. *doi:10.1001/jamanetworkopen.2022.2945.*

[149] Goldman-Mellor S, Olfson M, Lidon-Moyano C, Schoenbaum M. Association of Suicide and Other Mortality With Emergency Department Presentation. JAMA Netw Open. 2019 Dec 2;2(12):e1917571. *doi: 10.1001/jamanetworkopen.2019.17571.* PMID: 31834399; PMCID: PMC6991205.

[150] *https://www.sciencedirect.com/science/article/pii/S1553725024000679?via%3Dihub.*

[151] Miller IW, Camargo CA Jr, Arias SA, Sullivan AF, Allen MH, Goldstein AB, Manton AP, Espinola JA, Jones R, Hasegawa K, Boudreaux ED; ED–SAFE Investigators. Suicide Prevention in an Emergency Department Population: The ED–SAFE Study. JAMA Psychiatry. 2017 Jun 1;74(6):563–570. doi: 10.1001/jamapsychiatry.2017.0678. PMID: 28456130; PMCID: PMC5539839.

[152] *https://pubmed.ncbi.nlm.nih.gov/29998307/.*

support treatment engagement.'' [153] Each of these studies reported significantly lower suicide behaviors—attempts and/or deaths—among intervention patients compared to the respective control conditions.

In light of this, we are proposing to create a monthly billing code to describe the specific protocols involved in furnishing post-discharge follow-up contacts that are performed in conjunction with a discharge from the emergency department for a crisis encounter, as a bundled service describing four calls in a month, each lasting between 10–20 minutes. The proposed G-code is HCPCS code GFCI1: *Post discharge telephonic follow-up contacts performed in conjunction with a discharge from the emergency department for behavioral health or other crisis encounter, per calendar month.* We seek comment on whether we should consider finalizing a specified duration that HCPCS code GFCI1 could be billed) following discharge, for example, allowing this code to be billed for up to two months following discharge or whether a longer duration would be appropriate, the number of calls per month, the billing structure (for example, four calls for each discharged patient), and any other relevant feedback.

We are proposing to price this service based on a direct crosswalk to CPT code 99426 (*Principal care management; first 30 minutes of clinical staff time directed by a physician or other qualified healthcare professional*), which is assigned a work value of 1.00 work RVUs. Since CPT code 99426 describes care management for a single condition, we believe the work would be similar in nature and intensity. We note that under this proposal, proposed HCPCS code GFCI1 could be billed regardless of whether proposed HCPCS code GSPI1 was also furnished and billed for the same patient. We propose that the billing practitioner would need to meet a threshold of at least one real-time telephone interaction with the patient in order to bill HCPCS code GFCI1, and that unsuccessful attempts to reach the patient would not qualify as a real-time telephone interaction. We welcome comments on this proposed threshold to bill HCPCS code GFCI1, recognizing that while practitioners may attempt to reach the patient, there may be times when the patient cannot be reached. We are also proposing that the billing practitioner could not count time or effort more than once for the purposes of billing this code and another service.

Additionally, as we recognize that behavioral health practitioners, training programs, and institutions have worked conscientiously to have risk assessment and safety planning for high-risk patients integrated into their workflows for many years and that discharge instructions and after visit planning may represent one of many final products from the synthesis of all the steps involved in these encounters, we note that we do not intend to unnecessarily disaggregate aspects of streamlined clinical workflows that providers are successfully using to treat high risk patients. Moreover, we also recognize that practitioners may currently be billing for safety planning activities using existing coding, such as E/M visits, psychotherapy, and crisis management codes or potentially for follow-up calls using existing care management services. However, to the extent that this intervention is part of the standard of care, we believe that Medicare payment should accurately reflect the additional resource costs involved in furnishing this service.

Lastly, as applicable Part B cost sharing would apply for HCPCS code GFCI1, we are proposing to require the treating practitioner to obtain verbal (or written) beneficiary consent in advance of furnishing the services described by GFCI1, which would be documented by the treating practitioner in the medical record, similar to the conditions of payment associated with care management and other non-face-to-face services paid under the PFS. We note that under this proposal, obtaining advance consent would include: (1) ensuring that the patient is aware that Medicare cost sharing applies to these services; (2) furnishing and receiving the necessary information to enable the patient to receive these services (for example, obtaining the patient's telephone number(s)); and (3) confirming that the patient consents to the contacts.

2. Digital Mental Health Treatment (DMHT)

We are proposing Medicare payment to billing practitioners for digital mental health treatment (DMHT) devices furnished incident to or integral to professional behavioral health services used in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care. We are refining the digital cognitive behavioral therapy ''digital CBT'' terminology that we have used previously (88 FR 52262, 52370 through 52371, 88 FR 78818, 79012 and 79013). We are proposing Medicare payment to billing practitioners for digital mental health treatment (DMHT) devices furnished incident to or integral to professional behavioral health services used in conjunction with ongoing. In this proposed rule we use the term ''digital mental health treatment (DMHT) device'' to include the term ''digital CBT'' we used in prior rulemaking and in general to refer to software devices cleared by the Food and Drug Administration (FDA) that are intended to treat or alleviate a mental health condition, in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care, by generating and delivering a mental health treatment intervention that has a demonstrable positive therapeutic impact on a patient's health. We note first that the *Diagnostic and Statistical Manual of Mental Disorders-5 (DSM)* does not refer to psychiatric disorders but to mental disorders. In this section, following the DSM, we use the term behavioral health conditions and mental disorders interchangeably and to mean psychiatric disorders as referenced in FDA regulation, 21 CFR 882.5801. Second, we note that FDA guidance refers to computerized behavioral therapy by the acronym CBT. We aim to both provide access to vital behavioral health services and gather further information about the delivery of digital behavioral health therapies, their effectiveness, their adoption by practitioners as complements in the care they furnish, and their use by patients for the treatment of behavioral health conditions. We also recognize that there are certain statutory limitations on payment for products under the broader category of ''digital health interventions.'' We acknowledge that the field of digital therapeutics is evolving and are open to feedback from the public on this topic, including the CPT Editorial Panel. Additionally, we recognize that historically, the CPT Editorial Panel has frequently created CPT codes describing services that we originally established using G codes and adopted them through the CPT Editorial Panel process. We note that we would consider using any newly available CPT coding to describe services similar to those described here in future rulemaking.

a. Background

Over the last 5 years the AMA CPT Editorial Panel and CMS have

[153] Stanley B, Brown GK, Brenner LA, Galfalvy HC, Currier GW, Knox KL, Chaudhury SR, Bush AL, Green KL. Comparison of the Safety Planning Intervention With Follow-up vs Usual Care of Suicidal Patients Treated in the Emergency Department. JAMA Psychiatry. 2018 Sep 1;75(9):894–900. doi: 10.1001/jamapsychiatry.2018.1776. PMID: 29998307; PMCID: PMC6142908.

developed coding and separate payment for monitoring physiologic status using software enabled devices that capture and record or transmit data that may be reported to and interpreted by practitioners to manage a patient under a specific treatment plan. (83 FR 59452, 59574) Medicare payment has long been available for practitioner provision of monitoring equipment and other kinds of devices provided incident to or integral to the practitioner's professional services. Most recently we have finalized payment for devices which record data related to signs, symptoms, and functions of a therapeutic response (typically for use in association with physical or occupational therapy care) (86 FR 64996, 65114–65116).

However, technologies that rely primarily on software, licensing, and analysis fees, with minimal costs in equipment and hardware may not have been typical and are not well accounted for in our practice expense (PE) methodology. PE resources involved in furnishing services are characterized as either direct or indirect costs. Direct costs of the PE resources involved in furnishing a service are estimated for each HCPCS code and include clinical labor, medical supplies, and medical equipment. Indirect costs include administrative labor, office expenses, and all other expenses. Indirect PE is allocated to each service based on physician work, direct costs, and a specialty-specific indirect percentage. The source of the specialty specific indirect percentage is the Physician Practice Information Survey (PPIS), last administered in 2007 and 2008, prior to the adoption of digital therapy technologies (86 FR 65037). Nevertheless, in past rulemaking, we have recognized that in some cases practitioners do incur resource costs for the purchase and ongoing use of software (86 FR 65038).

In the CY 2023 PFS final rule, we finalized our proposal to accept the RUC recommendation to contractor price CPT code 98978 (*Remote therapeutic monitoring (e.g., therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor cognitive behavior therapy, each 30 days*), a PE-only device code (86 FR 69523, 69646). At the time, specialty societies indicated that the technologies for this service are still evolving, and that as a result, there were no invoices for devices specific to the cognitive behavioral therapy monitoring services described by the code that could be shared. There was no professional work associated with the code.

In the CY 2024 PFS proposed rule, we requested information on digital therapeutics for behavioral health. Among many questions, we asked how practitioners determine which patients might be best served by digital therapeutics and how practitioners monitor the effectiveness of prescribed interventions on an ongoing basis once the intervention has begun. We also asked how the treating clinician was involved in the services received. We asked what scientific and clinical evidence of effectiveness CMS should consider when determining whether digital therapeutics for behavioral health, including care for substance use disorders, depression, sleep disorders and other conditions are reasonable and necessary. We asked whether DMHT devices were used as incident to supplies or independent of a patient visit with a practitioner and if practitioners in such cases issued an order for such devices (88 FR 52262, 52370 through 52371). These factors related to the nature of this treatment compared to other PFS services pose challenges for fitting DMHT services into the existing benefit structure under the PFS.

Setting appropriate pricing under the PFS has also presented challenges. As noted previously, technologies that rely primarily on software, licensing, and analysis fees, with minimal costs in equipment and hardware are not well accounted for in our practice expense (PE) methodology, even though these items may be appropriately considered practice expenses. Consequently, over the past several years, we have relied on a crosswalk methodology to approximate relative resource costs for these kinds of services relative to other PFS services, or contractor pricing.

Interested parties requested that we adopt coding specifically for DMHT devices, where the digital software device is the actual therapy/intervention (the algorithm software is the DMHT) as opposed to a therapeutic monitoring device that transmits patient data as described by CPT code 98978 for which we finalized contractor pricing in CY 2023. Interested parties have also asked us to set national pricing for the service to supply the DMHT device and education/onboarding that reflects the direct practice expense incurred by practitioners when furnishing DMHT. One of the interested parties submitted invoices to provide data we could use as the basis to set payments for DMHT coding. The interested party submitted four invoices reflecting considerable variation in the cost of the DMHT treatment over 30-day and 90-day periods. There is still more variation in pricing for comparable products that are available for considerably lower prices in various markets, with prices ranging from free to $140 per year, based on an online search (*https://www.carepatron.com/app/cbt-therapy-apps*, accessed March 20, 2024).

As the field of innovative products including digital therapeutics and computerized behavioral therapy devices for psychiatric or mental disorders develops and expands, the FDA and Substance Abuse and Mental Health Services Administration (SAMHSA) among other agencies such as the Veterans Health Administration (VHA) are also monitoring the development of the field of digital therapeutic devices, including for behavioral health purposes. For example, VHA is providing digital behavioral health applications as self-help tools, not independent treatment interventions. The FDA has a regulatory framework, discussed below in this section, to classify devices and review computerized behavioral therapy devices for psychiatric disorders.

b. Payment for Digital Mental Health Treatment (DMHT) Devices

We recognize that digital therapeutics may offer innovative means to access certain behavioral health care services. The FDA definition of devices encompasses software intended by the manufacturer to be used, alone or in combination for the specific medical purpose of diagnosis, prevention monitoring treatment or alleviation of disease and does not achieve its primary intended action by pharmacological, immunological or metabolic means.[154] SAMHSA has defined digital therapeutics (DTx) in the behavioral health context as ''health software intended to treat or alleviate a disease, disorder, condition, or injury by generating and delivering a medical intervention that has a demonstrable positive therapeutic impact on a patient's health.'' [155] SAMHSA also notes that ''DTx may be used independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes.'' Given nationwide behavioral health workforce shortages combined with increasing demand for behavioral health care services, some Medicare beneficiaries may have limited

[154] *https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf.*

[155] *https://store.samhsa.gov/product/advisory-digital-therapeutics-management-and-treatment-behavioral-health/pep23-06-00-001.*

access to these services.[156] This proposal encompasses only part of what may be a spectrum of broadly similar products, most of which might require a new statutory Medicare benefit category. Our proposed coding and payment policy only applies to DMHT devices that have been cleared by the FDA. Many digital platforms and applications are marketed as behavioral health and wellness interventions; this proposal does not extend to such platforms and applications in part because other than some DTx, few have evidence demonstrating improved behavioral health outcomes.[157]

We propose to create three new HCPCS codes for DMHT devices modeled on coding for RTM services. Effective beginning in CY 2025, we propose that physicians and practitioners who are authorized to furnish services for the diagnosis and treatment of mental illness would be able to bill a new HCPCS code: GMBT1 (*Supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan*) for furnishing a DMHT device. GMBT1 would be payable only if the DMHT device has been FDA cleared and the billing practitioner is incurring the cost of furnishing the DMHT device to the beneficiary. Furnishing of the DMHT device must be incident to the billing practitioner's professional services in association with ongoing treatment under a plan of care by the billing practitioner. The billing practitioner must diagnose the patient and prescribe or order the DMHT device. The patient could then use the DMHT device at home or perhaps in an office or other outpatient setting, if that is how the device has been cleared by FDA for use under 21 CFR 882.5801. The DMHT device furnished must have demonstrated a reasonable assurance of safety and effectiveness. The FDA makes a determination of safety and effectiveness under 21 CFR 860.7. When making this determination, the FDA will consider a variety of factors including users, conditions of use, probable benefit to health weighed against probable injury, and reliability. The regulation at 21 CFR 860.7, states that ''[t]here is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks.'' GMBT1 would not be payable in cases where the billing practitioner incurs no cost in acquiring and furnishing the DMHT device, or a patient procures the DMHT device independent of the practitioner. We will continue to monitor how DMHT devices are used as part of overall care.

We seek comment about other parameters that we should consider regarding the services described by GMBT1:

- Whether payment should be made if the practitioner furnishes a digital device that has not been cleared by FDA for mental health treatment for a specific use, even if the digital device has been cleared by the FDA for another specific use;
- Whether payment should be made for DMHT devices cleared by the FDA not only under 21 CFR 882.5801 but also under other regulations;
- Whether and how payment might be limited if a patient discontinues use of the DMHT device before completing a course of treatment; and
- Whether and how payment might be limited to a set number of DMHT devices per calendar month per patient.

In light of the pricing variability, as discussed above, we are proposing contractor pricing for code GMBT1. We seek comment regarding what national pricing methodology we might consider, including what potential crosswalks would be appropriate.

We are also proposing to establish payment for two additional new codes. These proposed codes are GMBT2 (*First 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing data generated from the DMHT device from patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month*) and GMBT3 (*Each additional 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing data generated from the DMHT device from patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month*). Under this proposal, GMBT1 requires that the billing practitioner who diagnosed the patient and prescribed or ordered the DMHT device or that billing practitioner's clinical staff must monitor the patient's therapeutic response to the DMHT device and adjust the behavioral health therapy plan as needed. GMBT2 and GMBT3 should only be billed when there is ongoing use of the DMHT device and should not be billed in cases where the patient discontinues use of the DMHT device.

For GMBT2 (first 20 minutes of monthly treatment management services directly related to use of the DMHT device), we propose valuing the first 20 minutes of treatment management services based on a direct crosswalk to CPT code 98980 (remote therapeutic monitoring first 20 minutes), which is assigned a work RVU of .62. For GMBT3 (each additional 20 minutes of monthly treatment management services directly related to DMHT device), we propose to value this code based on a crosswalk to CPT code 98981 (remote therapeutic monitoring each additional 20 minutes), which is assigned a work RVU of .61. We believe that the work and PE described by these crosswalk codes are analogous to the services described in GMBT2 and GMBT3, respectively, because they include similar physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month. We welcome comments on the proposed RVUs.

3. Interprofessional Consultation Billed by Practitioners Authorized by Statute To Treat Behavioral Health Conditions

a. Background

In the CY 2019 PFS final rule (83 FR 59489), we finalized payment for six CPT codes regarding interprofessional consultations (99451, 99452, 99446, 99447, 99448, 99449). The six codes describe assessment and management services conducted through telephone, internet, or electronic health record consultations furnished when a patient's treating physician or other qualified healthcare professional requests the opinion and/or treatment advice of a consulting physician or qualified healthcare professional with specific specialty expertise to assist with the diagnosis and/or management of the patient's condition without the need for the patient's face-to-face contact with the consulting physician or qualified healthcare professional. We established coding and payment for

[156] *https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/behavioral-health-2013-2025.pdf.*

[157] *https://store.samhsa.gov/product/advisory-digital-therapeutics-management-and-treatment-behavioral-health/pep23-06-00-001.*

these services to reflect changing healthcare practices, technology, and the shift to treatment of chronic conditions in the Medicare population. In the CY 2019 PFS final rule (83 FR 59491), we established a policy to limit billing of these codes to the types of practitioners who can independently bill Medicare for E/M visits. We did not finalize the expansion of practitioners beyond those who can furnish E/M visits in the CY 2019 PFS final rule due to our belief that interprofessional consultations are primarily for the ongoing evaluation and management of the patient, including collaborative medical decision making among practitioners (83 FR 59491).

In the CY 2024 PFS proposed rule (88 FR 52369), we sought comment on expanding access to behavioral health services, including whether we should consider new coding to allow interprofessional consultation to be billed by practitioners in specialties whose covered services are limited by statute (Clinical psychologists at section 1861(ii) of the Act, Clinical social workers at section1861(hh) of the Act, Marriage and Family Therapists and Mental Health Counselors at sections 1861(lll)(1) and 1861(lll)(3) of the Act, respectively) to services for the diagnosis and treatment of mental illness (which includes substance use disorders). The CPT codes describing interprofessional consultation (CPT codes 99451, 99452, 99446, 99447, 99448, 99449) are currently limited to being billed by practitioners who can independently bill Medicare for E/M visits. As such, they cannot be billed by clinical psychologists, clinical social workers, marriage and family therapists, or mental health counselors because these practitioners cannot independently bill Medicare for E/M visits. We are proposing new codes that would allow clinical psychologists, clinical social workers, marriage and family therapists, and mental health counselors to bill for interprofessional consultations with other practitioners whose practice is similarly limited, as well as with physicians and practitioners who can bill Medicare for E/M services and would use the current CPT codes to bill for interpersonal consultations. These new codes would facilitate interprofessional consultations between treating/requesting practitioners and consultant practitioners, whether one or both of the practitioners is in a specialty whose practice is limited to the diagnosis and treatment of mental illness. When the treating/requesting practitioner or consultant practitioner is a physician or practitioner authorized to bill Medicare for E/M services, the practitioner would continue to bill using the current CPT codes that describe interprofessional consultation, listed previously in this section. Depending on which practitioner type is billing, and assuming all service requirements of the code descriptors are met, the consulting practitioner could bill the applicable codes, either HCPCS code (GIPC1–5) or CPT code (99451, 99452, 99446, 99447), determined by the amount of time spent on the consultation and whether a written and verbal consultation is provided or only a written consultation is provided. Similarly, depending on which practitioner type is billing, and assuming all service requirements of the code descriptors are met, the treating/requesting practitioner could bill either HCPCS code GIPC6 or CPT code 99449 for the time spent on their referral service.

We believe that proposing payment for these interprofessional consultations performed via communications technology such as telephone or internet (including videoconference) is consistent with our ongoing efforts to appropriately recognize and reflect behavioral health care within the PFS. Currently, there is no payment mechanism to recognize the time and effort of performing these services by clinical psychologists, clinical social workers, marriage and family therapists, or mental health counselors. We have also previously received comments from interested parties that by not making separate payment for these services, CMS would not be accurately paying for the work of both the treating and consulting practitioner in a consultative scenario. With the proliferation of team-based approaches to care that are often facilitated by electronic medical record technology, we believe that making separate payment for interprofessional consultations undertaken for the benefit of treating a patient will contribute to payment accuracy under the PFS for behavioral health services.

b. Coding

To further expand access to behavioral health services, we are proposing payment for six new G codes: GIPC1 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a verbal and written report to the patient's treating/requesting practitioner; 5–10 minutes of medical consultative discussion and review*), GIPC2 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a verbal and written report to the patient's treating/requesting practitioner; 11–20 minutes of medical consultative discussion and review*), GIPC3 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a verbal and written report to the patient's treating/requesting practitioner; 21–30 minutes of medical consultative discussion and review*), GIPC4 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a verbal and written report to the patient's treating/requesting practitioner; 31 or more minutes of medical consultative discussion and review*), GIPC5 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a written report to the patient's treating/requesting practitioner, 5 minutes or more of medical consultative time*), and GIPC6 (*Interprofessional telephone/internet/electronic health record referral service(s) provided by a treating/requesting practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, 30 minutes*). We welcome comments on this proposal.

Additionally, since these codes describe services that are furnished by the treating/requesting practitioner and the consultant practitioner without the involvement of the patient, we are proposing to require the treating practitioner to obtain the patient's consent in advance of these services, which would be documented by the treating practitioner in the medical record, similar to the conditions of payment associated with the CPT interprofessional consultation codes and certain other non-face-to-face services paid under the PFS. Obtaining advance patient consent includes ensuring that

the patient is aware that Medicare cost sharing applies to these services, including informing the patient that there may be cost sharing for two services (one for the treating/requesting practitioner's service and another for the consultant practitioner's service). We welcome comments on this proposal.

c. Valuation

We are proposing to value the six proposed new G codes based on crosswalks to the six CPT codes for interprofessional consultations for practitioners who can independently bill Medicare for E/M visits (CPT codes 99451, 99452, 99446, 99447, 99448, 99449). We are proposing a work RVU of 0.35 for GIPC1 based on a crosswalk to CPT code 99446, a work RVU of 0.70 for GIPC2 based on a crosswalk to CPT code 99447, a work RVU of 1.05 for GIPC3 based on a crosswalk to CPT code 99448), a work RVU of 1.40 for GIPC4 based on a crosswalk to CPT code 99449, a work RVU of 0.70 for GIPC5 based on a crosswalk to CPT code 99451, and a work RVU of 0.70 for GIPC6 based on a crosswalk to 99452. Since there are no direct PE inputs assigned to the six CPT codes describing interprofessional consultation services on which we are basing the proposed valuation for the new HCPCS codes GIPC1 through GIPC6, we are not proposing any direct PE inputs for these codes. We welcome comments on this proposal.

4. Comment Solicitation on Payment for Services Furnished in Additional Settings, Including Freestanding SUD Treatment Facilities, Crisis Stabilization Units, Urgent Care Centers, and Certified Community Behavioral Health Clinics (CCBHCs)

In the CY 2024 OPPS final rule (88 FR 81809 through 81858), we finalized payment for IOP services furnished in hospital outpatient departments (HOPDs), Community Mental Health Centers (CMHCs), Federally Qualified Health Centers (FQHCs), and Rural Health Clinics (RHCs), and Opioid Treatment Programs (OTPs). We note that Section 4124 of the Consolidated Appropriations Act (CAA), 2023, authorized payment for IOP services in HOPDs, CMHCs, FQHCs, RHCs, and that we additionally used existing statutory authority to propose and finalize payment for IOP services furnished in OTPs. CMS is monitoring utilization and uptake of IOP services in these settings. We have heard from other treatment settings that furnish IOP services that do not fall into the categories of HOPDs, CMHCs, FQHCs, RHCs, or OTPs, such as freestanding SUD facilities, that have an interest in billing Medicare for these services. In light of this, we are seeking comment on whether IOP services are furnished in other settings in order to determine whether potential coding and payment for IOP services under the PFS would facilitate these services being billed in additional settings.

In particular, we are interested in feedback on the following questions, as well as any other relevant feedback:

- To what extent do freestanding SUD facilities or other entities that furnish IOP services employ practitioner types who can supervise auxiliary personnel and bill Medicare for their services? For example, do they typically employ physicians, clinical psychologists, nurse practitioners, clinical nurse specialists, certified nurse midwives and physician assistants who are eligible to provide general supervision to auxiliary personnel who furnish behavioral health services?
- Would bundled payments under the PFS similar to those finalized in the CY 2024 OPPS final rule (88 FR 81809–81858) better facilitate billing for IOP services in a broader range of settings?
- If CMS outlined how freestanding SUD facilities could bill Medicare under the PFS, would there be an impact in underserved areas?
- To what extent do freestanding SUD facilities see patients with Medicare or who are dually eligible for Medicare and Medicaid?

Additionally, we are seeking comment on entities that offer community-based crisis stabilization, including 24/7 receiving and short-term stabilization centers, that provide immediate access to voluntary and/or involuntary care, without the need for a referral. Regarding such crisis stabilization units, we are interested in feedback on the following questions, as well as any other relevant feedback:

++ What kind of services do crisis stabilization units provide? Do crisis stabilization units provide services similar to those described by the psychotherapy for crisis codes (CPT codes 90839 and 90840)?

++ Does the definition of crisis stabilization unit vary by State? If so, what are the variations and similarities across States?

++ If CMS outlined how crisis stabilization units could bill Medicare under the PFS, would there be an impact in underserved areas?

++ To what extent do crisis stabilization units see patients with Medicare or who are dually eligible for Medicare and Medicaid?

++ To what extent do crisis stabilization units employ practitioner types who can supervise auxiliary personnel and bill Medicare for their services. For example, do crisis stabilization units typically employ physicians, clinical psychologists, nurse practitioners, clinical nurse specialists, certified nurse midwives and physician assistants who are eligible to provide general to auxiliary personnel who furnish behavioral health services?

Additionally, as a separate example, we've received information from interested parties that there is a similar concern regarding urgent care centers more broadly. These interested parties note that hospital emergency departments are often used by beneficiaries to address non-emergent urgent care needs that could be appropriately served in less acute settings, but where other settings, such as physician offices, urgent care centers or other clinics, are not available or readily accessible. Patients enter EDs to treat common conditions like allergic reactions, lacerations, sprains and fractures, common respiratory illnesses (for example, flu or RSV), and bacterial infections (for example, strep throat, urinary tract infections or foodborne illness). Conditions like these often can be treated in less acute settings. We are interested in system capacity and workforce issues broadly and are interested in hearing more on those issues, including how entities such as urgent care centers can play a role in addressing some of the capacity issues in emergency departments. In particular, we are interested in feedback on the following questions, as well as any other relevant feedback:

- What types of services would alternative settings to EDs need to offer to meet beneficiaries' non-emergent, urgent care needs?
- Does the current ''Urgent Care Facility'' Place of Service code (POS 20) adequately identify and define the scope of services furnished in such settings? Is this place of service code sufficiently distinct from others such as ''Walk-in Retail Health Clinic (POS 17) and ''Office'' (POS 11)? If not, how might these Place of Service code definitions be modified?
- Does the existing code set accurately describe and value services personally performed by professionals and costs incurred by the facility in these settings?
- How might potential strategies to reduce overcrowding and wait times in EDs advance equity in access to health care services?

Lastly, we are seeking comment regarding Certified Community Behavioral Health Clinics (CCBHCs).

Specifically, we are interested in feedback on the following questions:

++ What kind of services do CCBHCs provide? Do they provide IOP services, services for the treatment of substance use disorders, psychotherapy, behavioral health integration, community health integration, or principal illness navigation services to patients with either Medicare or another payer?

++ If CMS outlined how CCBHCs could bill Medicare under the PFS, would there be an impact in underserved areas?

++ To what extent do CCBHCs see patients with Medicare or who are dually eligible for Medicare and Medicaid?

++ To what extent do CCBHCs employ practitioner types who can supervise auxiliary personnel and bill Medicare for their services? For example, do CCBHCs employ physicians, clinical psychologists, nurse practitioners, clinical nurse specialists, certified nurse midwives and physician assistants who are eligible to provide general supervision to auxiliary personnel who furnish behavioral health services?

J. Proposals on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Services

1. Medicare Payment for Dental Services

a. Overview

Section 1862(a)(12) of the Act generally precludes payment under Medicare Parts A or B for any expenses incurred for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. (Collectively here, we will refer to ''the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth'' as ''dental services.'') That section of the statute also includes an exception to allow payment to be made for inpatient hospital services in connection with the provision of such dental services if the individual, because of their underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services. Our regulation at § 411.15(i) similarly excludes payment for dental services except for inpatient hospital services in connection with dental services when hospitalization is required because of: (1) the individual's underlying medical condition and clinical status; or (2) the severity of the dental procedure.

Fee for service (FFS) Medicare Parts A and B also make payment for certain dental services in circumstances where the services are not considered to be in connection with dental services within the meaning of section 1862(a)(12) of the Act. In the CY 2023 PFS final rule (87 FR 69663 through 69688), we clarified and codified at § 411.15(i)(3) that Medicare payment under Parts A and B could be made when dental services are furnished in either the inpatient or outpatient setting when the dental services are inextricably linked to, and substantially related and integral to the clinical success of, other covered services. We also added several examples of clinical scenarios that are considered to meet that standard under § 411.15(i)(3) and amended that regulation to add more examples in the CY 2024 PFS final rule (88 FR 79022 through 79029).

In the CY 2023 PFS final rule, we also established a process whereby we accept and consider submissions from the public (the ''public submission process'') to assist us to identify additional dental services that are inextricably linked to, and substantially related and integral to the clinical success of, other covered services (87 FR 69663 through 69688). Hereafter in this section we will refer to these services as dental services that are ''inextricably linked to other covered services.''

We also note that the examples provided in our regulation at § 411.15(i)(3)(i) are not exclusive. Medicare administrative contractors (MACs) retain discretion to determine on a claim-by-claim basis whether a patient's circumstances do or do not fit within the terms of the preclusion or exceptions specified in section 1862(a)(12) of the Act and § 411.15(i).

In the CY 2024 PFS final rule, we discussed our plans to issue educational and outreach materials to inform billing and payment for finalized policies for dental services. We reiterated our commitment to review submissions we receive through the public submissions process. We also expressed our intention to continue to engage in discussions with the public on a wide spectrum of issues relating to Medicare payment for dental services that may be inextricably linked to other covered services. We also described our partnership with the Agency for Healthcare Research and Quality (AHRQ) to assist us to review available clinical evidence and consider the relationship between dental services and specific covered medical services and to identify other potential clinical circumstances in which dental services are inextricably linked to other covered services (88 FR 79029).

In this proposed rule, we (1) describe recent literature review conducted by our partner agency, AHRQ, on the potential connection between sickle cell disease and hemophilia and dental services; (2) summarize submissions we received through the public submission process for consideration in CY 2025 rulemaking; (3) propose to codify in section § 411.15(i)(3)(i)(A) additional policies to permit payment for certain dental services that are inextricably linked to other covered services (certain dental services for patients receiving dialysis services to treat end-stage renal disease (ESRD)); (4) request public comment and information related to other clinical scenarios that may involve dental services that are inextricably linked to other covered services; and (5) include proposals related to Medicare billing and payment policy for dental services. We also include a request for information regarding oral sleep apnea appliances.

b. Consideration of Dental Services That May Be Inextricably Linked to Other Covered Services

We have partnered with AHRQ to help us consider the relationship between dental services and other specific covered services. Specifically, AHRQ reviews available clinical evidence regarding this relationship, and provides analysis of clinical scenarios where dental services may be inextricably linked to other covered services. To better address the public's immediate dental needs, AHRQ conducted rapid response reports instead of comprehensive assessments. With these rapid response reports, we can better specify which payments can be made under Medicare Parts A and B for certain dental services that are inextricably linked to other covered services.

Through the public submissions process for consideration in CY 2024 rulemaking, interested parties nominated dental services for individuals living with sickle cell disease (SCD) or hemophilia, urging us to consider adding payment for these services (88 FR 52374). The submissions included information and references supporting the inclusion of dental services that are inextricably linked to, and substantially related and integral to the clinical success of, the covered services used in the treatment of SCD or hemophilia, because such dental services serve to mitigate the substantial risk to the success of the medical services. Submissions supported the importance of preventing dental

infections among individuals with SCD to reduce the need for the extensive procedures that may lead to bleeding complications and hospitalization. They also provided information detailing increased dental caries and periodontal disease in people with SCD,[158] many of whom lose a number of teeth, which greatly limits nutrition, general well-being, and overall quality of life. Interested parties recommended that we adopt a policy to allow payment for dental services for individuals with hemophilia (88 FR 79032). They emphasized that periodic dental care reduces the risks of dental complications that may require hemostatic therapy or oral surgeries requiring clotting factor replacement treatment.[159] [160] [161] Many submitters suggested that maintaining good oral health leads to improved outcomes for patients with these two conditions.

Acknowledging the importance of dental health to overall well-being of patients with these two types of diseases, in the CY 2024 proposed rule, we summarized information provided by submitters utilizing the public submission process and solicited comment on whether certain dental services are inextricably linked to covered services in the treatment of SCD (88 FR 52374). In the CY 2024 PFS final rule, we noted that several commenters suggested expanding dental service coverage for individuals with SCD. They supported covering dental services essential for treating SCD, including hydroxyurea therapy. Another commenter advocated for expanding coverage for dental services in cases of pain crises or dental abscesses in individuals with SCD. They emphasized that improved access to dental care could improve the quality of life for individuals with SCD and reduce healthcare costs by enabling more suitable treatment options and decreasing hospital stays. One commenter questioned the clinical basis for providing dental benefits for SCD or hemophilia due to their low prevalence in the Medicare population. Ultimately, after consideration of public comments, we did not expand the examples under § 411.15(i)(3)(i) to include additional covered medical services for SCD. We concluded that the information provided by commenters did not sufficiently demonstrate that dental services are essential to the clinical success of hydroxyurea therapy or other treatments for SCD (88 FR 79032). Please refer to CY 2024 final rule (88 FR 79031 through 79032) for more detailed information.

In the CY 2024 PFS proposed rule, we similarly solicited comments on hemophilia regarding whether certain dental services are considered so integral to the primary covered services that the necessary dental interventions are inextricably linked to, and substantially related and integral to clinical success of, the primary covered services for individuals with hemophilia (88 FR 52382). Several commenters advocated for allowing Medicare Part A and Part B payment for dental services for individuals with hemophilia citing guidelines from Hemophilia Treatment Centers (HTCs), the Centers for Disease Control and Prevention (CDC), and the World Federation of Hemophilia (WFH). They emphasized the importance of good oral health to prevent complications like gum bleeding and major dental surgeries, especially in those with severe/moderate hemophilia. Another commenter supported this perspective, noting that regular dental care reduces the need for clotting factor replacement therapy. While we acknowledged the importance of maintaining oral health to prevent complications such as serious gum bleeding, especially problematic for those with hemophilia, we also reiterated that for the purposes of the PFS payment policy for dental services inextricably linked to covered medical services, our statute and regulations require that specific evidence supports the integral connection between dental services and clinical success in managing hemophilia-related medical services, and, therefore, we did not expand the examples under § 411.15(i)(3)(i) to include additional covered medical services for hemophilia. Please refer to CY 2024 final rule (88 FR 79032 through 79033) for more detailed information.

While interested parties have suggested the interaction of oral health care for SCD or hemophilia, we noted that further research is necessary to find specific evidence supporting specific medical services for which dental services are inextricably linked to their clinical success. To gain further understanding of any potential relationship between dental services and specific covered SCD or hemophilia medical services, we again partnered with researchers at the Agency for Healthcare Research and Quality (AHRQ) to review available clinical evidence regarding the relationship between dental services and covered SCD or hemophilia medical services. AHRQ created two rapid response reports, which summarized recent evidence, aiming to inform CMS policy development related to the possible linkage between dental services and treatment modalities and services for SCD or hemophilia patients. For more detailed information about the search strategies and findings, please refer to the two AHRQ rapid response reports available at *https://effectivehealthcare.ahrq.gov/products/sickle-cell-dental/research* and *https://effectivehealthcare.ahrq.hgov/products/hemophilia-dental/research*.

1. Consideration of Dental Services That May Be Inextricably Linked to Covered Services for the Treatment of Sickle Cell Disease

As stated in the AHRQ rapid response report, SCD is a genetic hematologic disorder affecting approximately 100,000 individuals in the U.S.,[162] characterized by abnormal hemoglobin formation in red blood cells, leading to complications such as pain, infection, acute chest syndrome, and stroke. Hydroxyurea, a commonly used therapeutic measure,[163] which increases fetal hemoglobin levels, which has a higher affinity for oxygen than adult hemoglobin. This therapy can prevent sickling or curvature of red blood cells and help SCD patients. SCD patients can experience dental complications due to

[158] Kakkar M, Holderle K, ShethM, Arany S, Schiff L, Planerova A. Orofacial Manifestation and Dental Management of Sickle Cell Disease: A Scoping Review. Anemia. 2021 Oct 22; 2021:5556708. *Doi: 10.1155/2021/5556708.* PMID: 34721900; PMCID: PMC8556080.

[159] Raso S, Napolitano M, Sirocchi D, Siragusa S, Hermans C. The important impact of dental care on haemostatic treatment burden in patients with mild haemophilia. Haemophilia. 2022 Nov;28(6):996–999. *doi:10.1111/hae.14626.* Epub 2022 Jul 25. PMID: 35879819.

[160] Srivastava A, Santagostino E, Dougall A, Kitchen S, Sutherland M, Pipe SW, Carcao M, Mahlangu J, Ragni MV, Windyga J, Llina´s A, Goddard NJ, Mohan R, Poonnoose PM, Feldman BM, Lewis SZ, van den Berg HM, Pierce GF; WFH Guidelines for the Management of Hemophilia panelists and co-authors. WFH Guidelines for the Management of Hemophilia, 3rd edition. Haemophilia. 2020 Aug;26 Suppl 6:1–158. *doi: 10.1111/hae.14046.* Epub 2020 Aug 3. Erratum in: Haemophilia. 2021 Jul;27(4):699. PMID: 32744769.

[161] Peisker A, Raschke GF, Schultze-Mosgau S. Management of dental extraction in patients with Haemophilia A and B: a report of 58 extractions. Med Oral Patol Oral Cir Bucal. 2014 Jan 1;19(1):e55–60. *doi: 10.4317/medoral.19191.* PMID:24121912; PMCID: PMC3909433.

[162] Prevention CDC. Learn more about sickle cell disease, Centers for Disease Control and Prevention. (Available at *https://www.cdc.gov/ncbddd/sicklecell/index.html.*)

[163] U.S. Food and Drug Administration. FDA approves hydroxyurea for treatment of pediatric patients with sickle cell anemia, U.S. Food and Drug Administration. (Available at *https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-hydroxyurea-treatment-pediatric-patients-sickle-cell-anemia.*)

ischemia,[164] including delayed tooth eruption, enamel disorders, and tongue cell changes. Ischemic and inflammation affects enamel, gums, and jawbones that can cause paresthesia and tooth pain. In response to a producing more red blood cells to make up for anemia, bone marrow expansion can lead to malocclusion and reduced bone density.[165] [166] The AHRQ's rapid response report highlights that despite hydroxyurea's long-term use to treat SCD, uncertainty remains regarding whether dental care before, during, or after treatment of SCD with hydroxyurea (and other lesser prescribed treatments) influences clinical outcomes in patients.

In their rapid response, the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram, a flow diagram used in systematic reviews and meta-analyses intended to describe findings of the review, revealed that initially, 762 records were identified from large databases, and 934 records were identified from grey literature sources covering 57 years. Following the exclusion of ineligible studies, a total of five unique records were included, extracted, and evaluated in the rapid response report. The rapid response report found that no studies examined the specific impact of dental care on SCD treatment outcomes; however, the rapid response identified three relevant clinical practice guidelines and two reviews with recommendations for dental care for patients with SCD. According to the rapid response, all guidelines and reviews highlighted the importance of preventive dental measures, with the Sickle Cell Society in the UK recommending the inclusion of a hematologist in the dental care team for SCD patients. However, these guidelines primarily focused on managing SCD during dental services rather than the impact of dental care on the improvement of SCD treatment outcomes, which differs from the regulatory standard in § 411.15(i)(3)(i) that the dental services are inextricably linked to, and substantially related and integral to the clinical success of, other covered services.

The two rapid reviews with recommendations highlighted several key areas of dental management for SCD patients. They emphasized the importance of preventive dental care to reduce the risk of oral infections, periodontal diseases, and major dental procedures. Additionally, the studies recommended that a complete blood count should be evaluated prior to invasive dental procedures to mitigate infection risks in SCD patients.[167] [168] Overall, the findings from the AHRQ rapid response reports underscore the gaps in the current literature concerning the management of oral health care for individuals with SCD. The body of evidence evaluating dental services before, during, or after the treatment of SCD is lacking in primary clinical data and is limited to available clinical practice guidelines and reviews with recommendations. While guidelines and reviews have addressed particular aspects of dental care, such as early intervention and the importance of collaboration between dentists and hematologists, there is an absence of primary evidence that informed the potential effect of dental care on SCD treatment outcomes.

2. Consideration of Dental Services That May Be Inextricably Linked to Covered Services for the Treatment of Hemophilia

As stated in their report, hemophilia is a rare inherited disorder characterized by the deficiency or absence of blood-clotting proteins, affecting approximately 20,000–33,000 males in the U.S.[169] There are three distinct types of hemophilia (A, B, and C) according to the specific clotting factor that is deficient or missing (VIII, IX, and XI, respectively). Treatment for all three types of hemophilia is similar but may vary based on the severity of disease, and typically involves replacing the deficient or missing clotting factor.[170] Anticoagulation issues in hemophilia patients can pose challenges for dental specialists due to the increased risk of secondary bleeding after oral surgery.[171] Severe hemophilia patients face spontaneous bleeding in joints, muscles, or soft tissues, sometimes life-threatening, while mild to moderate cases may experience excessive bleeding, including after dental extractions.[172]

According to the rapid response reports provided by AHRQ, clotting factor replacement therapy is the standard treatment for individuals with hemophilia. Replacement therapy, which can be self-administered or given at a hemophilia treatment center, can be used to stop a spontaneous bleeding episode (episodic care), or to prevent bleeding from occurring (prophylactic care). However, consistent/prolonged factor replacement can cause antibody inhibitor development.[173] While clotting factor replacement therapy remains the standard treatment for hemophilia, uncertainty persists regarding whether dental care before, during, or after treatment of hemophilia improves clinical outcomes in patients. Excessive bleeding, often associated with invasive or traumatic dental procedures, poses challenges when treating patients with hemophilia. Hence, the timing of dental treatment in relation to factor replacement therapy may influence outcomes.

In AHRQ's rapid response, a total of 1,414 records from large databases and 2,238 records from grey literature, spanning 73 years, were identified. Strictly following the exclusion criteria depicted in the PRISMA diagram, the response included, extracted, and evaluated a total of four unique publications in this rapid response. The rapid response report identified four publications: two practice guidelines and two reviews with recommendations. The included publications advised hemophilia patients to consult hematologists or hemophilia treatment centers before dental procedures. They emphasized interdisciplinary collaboration between dentists and hematologists for treatment planning. Included guidelines recommended performing dental services during hemophilia treatment with coagulation factor replacement therapy. However, all four reviewed publications mainly addressed hemophilia A and B, with little mention

[164] da Fonseca M, Oueis HS, Casamassimo PS. Sickle cell anemia: a review for the pediatric dentist. Pediatr Dent 2007;29(2):159–69. (In eng).

[165] Hsu LL, Fan-Hsu J. Evidence-based dental management in the new era of sickle cell disease: A scoping review. J Am Dent Assoc 2020;151(9):668–677.e9. (In eng). *DOI: 10.1016/j.adaj.2020.05.023*.

[166] Kane SF. The effects of oral health on systemic health. Gen Dent 2017;65(6):30–34. (In eng).

[167] Kawar N, Alrayyes S, Yang B, Aljewari H. Oral health management considerations for patients with sickle cell disease. Dis Mon 2018;64(6):296–301. (In eng). *DOI: 10.1016/j.disamonth.2017.12.005*.

[168] Kakkar M, Holderle K, Sheth M, Arany S, Schiff L, Planerova A. Orofacial Manifestation and Dental Management of Sickle Cell Disease: A Scoping Review. Anemia 2021;2021:5556708. (In eng). *DOI:10.1155/021/5556708*.

[169] Prevention CfDCa. Hemophilia Treatment. (*https://www.cdc.gov/ncbddd/hemophilia/treatment.html#:~:text=The%20best%20way%20to%20treat,concentrates%2C%20into%20a%20person's%20vein*.)

[170] Ibid.

[171] Givol N, Hirschhorn A, Lubetsky A, Bashari D, Kenet G. Oral surgery-associated postoperative bleeding in haemophilia patients—a tertiary centre's two decade experience. Haemophilia 2015;21(2):234–240. (In eng). *DOI: 10.1111/hae.12573*.

[172] Oomen I, Camelo RM, Rezende SM, et al. Determinants of successful immune tolerance induction in hemophilia A: systematic review and meta-analysis. Res Pract Thromb Haemost 2023;7(1):100020. (In eng). *DOI: 10.1016/j.rpth.2022.100020*.

[173] Castaman G, Matino D. Hemophilia A and B: molecular and clinical similarities and differences. Haematologica 2019;104(9):1702–1709. (In eng). *DOI: 10.3324/haematol.2019.221093*.

of hemophilia C. Similar to the findings related to SCD, the body of evidence evaluating dental services before, during, or after the treatment of hemophilia is lacking in primary clinical data and is currently limited to available guidelines. These guidelines emphasize the importance of professional dental care during hemophilia treatment with clotting factor replacement therapy to reduce bleeding complications, rather than the inextricable link between certain dental services and covered services for hemophilia, which is the regulatory standard in § 411.15(i)(3)(i) for clinical scenarios under which payment can be made for dental services under Medicare Parts A and B.

After reviewing AHRQ's comprehensive rapid reviews for both SCD and hemophilia, we found the evidence related to the linkage between dental services and outcomes for covered medical services for both SCD and hemophilia lacking in the current research and literature. Both rapid responses noted a limited number of studies examining the impact of dental care on outcomes for individuals with SCD or hemophilia. Currently, the evidence base does not appear to support that dental services may be inextricably linked to covered services for SCD or hemophilia. Also, the body of evidence evaluating dental services before, during, or after the treatment of SCD and hemophilia lacks primary clinical data and relies on available guidelines and reviews. Given limited information, however, both the SCD and hemophilia rapid responses support the need for preventive care and patient education as essential practices for both SCD and hemophilia patients to minimize the likelihood of oral infections, periodontal disease, and major dental procedures. In addition, both rapid response reports recommend collaborative efforts between dentists, hematologists, and specialized clinics as crucial for improved patient care, despite the lack of primary evidence informing the potential effect of dental care on treatment. While both rapid response reports discuss their findings on the importance of a multidisciplinary approach, both rapid response reports also found that the current reviews and guidelines do not address dental care as a standard of care that is inextricably linked to hemophilia or SCD treatment. Instead, their focus was on managing the respective conditions during dental services, not on the inextricable linkage between the dental and medical services.

In conclusion, interested parties, including industry organizations, public commenters, and organizations submitting through the public submissions process, requested that CMS consider the conditions of SCD and hemophilia for the purposes of the Medicare Parts A and B payment policy for dental services that are inextricably linked to other covered services. As part of our commitment to exploring the inextricable link between dental and covered services associated with SCD and hemophilia, we partnered with AHRQ to generate comprehensive rapid responses on these topics. However, the AHRQ's rapid response reports show that the current evidence base does not appear to support that dental services may be inextricably linked to services for SCD or hemophilia within the meaning of the standard at § 411.15(i)(3), and we are not proposing to add these conditions to our regulation. Moreover, the findings of the AHRQ rapid response reports highlight that this area merits further study by researchers and industry in order to further explore potential connections between dental services and improved outcomes for individuals with SCD or hemophilia. Given the new and evolving therapies and treatments in this space, we will consider conducting additional evaluations as new studies are carried out to examining the impact of dental services on SCD and hemophilia outcomes and will take any future studies into consideration.

We continue to seek clinical evidence demonstrating the integral connection between dental services and other covered services for SCD and hemophilia, and we welcome any comments or literature regarding these two conditions. We are not proposing to amend § 411.15(i)(3)(i) as we have not identified additional dental services that are inextricably linked to certain services associated with SCD or hemophilia. However, we remain open to considering any such services identified by public commenters, and, if sufficient evidence is presented, we may consider adding such services to our regulations in the final rule. In addition, we encourage interested parties to supply additional submissions for consideration in future PFS rulemaking through the public submission process, which may include relevant medical evidence, peer-reviewed literature, clinical guidelines, or supporting documentation as described in section II.J.1.c. of this proposed rule.

c. Submissions Received Through Public Submission Process

As we have in the CY 2023 and CY 2024 PFS final rules, we continue to encourage interested parties to engage with us regularly and to submit recommendations through our public submissions process for our consideration of additional clinical scenarios where dental services may be inextricably linked to covered services under § 411.15(i)(3)(i). Through our annual public submissions process, interested parties should provide clinical evidence and other documentation to support their recommendations (87 FR 69685). We are using the PFS annual rulemaking process to discuss public submissions and to consider whether the clinical scenario described in the submissions should be added to § 411.15(i)(3)(i) as an example of a circumstance where payment can be made for dental services inextricably linked to other covered services. Using our annual notice and comment rulemaking process to discuss submitted recommendations allows the public to comment and submit further medical evidence and important feedback to assist us in evaluating whether certain dental services furnished in certain clinical scenarios would meet the standard to permit Medicare payment for the dental services.

We review clinical evidence included in submissions and public comments in rulemaking, as well as information and analysis provided by AHRQ in rapid response reports, to assess whether there is an inextricable link between certain dental services and certain covered services. We would find that there is an inextricable link where the standard of care for a service is such that the practitioner would not proceed with the procedure or service without performing the dental service(s), for example, because the covered services would or could be significantly and materially compromised absent the provision of the inextricably-linked dental services, or where dental services are a clinical prerequisite to proceeding with the primary medical procedure and/or treatment. As such, documentation accompanying recommendations should include medical evidence to support that certain dental services are inextricably linked to certain covered services. Specifically, as we specified in the CY 2023 PFS final rule, we request that the medical evidence included in submissions through the public submissions process should:

(1) Provide support that the provision of certain dental services leads to improved healing, improved quality of surgery outcomes, and the reduced likelihood of readmission and/or surgical revisions because an infection has interfered with the integration of the

medical implant and/or interfered with the medical implant to the skeletal structure;

(2) Be clinically meaningful and demonstrate that the dental services result in a material difference in terms of the clinical outcomes and success of the procedure such that the dental services are inextricably linked to other covered services; and,

(3) Be compelling to support that certain dental services would result in clinically significant improvements in quality and safety outcomes (for example, fewer revisions, fewer readmissions, more rapid healing, quicker discharge, and quicker rehabilitation for the patient) (87 FR 69686).

This evidence should include at least one of the following:

(1) Relevant peer-reviewed medical literature and research/studies regarding the medical scenarios requiring medically necessary dental care;

(2) Evidence of clinical guidelines or generally accepted standards of care for the suggested clinical scenario;

(3) Other ancillary services that may be integral to the covered services; and/or

(4) Other supporting documentation to justify the inclusion of the proposed medical clinical scenario requiring dental services (87 FR 69686).

Submissions should focus on the inextricably linked relationship between dental services and other services necessary to diagnose and treat the individual's underlying medical condition and clinical status, and whether it would not be clinically advisable to move forward with the other covered services without performing certain dental services. To be considered for purposes of CY 2026 PFS rulemaking, submissions through our public submissions process should be received by February 10, 2025, via email at *MedicarePhysicianFeeSchedule@cms.hhs.gov.* To facilitate processing, interested parties should include the words ''dental recommendations for CY 2026 review'' in the subject line of their email submission. We continue to stress to submitters that recommendations must include at least one of the types of evidence listed earlier. We further note that we may also consider recommendations that are submitted as public comments during the comment period following the annual publication of the PFS proposed rule.

We thank all those who submitted recommendations for additional clinical scenarios for which they believe Medicare payment for dental services will be consistent with the policies we codified at § 411.15(i)(3)(i), under which Medicare payment may be made for dental services when they are inextricably linked to other covered services. We received thirteen submissions from various organizations and individuals on or before February 10, 2024. Several submitters represented dozens or hundreds of other organizations in making these recommendations. We received one submission after the deadline that presented nominations for clinical scenarios addressed by other submitters, and a proposal outside the scope of clinical scenarios where dental services may be inextricably linked to covered medical services under § 411.15(i)(3)(i).

One submitter recommended that oral health care is essential to the success of treatments for individuals with sickle cell disease and other hematologic disorders. The submitter asserted that providing appropriate and timely dental care is a crucial component for the successful treatment of many hematologic diseases, including SCD, hemophilia, and many blood cancers, such as acute myeloid leukemia, acute lymphoblastic leukemia, chronic lymphocytic leukemia, chronic myeloid leukemia, and multiple myeloma. The submitter noted that we finalized that payment can be made for certain dental services prior to or contemporaneously with chemotherapy, CAR T-Cell therapy, and the administration of high-dose bone-modifying agents (anti-resorptive therapy), when used in the treatment of cancer. The evidence submitted showed that among individuals with a sickle cell crisis, those with dental infections were 72% more likely to be admitted to the hospital than those without dental infections. The same submitter also requested that we consider payment of dental services following organ transplantations (including bone marrow or hematopoietic stem cell transplantation (HSTC)) because maintenance of oral hygiene after HSCT minimizes the severity of oral and dental infections, which is important because chronic graft versus host disease (cGVHD) is common following allogeneic HSCT. The submitter stated that frequent dental evaluations of patients with cGVHD are critical because of the increased rate of dental caries associated with this disease; furthermore, gingivitis and periodontal disease should be monitored and managed appropriately to avoid additional infection. Finally, the submitter also stated that multiple tooth extractions without replacement of dentition leave patients with a poor capacity to eat and may negatively impact the success of the transplant and quality of life. This submitter also recommended including cell and gene therapy for SCD as a clinical treatment scenario for future consideration of potentially inextricably linked dental services.

Another submitter asserted that patients frequently present with complications extending three years or more following the direct treatment of not only head and neck cancers but also other cancer types. The submitter also asserted that a comparable trend may be seen in patients experiencing complications following anti-resorptive drug therapy, for non-cancer-related conditions. They recommended that payment be available for specific dental services during a minimum of 2 years post-treatment for head and neck cancer and up to 5 years for those who have received radiotherapy. They emphasized the current evidence and literature as supporting the provision of Medicare payment for a minimum of 2 years, with the understanding that some patients may require dental or oral healthcare beyond this period due to delayed or late-onset complications, and that the timeline for the emergence of oral or dental complications post-treatment is not uniformly linear and can significantly vary among patients. They also stated that literature supports the extension of Medicare payment to include certain dental services furnished post-anti-resorptive therapy, when used in the treatment of cancer for at least two years following treatment. Lastly, this submitter stated there is an inextricable risk of the development of severe dental and oral complications, such as osteoradionecrosis/medication-related osteonecrosis of the jaw, in patients who have undergone the specific treatments for which we have identified certain inextricably linked dental services. They suggested that once patients receive these treatments, patients are perpetually at risk for developing such complications and recommended that current Medicare payment for dental services should align with the long-term healthcare needs of these patients.

We are not accepting the commenters' suggestion to include specific time limits within the exception in § 411.15(i)(3). We note again that MACs have the flexibility to determine on a claim-by-claim basis whether payment can be made for certain dental services for beneficiaries, such as those receiving other immunotherapies that may involve a lymphodepleting component, consistent with § 411.15(i)(3). That regulation states the general rule that

Medicare Parts A and B payment can be made for certain dental services that are inextricably linked to, and substantially related and integral to the clinical success of, covered services; and then provides a non-exclusive list of examples of clinical scenarios under which payment can be made. Thus, a MAC has discretion to decide on a case-by-case basis that payment can be made for certain dental services in other circumstances not specifically addressed under § 411.15(i)(3)(i)

Several submitters recommended that we provide for payment of medically necessary dental services for individuals with autoimmune diseases who are initiating or undergoing immunosuppressive or immunomodulator therapy (''immunosuppressive therapy''). They stated that immunosuppressive therapy can be severely complicated and compromised by oral/dental disease and conditions. The submitters provided references to numerous clinical studies and other supporting documentation in support of dental services in these clinical circumstances being inextricably linked to immunosuppressive therapies for which payment may be made in accordance with § 411.15(i)(3). They noted that while higher dosing is used for cancer chemotherapy and organ transplant rejection prevention, the therapy's duration is generally much shorter than when used in autoimmune disease therapy and that the longer-term duration of use for managing symptoms of autoimmune disease can expose patients to ongoing serious risk of complicating infections for decades. They relayed that the American College of Rheumatology states it is vital for patients to receive appropriate dental evaluation and prompt treatment so they can continue their immune suppressant medications. The submitter explained that dental infections could spread more easily, and therefore faster, when host immunity is compromised by immunosuppressing/immunomodulating drugs via three pathways for the bacteria to spread: locally through facial spaces, through the bloodstream, and by aspiration. They stated that outcomes similar to systemic infection or sepsis and other complications can follow for those receiving immunosuppressive therapy to treat autoimmune diseases. They recommended immunosuppressive therapy to treat autoimmune diseases should not proceed until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection. We discuss these recommendations and supporting evidence in section II.J.4. of this proposed rule.

Several submitters recommended that dental treatments can be integral to the clinical success of covered nephrology-related medical services including services received by beneficiaries who are immunocompromised by end-stage renal disease (ESRD), chronic kidney disease (CKD), other renal diseases, as well as kidney transplant candidates maintained on immunosuppressive medications. They stated that all of these patients are at increased risk of infection, complications, and malnutrition from dentally sourced pathogens. Submitters stated that Medicare ESRD beneficiaries on dialysis are at greater risk for developing complications such as cardiovascular conditions, malnutrition, anemia, and infections, making dental services more critical to the success of kidney care treatments. They further stated that pre-transplantation dental care involves eliminating possible sources of oral infection that can lead to a systemic infection following transplant and that without access to dental services, individuals on dialysis may not qualify for kidney transplantation or may have severe complications after the transplant. One of the submitters noted that dialysis clinicians report that many bloodstream infections (BSI) begin with bacteria in the mouth and that regular dental visits could have a positive impact on reducing BSI. They added that the Society for Vascular Surgery has noted that transient bacteremia from dental infections can seed hemodialysis access grafts. Among strategies to prevent infection of vascular grafts, recommended preoperative measures include identifying and treating remote site infections, including dental sites. We discuss these recommendations and supporting evidence in section II.J.2. of this proposed rule.

More than half of the submissions expressed support for almost identical proposals from a couple of other submitters, recommending that dental services are inextricably linked to covered medical services used for the treatment of Medicare beneficiaries with diabetes. They agreed that the delivery of appropriate dental services in accordance with clinical guidelines and standard of care is substantially related and integral to the optimal outcome of these covered medical services. They offered clinical studies documenting that treatment of oral infections, such as periodontitis and its related inflammation, meaningfully improves the treatment and management of diabetes. They stated, by contrast, the absence of treatment of chronic dental infections complicates covered medical treatment for the management of diabetes and exacerbates insulin resistance, worsens glycemic control, and other diabetes related complications. They noted that the relationship between oral diseases and diabetes mellitus is complex. Diabetes is known to increase the risk and severity of oral diseases, such as periodontitis (gum inflammation and bone loss), tooth loss, dry mouth, and oral fungal infections. Additionally, oral diseases are documented as affecting blood glucose control and contributing to the development of diabetes complications, such as retinopathy, neuropathy, cardiovascular disease, and kidney disease. They believe reciprocal management of glycemic control and periodontal disease decreases risk for and actual cases and severity of diabetes and periodontal disease. We discuss these recommendations and the supporting clinical evidence in section II.J.3 of this proposed rule.

2. Proposed Additions to Current Policies Permitting Payment for Dental Services Inextricably Linked to Other Covered Services

We have received information and requests from interested parties, including entities submitting information through the public submissions process as well as organizations providing comments in response to prior rulemaking efforts, that an inextricable linkage exists between dental services and dialysis treatment services for individuals diagnosed with end-stage renal disease (ESRD) who are receiving dialysis services, particularly those experiencing comorbidities. Commenters and submitters have stated that dental treatment is inextricably linked and integral, and substantially related to the clinical success and outcomes of covered dialysis medical services.

In the CY 2024 PFS final rule, we stated that commenters had provided comments in response to the CY 2024 PFS proposed rule supporting the coverage of annual dental examinations, and treatment as clinically indicated, for individuals with chronic kidney disease and ESRD. The commenters stated that chronic immunosuppression increases the risk of dental infections leading to potentially deadly complications including BSI, peritoneal dialysis-associated peritonitis, and the exacerbation of chronic cardiovascular conditions. They also stated that when established by patient-specific medical and dental parameters, dental services can be unquestionably integral to the

outcome of covered medical procedures. We thanked the commenters for the information they submitted regarding these suggestions; however, at that time, commenters did not provide sufficient evidence to support an inextricable link between certain dental services and certain covered services for chronic kidney disease and ESRD (88 FR 79034).

Additionally, submitters provided information through the public submissions process as described in section II.J.1.c. of this proposed rule for our consideration in CY 2025 rulemaking. The submitters stated that there is a connection between dental services to identify and address dental or oral infections and covered medical services for individuals receiving dialysis in the treatment of ESRD.

ESRD is a medical condition in which a person's kidneys successively experience loss of functionality on a permanent basis, leading to the need for a regular course of long-term dialysis or a kidney transplant to maintain life.[174]

Chronic kidney disease (CKD) is a progressively debilitating disease and is marked by the presence of kidney damage or reduction in the kidneys' filtration rate. CKD is a state of progressive loss of kidney function, in that the disease worsens over time and cannot be reversed, ultimately resulting in the need for renal replacement therapy, generally dialysis or transplantation.[175] The Kidney Disease Improving Global Outcomes (KDIGO) Foundation established guidelines that define five stages of CKD using kidney damage markers, including factors that determine proteinuria (level of protein in the urine) and glomerular filtration rate (level of kidney function/filtration) in its KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease.[176] Chronic kidney disease is generally defined as the presence of two factors (glomerular filtration rate [GFR] less than 60 mL/min and albumin greater than 30 mg per gram of creatinine) along with abnormalities of kidney structure or function for greater than three months. Stage 5 of CKD is labeled end-stage renal disease (ESRD) with a GFR of less than 15 mL/min.[177] According to the NIH, more than 500,000 people in the United States live with ESRD.[178]

Per the American Academy of Family Physicians, individuals with ESRD are typically referred to nephrologists for the development of treatment plans. Collectively the various modalities utilized to replicate kidney function are referred to as renal replacement therapy (RRT). Most ESRD patients are treated with dialysis, regardless of whether transplantation ultimately occurs. Generally, kidney transplantation typically yields the best patient outcomes; however, not all patients with ESRD are eligible for or able to undergo transplantation, and therefore continue dialysis treatment.[179] Standards of medical care for CKD outline the need for monitoring for signs of progression of the disease and early referral to specialists for RRT.[180] Dialysis is generally supplied via two primary modes: hemodialysis or peritoneal dialysis. In hemodialysis, blood is filtered through a dialyzer, outside of the body. A dialyzer is sometimes referred to as an ''artificial kidney.''[181] To access the circulatory system, several access points may be placed and utilized, including an arteriovenous (AV) fistula, AV graft, and in some cases a central venous catheter.[182] [183] [184] In peritoneal dialysis, a fixed catheter is placed in the abdomen, and dialysis solution is administered into the abdomen. The solution absorbs wastes and excess fluid from the patient's body. [185] [186]

Submissions we received through the public submissions process for consideration in CY 2025 rulemaking provided information regarding the potential linkage between dental services and specific covered medical services associated with ESRD and dialysis including:

- CPT codes 36901–36906: Dialysis circuit procedures;
- CPT codes 90935, 90937, 90940: Hemodialysis procedures;
- CPT code 90961: Physician or other qualified healthcare professional visits for ESRD;
- CPT codes 90989–90999: Other dialysis procedures; and,
- DRG code 872: Hospitalization for septicemia or severe sepsis.

We note that Medicare provides coverage for individuals with ESRD, regardless of age, when certain requirements are met.[187]

We also note that dialysis procedures may be utilized for individuals who do not have ESRD in the treatment of acute intoxication or poisoning. For example, in the case of a patient experiencing poisoning, dialysis hemoperfusion may be employed, which passes the blood through a column packed with granules that include a resin that act as absorbents. In this procedure, physicochemical properties of an absorbent are used to remove toxins. Conversely, in hemodialysis utilized in the treatment of ESRD, there is a concentration gradient between the blood and the solvent across the dialysis membrane.[188] We note that the patient accessing dialysis treatment for the treatment of acute intoxication or poisoning would not present with the same diagnostic profile, treatment needs, nor face the same risks of immunodeficiency and infection as individuals with ESRD as described below.[189]

Periodontal diseases and dental caries are the main chronic infectious diseases of the oral cavity. Periodontal diseases include a group of chronic inflammatory diseases that affect the periodontal supporting tissues of teeth and encompass destructive and nondestructive diseases. Gingivitis is inflammation of the soft tissue without apical migration of the junctional epithelium. It is a reversible, nondestructive disease that does not involve loss of periodontal tissues. Periodontitis is inflammation of the periodontium that is accompanied by apical migration of the junctional epithelium, leading to destruction of the

[174] *https://www.cms.gov/medicare/coordination-benefits-recovery/overview/end-stage-renal-disease-esrd.*

[175] *https://www.ncbi.nlm.nih.gov/books/NBK535404/.*

[176] *https://kdigo.org/wp-content/uploads/2017/02/KDIGO_2012_CKD_GL.pdf.*

[177] *https://www.ncbi.nlm.nih.gov/books/NBK499861/.*

[178] *https://www.ncbi.nlm.nih.gov/books/NBK499861/.*

[179] Am Fam Physician. 2021;104(5):493–499. *https://www.aafp.org/pubs/afp/issues/2021/1100/p493.html.*

[180] *https://pubmed.ncbi.nlm.nih.gov/29763036/.*

[181] *https://www.niddk.nih.gov/health-information/kidney-disease/kidney-failure/hemodialysis.*

[182] *https://www.ncbi.nlm.nih.gov/books/NBK563296/.*

[183] *https://www.mayoclinic.org/tests-procedures/hemodialysis/about/pac-20384824.*

[184] *https://www.cdc.gov/dialysis/patient/.*

[185] *https://www.mayoclinic.org/tests-procedures/peritoneal-dialysis/about/pac-20384725*

[186] *https://www.niddk.nih.gov/health-information/kidney-disease/kidney-failure/peritoneal-dialysis.*

[187] *https://www.cms.gov/medicare/coordination-benefits-recovery/overview/end-stage-renal-disease-esrd.*

[188] Durakovic Z. Combined hemoperfusion and hemodialysis treatment of poisoning with cholinesterase inhibitors. Korean J Intern Med. 1993 Jul;8(2):99–102. *doi: 10.3904/kjim.1993.8.2.99.* PMID: 8031730; PMCID: PMC4532091. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4532091.*

[189] Ouellet G, Bouchard J, Ghannoum M, Decker BS. Available extracorporeal treatments for poisoning: overview and limitations. Semin Dial. 2014 Jul;27(4):342–9. *https://pubmed.ncbi.nlm.nih.gov/24697909/.*

connective tissue attachment and alveolar bone loss.[190]

Periodontitis serves as a prime example of a disrupted balance between the local microbiome and the host's inflammatory response, a condition known as dysbiosis. Although the inflammatory response is ostensibly triggered to manage the microbial threat, it proves to be ineffective and inadequately regulated in individuals prone to the condition. This leads to the inflammatory destruction of the periodontium, which encompasses the tissues that encase and support the teeth, including the gingiva, periodontal ligament, and alveolar bone. Without appropriate treatment, this disease can progress to tooth loss, adversely affecting chewing, appearance, and overall quality of life.[191]

In 2017, the American Academy of Periodontology (AAP) and the European Federation of Periodontology (EFP) co-presented the 2017 Classification of Periodontal and Peri-Implant Diseases and Conditions. This disease classification framework serves to guide treatment planning for periodontitis and aims to support customized approaches to patient care. The revised classification includes a multi-dimensional staging and grading system for periodontitis classification, a recategorization of various forms of periodontitis, and a classification for peri-implant diseases and conditions.[192]

Individuals with ESRD experience compromised immune systems as the immune system and the kidneys are closely integrated and interdependent. In healthy individuals, the kidneys contribute to immune homeostasis and regulation, while components of the immune system mediate many acute forms of renal disease and play a central role in the progression of chronic kidney disease. A dysregulated immune system can have either direct or indirect renal effects.[193] Moreover, uremia, the buildup of waste products in the blood that occurs as a result of declining or decreasing kidney function, can lead to inflammation and reduction in the immune system's ability to function as evidenced by an increased risk of viral-associated cancers, increased susceptibility to infections, and decreased vaccination responses in patients with ESRD.[194] ESRD is also characterized by diminished endocrine and metabolic functions of the kidney with subsequent retention and accumulation of toxic metabolites.[195] Additionally, the presence of indwelling catheters and grafts utilized for the administration of dialysis, malnutrition, dysregulated inflammation, and acquired immune dysfunction due to uremia contribute to the immune deficiency in ESRD and increase susceptibility to infection.[196] Notably, infection is the second leading cause of death in hemodialysis patients.[197] [198]

Several submitters providing information through the public submissions process stated that comorbidities frequently occur in the ESRD patient population and can cause complications for the patient, potentially jeopardizing the outcomes of the dialysis treatment. For example, submitters stated that comorbid diabetes can result in clinical complications for individuals receiving dialysis services in the treatment of ESRD, stating that periodontitis can worsen blood glucose control in diabetics by increasing levels of inflammatory mediators and may interfere with insulin, resulting in clinical complications. Additionally, periodontitis is associated with oral health-related quality of life in individuals with ESRD. One study evaluated whether periodontitis may be independently associated with oral health-related quality of life (OHRQoL) in individuals with ESRD. Researchers assessed 180 adults with ESRD and evaluated for impacts on various domains, and found that periodontitis exerts an influence on OHRQoL in individuals with ESRD, with a more severe condition impacting different domains.[199] Moreover, a prospective cohort study aimed to determine the association between an index of radiographically assessed oral health, Panoramic Tomographic Index (PTI), and cardiovascular and all-cause mortality, major adverse cardiovascular events (MACEs) and episodes of bacteremia and laboratory measurements during a three-year prospective follow-up in chronic kidney disease (CKD) stage 4–5 patients not on maintenance dialysis at baseline. The study showed that radiographically assessed and indexed dental health is independently associated with all-cause and cardiovascular mortality and MACEs in CKD stage 4–5 patients transitioning to maintenance dialysis and renal transplantation during follow-up (but not with the incidence of bacteremia).[200]

Submitters providing information through the public process also stated that BSI, poor glycemic control, and other complications arising from dental infection can jeopardize the clinical success of medical therapies employed to manage ESRD. Research provided by submitters described that issues and changes in the mouth and oral cavity, such as periodontitis and other consequences of poor oral health, frequently occur in patients with CKD and may contribute to increased morbidity and mortality because of systemic consequences such as inflammation, infections, protein-energy wasting, and atherosclerotic complications.[201]

Several submitters also stated that addressing oral health issues, including identifying and resolving dental infections through the provision of dental and oral services, can be inextricably linked and integral and related to the clinical success of Medicare covered dialysis services for the treatment of ESRD. The submitters

[190] Albandar, J.M. (2005). Epidemiology and risk factors of periodontal diseases. *Dent Clin North Am, 49*(3), 517–532, v-vi. *doi:10.1016/j.cden.2005.03.003.*

[191] Hajishengallis, G., & Chavakis, T. (2021). Local and systemic mechanisms linking periodontal disease and inflammatory comorbidities. *Nature Reviews Immunology, 21*(7), 426–440. *doi:10.1038/s41577–020–00488–6.*

[192] *https://www.perio.org/wp-content/uploads/2019/08/Staging-and-Grading-Periodontitis.pdf.*

[193] Tecklenborg J, Clayton D, Siebert S, Coley SM. The role of the immune system in kidney disease. Clin Exp Immunol. 2018 May;192(2):142–150. *doi: 10.1111/cei.13119.* Epub 2018 Mar 24. PMID: 29453850; PMCID: PMC5904695.

[194] Betjes MG. Immune cell dysfunction and inflammation in end-stage renal disease. Nat Rev Nephrol. 2013 May;9(5):255–65. doi: 10.1038/nrneph.2013.44. Epub 2013 Mar 19. PMID: 23507826. *https://pubmed.ncbi.nlm.nih.gov/23507826/.*

[195] Costantinides F, Castronovo G, Vettori E, Frattini C, Artero ML, Bevilacqua L, Berton F, Nicolin V, Di Lenarda R. Dental Care for Patients with End-Stage Renal Disease and Undergoing Hemodialysis. Int J Dent. 2018 Nov 13;2018:9610892. *doi: 10.1155/2018/9610892.* PMID: 30538746; PMCID: PMC6258100.

[196] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7404977/.*

[197] U.S. Renal Data System. USRDS 2015 Annual Data Report: Atlas of End-Stage Renal Disease in the United States, Bethesda, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2015.

[198] Dalrymple LS, et al. Infection-related hospitalizations in older patients with ESRD. Am. J. Kidney Dis. 2010;56:522–530. *doi: 10.1053/j.ajkd.2010.04.016.*

[199] Oliveira, L.M., Sari, D., Schoffer, C., Santi, S.S., Antoniazzi, R.P., & Zanatta, F.B. (2020). Periodontitis is associated with oral health-related quality of life in individuals with end-stage renal disease. Journal of Clinical Periodontology, 47(3), 319–329. *doi:10.1111/jcpe.13233.*

[200] Jarvisalo, M.J., Jokihaka, V., Hakamaki, M., Lankinen, R., Helin, H., Koivuviita, N.S., . . . Metsarinne, K. (2021). Dental health assessed using panoramic radiograph and adverse events in chronic kidney disease stage 4–5 patients transitioning to dialysis and transplantation-A prospective cohort study. PLOS ONE, 16(9), e0258055. *doi:10.1371/journal.pone.*0258055.

[201] Harun Akar, Gulcan Coskun Akar, Juan Jesus Carrero, Peter Stenvinkel, and Bengt Lindholm. Systemic Consequences of Poor Oral Health in Chronic Kidney Disease Patients, Clin J Am Soc Nephrol 6: 218–226, 2011. *doi: 10.2215/CJN.05470610.*

stated that the consequences of poor oral health are worse for ESRD patients than the general population due to ESRD patient characteristics such as advanced age, higher prevalence of comorbid diabetes, polypharmacy, and impaired immune function, and that medically necessary dental care may improve the clinical success of the dialysis services.

A few submitters supplied a general position paper on the need for dental care and services in the ESRD patient population receiving dialysis services, describing the unique risks for individuals with ESRD and the increased risk of infection from oral sources. Specifically, the position paper states that ''oral diseases represent a potential and preventable cause of poor health outcomes in people with ESRD due to their relation to infection, inflammation, and malnutrition. Oral health represents a potential determinant of health outcomes in patients with end-stage renal diseases (ESRD).''[202] Several submitters also provided a cohort outcomes study of 675 randomly selected individuals receiving peritoneal dialysis services.[203] The study outcomes described that ''poor oral health was associated with lower educational levels, diabetes, older age, marriage, and worse nutritional indicators (including lower time-averaged serum albumin and phosphate concentrations).''[204]

The research further isolated that poor oral health is independently associated with an increased risk of peritonitis, an infection of the peritoneum where the peritoneal access graft is placed, and mortality in patients receiving peritoneal dialysis. The authors describe that ''after adjusting for age, sex, comorbidities, serum albumin, shared frailty by study sites, and PD vintage, poor oral health was associated with increased risks of peritonitis (adjusted hazard ratio [HR] = 1.45, 95 percent confidence interval [CI]: 1.06–2.00) and all-cause mortality (adjusted HR = 1.55, 95 percent CI: 1.04–2.32) but not hemodialysis (HD) transfer (adjusted HR = 1.89, 95 percent CI: 0.87–4.10) compared to participants with good oral health.'' Furthermore, the study explained that ''poor oral health status was present in one-fourth of peritoneal dialysis patients and was independently associated with a higher risk of peritonitis and death.''[205] Moreover, submitters provided information that suggests that patients with ESRD receiving hemodialysis services and receiving preventive oral and dental services experience increased survival while those not receiving dental services were associated with increased mortality. A prospective cohort outcomes study of 4,205 hemodialysis patients assessed the impact of dental health on mortality from 2010 to 2012. The study described that ''in adults treated with hemodialysis, poorer dental health was associated with early death, whereas preventive dental health practices were associated with longer survival.''[206]

Additionally, in a systematic review supplied by several submitters, studies show that patients on RRT (for example hemodialysis, peritoneal dialysis, and/or transplantation) experience a high prevalence of dental caries, common chronic infection resulting from tooth-adherent cariogenic bacteria.[207] The observational data presented in the review suggests a link between oral health and mortality in patients on RRT.[208] The review highlighted the need for further research in this area but also stated that improved, multidisciplinary, patient-centered dental care concepts are required to support dental and overall oral health in individuals on RRT.

Several submitters also noted that the Society for Vascular Surgery has stated that transient bacteremia from dental infections can seed hemodialysis access grafts. Among strategies to prevent infection of vascular grafts, recommended preoperative measures include identifying and treating remote site infections, including dental or oral sites of infection.[209] [210] Statements regarding best practices for managing infection control advise that sources of infection, including those within the oral cavity, should be addressed in order to minimize the risk of broader infection in the ESRD patient receiving hemodialysis.[211]

In conclusion, the evidence base indicates that evaluation for and treatment of oral infection leads to improved outcomes and reduced risk of mortality for individuals with ESRD receiving covered dialysis services.

In the CY 2023 PFS final rule, we agreed with commenters that there is clinical evidence to support that medically necessary dental care may advance the clinical success of organ transplants and finalized that payment can be made under Medicare Parts A and B for dental services such as dental examinations, including necessary treatment, performed as part of a comprehensive workup prior to organ transplant surgery and medically necessary diagnostic and treatment services immediately necessary to eliminate or eradicate the infection or its source that are provided before transplantation because such services are inextricably linked to, and substantially related and integral to the clinical success of, the organ transplant procedure (87 FR 69676).

Furthermore, we stated that we appreciated commenters' feedback regarding those individuals who are awaiting organ transplantation and the commenters' request that Medicare provide payment for medically necessary dental services prior to transplantation. We described that in a case where an individual is awaiting organ transplantation, we believe that it is appropriate for Medicare to provide payment for, including but not limited to, an oral or dental examination, and medically necessary diagnosis and treatment for only those services that are considered immediately necessary to eliminate or eradicate the infection or its source prior to the organ transplant (87 FR 69676).

In consideration of research and recommendations provided by the public and our analyses of the studies and research available regarding the connection between dental services and the clinical success of dialysis services for individuals with ESRD, we believe that dental services to diagnose and treat infection prior to dialysis services in the treatment of ESRD represent a clinically analogous scenario to dental services for which Medicare payment under Parts A and B is currently permitted when furnished in the

[202] Costantinides F, Castronovo G, Vettori E, Frattini C, Artero ML, Bevilacqua L, Berton F, Nicolin V, Di Lenarda R. Dental Care for Patients with End-Stage Renal Disease and Undergoing Hemodialysis. Int J Dent. 2018 Nov 13;2018:9610892. *doi: 10.1155/2018/9610892.* PMID: 30538746; PMCID: PMC6258100.

[203] Sirirat Purisinsith, Patnarin Kanjanabuch, Jeerath Phannajit, Bruce Robinson, Kriang Tungsanga, et al. ''Oral Health-Related Quality of Life, A Proxy of Poor Outcomes in Patients on Peritoneal Dialysis.'' *doi: https://doi.org/10.1016/j.ekir.2022.07.008* (August 5, 2022).

[204] Ibid.

[205] Ibid.

[206] See, *e.g.,* Palmer S.C., Ruospo M., Wong G., et al. Oral-D study investigators. Dental health and mortality in people with end-stage kidney disease treated with hemodialysis: a multinational cohort study. American Journal of Kidney Diseases. 2015;66:666–676.

[207] *https://www.ncbi.nlm.nih.gov/books/NBK551699/.*

[208] Deborah Kreher et.al., Prevalence of Dental Caries in Patients on Renal Replacement Therapy—A Systematic Review J. Clin. Med. 2023, 12, 1507. *https://doi.org/10.3390/jcm12041507.*

[209] Surgical Site Infection Toolkit, CDC, SSI Toolkit Activity C: ELC Prevention Collaboratives (*cdc.gov*).

[210] Pear S, Patient Risk Factors and Best Practices for Surgical Site Infection Prevention, *https://www.halyardhealth.com/wp-content/uploads/patient_risk_factors_best_practices_ssi.pdf.*

[211] Ibid.

inpatient or outpatient setting, such as prior to organ transplant. The clinical evidence supports that the medically necessary dental care may similarly advance the clinical success of dialysis services in the treatment of ESRD because an oral or dental infection can present substantial risk to the success and outcomes of these procedures (including the risk of systemic infection, BSI, sepsis, and death).

As such, we believe that if a patient requiring dialysis services in the treatment of ESRD has an oral infection, the success of those dialysis services could be compromised if the infection is not properly diagnosed and treated prior to the covered medical services. Without an oral or dental examination to identify such an infection and the provision of necessary treatment, such as restorative dental services, to eradicate the infection prior to the dialysis procedure, the patient's ability to complete the dialysis services could be seriously complicated or compromised and the risk of infection would further increase the risk of mortality for the patient.

Examples of restorative dental services to eradicate infection could include: extractions (removal of the entire infection, such as pulling of teeth—for example, CDT D7140, D7210), restorations (removal of the infection from tooth/actual structure, such as fillings—for example, CDT D2000–2999), periodontal therapy (removal of the infection that is surrounding the tooth, such as scaling and root planning—for example, CDT D4000–4999, more specifically D4341, D4342, D4335 and D4910), or endodontic therapy (removal of infection from the inside of the tooth and surrounding structures, such as root canal—for example, CDT D3000–3999).

If such an infection is not treated prior to dialysis services in the treatment of ESRD, then there is an increased likelihood for morbidity and mortality resulting from spreading of the local infection to BSI and sepsis. Likewise, we believe that infections occurring during the course of dialysis treatment should similarly be addressed and resolved in order to minimize the risk of infection and death for the patient with ESRD receiving dialysis services.

Because an oral or dental infection can present substantial risk to the success of dialysis treatment for ESRD, we believe dental services furnished to identify, diagnose, and treat oral or dental infections prior to or contemporaneously with dialysis services in the treatment of ESRD are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to, and substantially related and integral to the clinical success of, these other covered medical services. We note that, in these circumstances, the necessary treatment to eradicate an infection may not be the totality of recommended dental services for a given patient. For example, if an infected tooth is identified in a patient requiring dialysis services in the treatment of ESRD, the necessary treatment would be to eradicate the infection, which could result in the tooth being extracted. Additional dental services, such as a dental implant or crown, may not be considered immediately necessary to eliminate or eradicate the infection or its source prior to surgery. Therefore, such additional services would not be inextricably linked to, and substantially related and integral to the clinical success of, Medicare-covered dialysis services when used in the treatment of ESRD. As such, no Medicare payment would be made for the additional services that are not immediately necessary prior to or contemporaneously with dialysis for ESRD to eliminate or eradicate the infection.

In conclusion, we are proposing to add this clinical scenario to the examples of clinical scenarios under which payment can be made for certain dental services in our regulation at § 411.15(i)(3)(i)(A). Specifically, we propose to amend the regulation at paragraph A to include dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered dialysis services when used in the treatment of ESRD; and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with Medicare-covered dialysis services when used in the treatment of ESRD. We seek comments on all aspects of this proposal.

3. Request for Comment on Dental Services Integral To Specific Covered Services to Treat Diabetes

As described in section II.J.1.c. of this proposed rule, we have received information from interested parties, including submitters providing evidence through the public submissions process as well as commenters on prior proposed rules suggesting that dental services are inextricably linked to treatment services for individuals with diabetes mellitus. Several interested parties using the public submissions process have urged us to provide Medicare payment for dental services for individuals diagnosed with diabetes for consideration in CY 2025 rule making. These submissions included information and references supporting oral and dental treatment of advanced periodontitis among individuals with diabetes to improve markers related to management of the diabetes.

Submitters stated that clinical studies demonstrate that dental treatments for oral infections, such as advanced periodontitis and related inflammation, meaningfully advance and improve the treatment of, management of, and outcomes for patients with diabetes. Submitters also stated that conversely, the absence of treatment of chronic dental infections in turn complicates covered medical treatment for the management of diabetes and potentially exacerbates insulin resistance, worsens glycemic control, and other diabetes-related complications, leading to poor outcomes for the individuals with diabetes. Submitters also noted that studies demonstrate cost savings when dental services are employed in the treatment of individuals with diabetes and also serve to advance health equity among vulnerable populations.

Submitters provided information detailing the increased risk of dental caries and periodontal disease in people with diabetes, many of whom lose teeth, which greatly limits nutrition, general well-being, and overall quality of life. Submitted studies demonstrated the bidirectional nature of periodontal disease and diabetes, suggesting that both conditions influence each other and can worsen or conversely improve outcomes.

As described by submitters, numerous basic and clinical studies describe the relationship between oral diseases and inflammation in persons with diabetes, which increases risks for micro- and macrovascular complications including retinopathy, nephropathy, neuropathy, cardiovascular diseases, and stroke. Several submitters stated that there is a documented reduction in hospitalizations in persons with diabetes who receive conservative periodontal treatment. Consequently, submitters stated that periodontal treatment is recommended for patients with diabetes by American Diabetes Association Clinical Guidelines and is also promoted by the American Association of Clinical Endocrinologists and others.[212]

[212] Nuha A. El Sayed, Grazia Aleppo, Vanita R. Aroda, Raveendhara R. Bannuru, Florence M.

Diabetes mellitus is a chronic, metabolic disease characterized by elevated levels of blood glucose (or blood sugar), which, over time, may lead to serious damage to the heart, blood vessels, eyes, kidneys, and nerves. Type 2 diabetes, which usually occurs in adults, causes the body to become resistant to insulin or not to make enough insulin. Type 1 diabetes, previously referred to as juvenile diabetes or insulin-dependent diabetes, is a chronic condition in which the pancreas produces little or no insulin.[213]

A primary goal for the treatment of diabetes is glycemic control and requires accurate individualization and customization of available treatment options. Interventions to address lipoproteins, blood pressure, weight control, mental health, and lifestyle are important factors that contribute to quality of life and the frequency of diabetes-associated complications.[214] According to recent statistics from the Centers for Disease Control and Prevention, approximately 38 million people in the United States may have diabetes, and the CDC estimates that 1 in 5 of them do not know they have the condition. Approximately 98 million U.S. adults likely have prediabetes, and more than 8 in 10 of them may not know they have prediabetes. Notably, diabetes is the eighth leading cause of death in the United States (and may be underreported). Type 2 diabetes accounts for approximately 90 to 95 percent of all diagnosed cases of diabetes, while Type 1 diabetes accounts for approximately 5–10 percent. The CDC reports that over the last 20 years, the number of adults diagnosed with diabetes has more than doubled as the American population has aged and become more overweight or obese.[215]

One key marker for the measurement of glycemic control, a key goal in the treatment of diabetes, in individuals with diabetes is the hemoglobin A1c test. The hemoglobin A1c (also referred to as glycated hemoglobin, glycosylated hemoglobin, HbA1c, or A1c) test is used to evaluate a person's level of glucose control and shows an average of the blood sugar level over the past 90 days and represents a percentage.[216]

Submitters through the public submissions process provided multiple research studies regarding the interaction between dental services and outcomes for medical services to treat diabetes. The Cochrane Library (ISSN 1465–1858) is a collection of databases that contain high-quality, independent evidence to inform healthcare decision-making. The Cochrane Library is owned by Cochrane and published by Wiley.[217] In the Cochrane Review entitled *Treatment of periodontitis for glycaemic control in people with diabetes mellitus,* evidence from 30 trials (results from 2,443 participants) showed that periodontitis treatment reduces blood sugar levels (measured by HbA1c) in diabetic patients on average by 0.43 percentage points (for example, from 7.43 to 7 percent; 4.7 mmol/mol) 3 to 4 months after receiving the treatment compared with no active treatment or usual care. A difference of 0.30 percent (3.3 mmol/mol) was seen after 6 months (12 studies), and 0.50 percent (5.4 mmol/mol) at 12 months (one study).[218] All studies in the review used a parallel randomized controlled trials (RCT) design and followed participants for between 3 and 12 months. The studies generally focused on people with type 2 diabetes, save one study that included participants with type 1 or type 2 diabetes. Most studies were mixed in terms of whether metabolic control of participants at baseline was good, fair, or poor and were carried out in secondary care. Researchers compared periodontitis treatment with control, which could be no (or delayed) treatment or usual care (oral hygiene instruction (OHI) or supragingival scaling with or without OHI). The degree and nature of advanced periodontitis were not specifically defined in the context of the studies. Additionally, the studies did not control for other types of interventions deployed in the treatment of diabetes (that is, strategies used to manage glycemic control), so patients may have been receiving other types of treatment during the study periods.

The types of periodontal treatment provided covered a wide range of oral services: subgingival instrumentation, surgical periodontitis treatment–flap surgery or gingivectomy; antimicrobial therapy (encompassing antibacterials and antibiotics), either locally applied (including mouth rinses, gels, or dentifrices) or systemically administered; other drug therapy with a possible benefit of improving the periodontal condition of the participant; other novel interventions to manage periodontitis; supragingival scaling (also known as professional mechanical plaque removal (PMPR)); oral hygiene instruction; and/or, education or support sessions to improve self-help or self-awareness of oral hygiene.

In summary, the Cochrane review demonstrated that individuals with diabetes who have periodontitis who receive dental services for the treatment of the periodontitis experience a statistically significant reduction of HbA1c. Again, measurement of HbA1c is a metric for gauging glycemic control and is a primary goal of treatment for all individuals with diabetes. The study suggests that individuals with diabetes who also have a diagnosis of periodontitis who receive treatment to address the periodontitis subsequently experience a reduction in HbA1c. The study authors described the clinical outcomes related to preventive dental care, conservative periodontal treatment, and reduction in HbA1c as statistically and clinically significant. Moreover, the authors of the research stated that ''further trials evaluating no treatment vs usual care are unlikely to change this conclusion.'' [219]

Submitters providing information through the public submissions process suggested that dental services could be inextricably linked to the following specific medical services in the treatment of diabetes:

- CPT 36901–36906: Dialysis circuit procedures.
- CPT 82947: Chemistry procedures, blood glucose testing.
- CPT 83036: Hemoglobin A1C testing.
- CPT 90935, 90937, 90940: Hemodialysis procedures.
- CPT 90961: Physician or other qualified healthcare professional visits for ESRD.

Brown, Dennis Bruemmer, Billy S. Collins, Kenneth Cusi, Sandeep R. Das, Christopher H. Gibbons, John M. Giurini, Marisa E. Hilliard, Diana Isaacs, Eric L. Johnson, Scott Kahan, Kamlesh Khunti, Mikhail Kosiborod, Jose Leon, Sarah K. Lyons, Lisa Murdock, Mary Lou Perry, Priya Prahalad, Richard E. Pratley, Jane Jeffrie Seley, Robert C. Stanton, Jennifer K. Sun, Crystal C. Woodward, Deborah Young-Hyman, Robert A. Gabbay; on behalf of the American Diabetes Association, Summary of Revisions: Standards of Care in Diabetes—2023. Diabetes Care 1 January 2023; 46 (Supplement_1): S5–S9. *https://doi.org/10.2337/dc23-Srev.*

[213] *https://www.who.int/health-topics/diabetes.*

[214] Melmer A, Laimer M. Treatment Goals in Diabetes. Endocr Dev. 2016;31:1–27. doi: 10.1159/000439364. Epub 2016 Jan 19. PMID: 26824869.*https://pubmed.ncbi.nlm.nih.gov/26824869/.*

[215] *https://www.cdc.gov/diabetes/basics/quick-facts.html.*

[216] *https://www.ncbi.nlm.nih.gov/books/NBK549816/.*

[217] *https://www.cochranelibrary.com/about/about-cochrane-library.*

[218] Simpson TC, et al. Treatment of periodontitis for glycaemic control in people with diabetes mellitus. Cochrane Database Syst Rev. 2022;4:CD004714 *https://www.ncbi.nlm.nih.gov/pubmed/35420698.*

[219] Simpson TC, et al. Treatment of periodontitis for glycaemic control in people with diabetes mellitus. Cochrane Database Syst Rev. 2022;4:CD004714 *https://www.ncbi.nlm.nih.gov/pubmed/35420698.*

- CPT 90989–90999: Other dialysis procedures.
- CPT 92227–92229: Diabetic retinopathy screening.
- CPT 99091: Collection and interpretation of physiologic data.
- CPT 99202–99215: Evaluation and Management (E/M) Services.
- CPT 99211: Office visit for an established patient.
- CPT 99487: Complex chronic care management services.
- CPT 99490–99491: Chronic care management services.
- CPT 99497: Remote physiologic monitoring services.
- CPT 99605–99607: Medication Management.
- CPT 99802–99804: Assessment, Intervention, Face to Face (F2F).
- DRG 637: Hospitalization for diabetes with major complications.
- G0108: Diabetes Self-Management Training.
- G0109: Group Diabetes Self-Management Training.
- G0270: Nutrition Therapy.
- G0466: FQHC visit new patient.
- G0467: FQHC visit established patient.

As described in this section, research provided by submitters suggests that periodontal treatment for an individual with both a diagnosis of diabetes and periodontitis led to improved HbA1c measures.

We have explained that there are instances where dental services are so integral to other medically necessary services that they are inextricably linked to the clinical success of that medical service(s), and, as such, they are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth within the meaning of section 1862(a)(12) of the Act. Rather, these dental services are inextricably linked to the clinical success of an otherwise covered medical service and are payable under Medicare Parts A and B.

In the case of an individual with diabetes who also has a diagnosis of periodontitis, oral services and treatment to address the periodontitis potentially lead to a reduction in HbA1c, a marker of glycemic control that may be used to determine the effectiveness of interventions for treatment of diabetes. In the description of the studies submitted, the research seems to indicate that the improvement of glycemic control as evidenced by the HbA1c is due to the provision of treatment for the periodontitis. The dental and oral services may not be integral to other specific medically necessary, covered services, but rather the dental and oral services may serve to influence clinical outcomes directly. The studies compare the impact of the treatment for the periodontitis to the impact of pharmacological interventions.

We recognize that evidence submitted by interested parties demonstrates that an individual with both a diagnosis of diabetes and a diagnosis of periodontitis who in turn receives periodontal treatment services may experience improvements in markers for HbA1c, which is a key target outcome for the patient population with diabetes. However, the interaction between these diagnoses and the potential improvements due to periodontal treatment services does not appear to align with the framework we have established to pay for dental services inextricably linked to covered services; in our framework, the delivery of certain dental services are integral to the successful completion of or outcomes related to the covered services.

Under § 411.15(i)(3), we have specified that payment can be made for certain dental services that are inextricably linked to other services when the specific covered services with which the dental services are inextricably linked are identified. The studies that have been provided to CMS through submissions have not identified any specific covered services for the treatment of diabetes to which dental services are inextricably linked. Rather, the studies indicate that the primary treatment of periodontal disease in patients with diabetes generally leads to better outcomes in the management of the patients' diabetes. While the research makes the case that the dental services are medically necessary for patients with diabetes, medical necessity alone does not permit payment for dental services given the broad statutory prohibition under section 1862(a)(12) on payment for services ''in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth.'' In the case of patients with diabetes, the research does not appear to show that certain dental services are inextricably linked with certain other covered services for the treatment of diabetes, in accordance with our regulation at § 411.15(i)(3) such that the statutory prohibition under section 1862(a)(12) does not apply.

We note that some of the examples of medical services for diabetes treatment provided by submitters are general in nature and not specific to patients with diabetes who may also have periodontal disease, including CPT codes 99202–99215: Evaluation and Management (E/M) Services that broadly describe outpatient office visits for the diagnosis and medical management of practically any illness, disease, or condition.

Additionally, submitters providing evidence for our consideration suggested that the services described by codes for diabetes self-management training (for example, G0108: *Diabetes Self-Management Training,* and G0109: *Group Diabetes Self-Management Training*) are services with which dental services may be inextricably linked. However, we were not persuaded by this evidence and do not believe that dental services would be inextricably linked to improved outcomes for services for DSMT. Therefore, we seek comment from the public regarding specific covered services for management of patients with diabetes with which dental services may be inextricably linked. At this time, we are not proposing to amend § 411.15(i)(3)(i) as we have not identified additional dental services that are inextricably linked to certain services in the treatment of diabetes. However, we note that we remain open to considering any such services identified by public commenters, and, if sufficient evidence is presented, we may consider adding such services to our regulations in the final rule.

In the context of payment for dental services for an individual with diabetes, we seek information from the public regarding what the coordination between a medical and dental professional would entail in the scenario where an individual with a diagnosis of diabetes presents with suspected periodontitis. In the CY 2023 PFS final rule, we explained that we would make payment when a doctor of dental medicine or dental surgery (referred to as a dentist) furnishes dental services that are an integral part of the covered primary procedure or service furnished by another physician, or non-physician practitioner, treating the primary medical illness. However, if there is no exchange of information, or integration, between the medical professional (physician or other non-physician practitioner) in regard to the primary medical service and the dentist in regard to the dental services, then there would not be an inextricable link between the dental and covered medical service within the meaning of our regulation at § 411.15(i)(3). Without both integration between the Medicare enrolled medical and dental professional, and the inextricable link between the dental and covered services, Medicare payment for dental services would be prohibited under section 1862(a)(12) because the services

are in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth; though they may be covered by types of supplemental health or dental coverage (87 FR 69687 through 69688).

In a situation where a medical professional believes that an individual with a diagnosis of diabetes may also have a diagnosis of periodontitis, how are recommendations conveyed between the medical and dental professionals? What coordination, if any, occurs between the medical and dental professionals? We expect that inextricably linked services related to the treatment of periodontitis in an individual with diabetes would require significant communication between the medical and dental professionals.

Additionally, we have stated that an inextricable linkage may exist between dental services and covered services when the standard of care for the medical service is such that the practitioner would not proceed with the medical procedure or service without performing the dental services, because the covered medical services would or could be significantly and materially compromised, or where dental services are a clinical prerequisite to proceeding with the primary medical procedure and/or treatment (87 FR 69669). While evidence supports that individuals with diabetes and periodontitis who receive periodontal treatment experience improvements in their HbA1c markers, dental services do not appear to serve as a precondition to overall treatment for the diabetes. We seek information from the public on how oral treatment services may be a clinical prerequisite in the treatment protocol for the care of individuals with diabetes.

We note that there does not appear to be a clear or singular definitional framework for categorizing the state of diabetes, such as ''controlled'' or ''uncontrolled'' diabetes. Research submitted by the public discusses improvements in glycemic control as evidence by HbA1c markers, but does not delineate the characteristics of a patient that would require direct clinical intervention (pharmacological, behavioral, usage of DME such as insulin pumps, etc.) versus a patient that would not require interventions given that their disease state is not within a concerning range requiring direct medical treatment.

In the current literature, there are two types of severity measures that can help categorizing the state of diabetes: the severity of diabetes itself and the severity of periodontal disease among individuals with diabetes. With respect to the severity of diabetes, the American Diabetes Association recommends that most adults with diabetes aim for a HbA1c level below 7.0% (<53 mmol/mol), along with other recommended targets such as blood pressure below 130/80 mmHg and LDL cholesterol below 100 mg/dL.[220] In the current literature, uncontrolled hyperglycemia is typically defined as a HbA1c level above 8.0% (>64 mmol/mol), according to guidelines from various medical organizations including the ADA, American College of Physicians, Association of Clinical Endocrinologists, and American College of Endocrinology.[221] [222] [223] [224] Based on the literature, this threshold serves as a ''take action'' point in managing diabetes and has been used in previous studies to indicate poor glycemic control. Achieving and maintaining target HbA1c levels is essential for individuals with diabetes (as well as the general population) and is a key goal of treatment. Moreover, we note that for the purposes of Quality Payment Program (QPP) measures, CMS has issued measures for diabetes (*e.g.* Quality ID #1 (NQF 0059): Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)).[225] The measure is described as ''Percentage of patients 18–75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.'' Furthermore, measures of HbA1c may fluctuate over time; therefore, a strict threshold could lead to incentives for multiple rounds of testing in order to aim for the levels established. In general, guidelines exist, but standards vary for defining diabetes states based on multiple severity measures.

In addition, the severity of periodontal disease is not uniformly defined. ICD–10 codes, such as K05.2 for Aggressive Periodontitis and K05.3 for Chronic Periodontitis may be utilized to describe more severe instances of periodontitis (and in this instance when such diagnosis codes are also partnered with diagnoses related to diabetes for a particular individual). Another approach involves using the Armitage criteria for periodontal diagnosis.[226] [227] Severity assessment can be based on the clinical attachment level (CAL), with CAL between 1 mm and 2 mm classified as slight, 3 mm and 4 mm as moderate, and ≥5 mm as severe.[228] Again, some standards exist relative to the staging of periodontitis, but such criteria vary. Additionally, we believe that the current practice of medicine would allow for variation in clinical attributes as well as judgment and discernment by the referring practitioner regarding the clinical status of the individual when determining the need for consultation with other practitioner types, including the dentist. We seek comment on whether clinical standards exist that describe and define the disease state of diabetes that would serve to inform the selection of treatment modalities, including potential referrals to dental professionals with respect to concerns related to oral health. We also seek comment from the public regarding the ways that CMS could ensure that practitioners do not decrease the quality of diabetes treatment in an effort to maintain a beneficiary's potential access to Medicare payment for dental services.

Evidence supplied by submitters also described periodontitis but without clear and consistent definitional structure. The 2017 World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions resulted in a new classification of periodontitis characterized by a multidimensional staging and grading system. The staging considers the aspects of severity, complexity, extent, and distribution while the grading

[220] American Diabetes Association. ''Standards of medical care in diabetes—2011.'' Diabetes care vol. 34 Suppl 1, Suppl 1 (2011): S11–61. *doi:10.2337/dc11–S011.*

[221] Liu, Longjian et al. ''Burden of Uncontrolled Hyperglycemia and Its Association with Patients Characteristics and Socioeconomic Status in Philadelphia, USA.'' Health equity vol. 4,1 525–532. 30 Dec. 2020, *doi:10.1089/heq.2020.0076.*

[222] Qaseem, Amir et al. ''Glycemic control and type 2 diabetes mellitus: the optimal hemoglobin A1c targets. A guidance statement from the American College of Physicians.'' Annals of internal medicine vol. 147,6 (2007): 417–22. *doi:10.7326/0003–4819–147–6–200709180–00012.*

[223] Cortez-Espinosa, Nancy et al. ''Abnormal expression and function of Dectin-1 receptor in type 2 diabetes mellitus patients with poor glycemic control (HbA1c>8%).'' Metabolism: clinical and experimental vol. 61,11 (2012): 1538–46. *doi:10.1016/j.metabol.2012.03.020.*

[224] Hu, Huanhuan et al. ''Hba1c, Blood Pressure, and Lipid Control in People with Diabetes: Japan Epidemiology Collaboration on Occupational Health Study.'' PloS one vol. 11,7 e0159071. 20 Jul. 2016, *doi:10.1371/journal.pone.0159071.*

[225] *https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2023_Measure_001_MIPSCQM.pdf.*

[226] Armitage, G C. ''Development of a classification system for periodontal diseases and conditions.'' Annals of periodontology vol. 4,1 (1999): 1–6. *doi:10.1902/annals.1999.4.1.1.*

[227] Caton, Jack G et al. ''A new classification scheme for periodontal and peri-implant diseases and conditions—Introduction and key changes from the 1999 classification.'' Journal of clinical periodontology vol. 45 Suppl 20 (2018): S1–S8. *doi:10.1111/jcpe.12935.*

[228] Pinho, M Morado et al. ''Periodontitis and atherosclerosis: an observational study.'' Journal of periodontal research vol. 48,4 (2013): 452–7. *doi:10.1111/jre.12026.*

contemplates primary criteria such as progression and grade modifiers, including risk factors such as smoking and diabetes.[229]

For the purposes of our consideration of medical services for the treatment of diabetes for individuals with diabetes who have periodontitis, we seek comment from the public on clinical criteria that would determine eligibility for effectiveness of periodontal treatment as described in the Cochrane review and other studies. We do not believe that a condition such as gingivitis or early stages of periodontitis would require oral treatment that in turn would influence the outcomes for an individual with diabetes. However, we seek information to address the following questions. At what stages and grading would the periodontitis be considered advanced and/or requiring dental and oral treatment intervention? What types of practitioners are able to make determinations regarding the staging of periodontitis? We also seek comment on patient eligibility. What determines patient eligibility for treatment for advanced periodontitis? Are there other criteria for consideration?

Additionally, we seek comment on the duration of potential periodontal treatment. How is the length of treatment determined? If a patient's clinical status improves with respect to the periodontal disease, what factors determine when periodontal treatment comes to an end? What does maintenance treatment entail? What services are provided in treatment of advanced periodontal disease? What is the service definition? Are services bundled? If yes, what is included in the bundle? When are the services provided and over what period? Is it provided over a calendar month period? A single day? Multiple days? Are services timed? Who provides the services? What specific terminology is involved? Are these services ever provided under supervision? Or ''incident to'' by other clinical staff?

We also seek information on how services for advanced periodontal disease are provided. Where and how are services for treatment of advanced periodontal disease provided? Are there any special rules, such as obtaining advance consent or performance of an initiating visit?

We also seek information regarding coding and billing of periodontal services. What coding is utilized for the treatment services for advanced periodontal disease? What claims format is employed for the submission of claims with related oral and dental services (for example, 837D and/or 837P)?

Additionally, we seek comment from the public regarding the risk of recurrence of periodontal disease for this patient population. What is the level of risk for re-development of advanced periodontitis and likelihood of recurrence?

We also seek information regarding the role of caries in management of diabetes. What is the prevalence of caries in this patient population? What is the impact of caries on management of diabetes?

We also seek information regarding the disease state of the diabetes itself and its interaction with dental services. Does evidence exist to support that certain characteristics related to diabetes management (for example, maintenance of HbA1c) are more closely tied to certain oral interventions' ability to yield clinical improvements?

We reiterate that section 1862(a)(12) of the Act generally precludes payment under Medicare Parts A or B for any expenses incurred for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. Thus, payment is permitted only where the dental services are inextricably linked to covered medical services. We believe that general maintenance and management of oral disease processes clearly falls within the statutory exclusion and therefore Medicare would not permit payment for routine dental and oral services.

We note that many submitters stated that good dental and oral health benefits a patient's overall health in general. Several commenters responding to the CY 2023 PFS proposed rule also expressed that good oral hygiene, along with routine dental services, contributes to better outcomes for patients. We recognized in the CY 2023 PFS final rule in response to those comments that there is a great deal of evidence suggesting that dental health is generally an important component of overall health; however, we are interested in comments on whether certain dental services are considered so integral to the primary covered services that the necessary dental interventions are inextricably linked to, and substantially related and integral to clinical success of, the primary covered services such that they are not subject to the statutory preclusion on Medicare payment for dental services under section 1862(a)(12) of the Act (88 FR 79033).

In summary, we seek comment on whether certain dental services are inextricably linked to certain other covered services for diabetes, supported by clinical evidence as described in section II.J.1.c. of this proposed rule. We also seek comment specifically on whether dental services such as prophylaxis are a standard of care in the management of diabetes. We are committed to continuing to explore the potential inextricable relationship between dental services and covered medical services utilized in treatment for individuals with diabetes. We thank submitters for the information they provided through the public submissions process and may consider revisions to the clinical examples codified in our regulations at § 411.15(i)(3)(i) based upon additional data and information received in response to this proposed rule.

4. Request for Comment on Dental Services Integral To Specific Covered Services To Treat Systemic Autoimmune Disease Requiring Immunosuppressive Therapies

We have received information from submitters suggesting that certain dental services are inextricably linked to immunosuppressive therapies for individuals with autoimmune disorders.

According to the NIH's National Institute of Environmental Health Sciences, a healthy immune system is able to defend the body against disease and infection. However, if the immune system malfunctions, it may mistakenly attack healthy cells, tissues, and organs. This scenario is called autoimmune disease, and these attacks can affect any part of the body, weaken bodily function, and in some cases become life-threatening.[230] There are over 100 autoimmune diseases, including Type 1 diabetes, multiple sclerosis, lupus, rheumatoid arthritis, and inflammatory bowel disease. There are also other autoimmune diseases that are rare and difficult to diagnose. In some cases, patients may suffer for years before receiving a proper diagnosis, and most of these diseases have no cure. Additionally, some autoimmune diseases require lifelong treatment for system management.[231]

Autoimmune diseases are continuously affecting more people. Estimates indicate that as many as 50 million people in the U.S. have an autoimmune disease, making it the third

[229] Tables from Tonetti, Greenwell, Kornman. J Periodontol 2018;89 (Suppl 1): S159–S172. *https://www.perio.org/wp-content/uploads/2019/08/Staging-and-Grading-Periodontitis.pdf.*

[230] *https://www.niehs.nih.gov/health/topics/conditions/autoimmune.*

[231] Ibid.

most prevalent disease category, surpassed only by cancer and cardiac disease. Generally speaking, a person's genes in combination with infections and other environmental exposures likely play a significant role in disease development, though in some instances pathology may be unknown. Additionally, nearly 80 percent of people with a chronic autoimmune condition are women.[232] Symptoms of autoimmune diseases can include: fatigue, pain, dermatologic manifestations, weight loss or gain, insomnia, fever, and myriad other symptoms.[233]

Many treatment modalities are employed in the management of autoimmune diseases. Treatments could include use of oral medications, including steroids, anti-inflammatory medications, as well as infusion immunotherapy. Some autoimmune conditions may present in a localized fashion, such as Sjogren's, and many of the independent organ inflammations, require immunosuppressive therapies, and may progress to a more systemic involvement. Conversely, some systemic autoimmune diseases, like sarcoidosis, may not require immunosuppression in mild cases.

Submissions through the public submissions process urged us to provide that payment can be made for dental services for individuals with autoimmune diseases receiving immunosuppressive therapy. In submissions, several interested parties have asserted that immunosuppressive therapies utilized in the treatment of autoimmune disease have similar immunosuppressive effects as those of toxic chemotherapy utilized in the treatment of cancer and that these treatments are analogous to the clinical examples finalized in CY 2024 PFS rulemaking for dental services inextricably linked to covered medical services in the treatment of cancer.

Submitters stated that oral and dental treatment is also often integral to the successful care and management of beneficiaries with autoimmune diseases who are initiating or undergoing immunosuppressive or immunomodulator therapy because the absence of medically necessary oral and dental treatment can pose serious complications to those beneficiaries and the covered medical services they receive. Submitters state that, for example, dental infections can spread quickly when host immunity is compromised by immunosuppressing or immunomodulating drugs utilized in treatment. As such, submitters note that the American College of Physicians has described that the implications of dental disease in patients who are undergoing immunosuppressive therapy extend beyond their oral disease, with potentially life-threatening complications if the dental problems are not treated. For these reasons, submitters state that the covered services upon which immunocompromised patients depend (for example, immunosuppressive therapy) should not proceed until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection.

Submitters provided information regarding specific covered services that they believe could be associated with treatments for immunosuppressive therapy for the treatment of autoimmune disease and that may increase infection risk, such as:

- CPT codes 99212–99215: Evaluation and Management (E/M) Services.
- CPT codes 96365–96368: Infusion services.

Submitters also provided coding information related to drug therapies, such as CPT codes for immunosuppressant drugs, including:

- J0129: Abatacept (Orencia) for Rheumatoid Arthritis.
- J0135: Adalimumad (Humira) for Crohn's, Ulcerative Colitis, Rheumatoid Arthritis.
- J0490: Belimumab (Benlysta) for systemic lupus erythematosus (SLE), Lupus Nephritis, and Sjögren's.
- J0491: Anifrolumab-fnia (Saphnelo) for systemic lupus erythematosus (SLE).
- J1303: Ravulizumab-cwvz (Ultomiris) for Generalized Myasthenia Gravis.
- J1438: Etanercept (Enbrel) for Rheumatoid Arthritis, Ankylosing Spondylitis.
- J1595: Glatiramer (Copaxone) for Multiple Sclerosis.
- J1602: Golimumab (Simponi) for Rheumatoid Arthritis, UC, Ankylosing Spondylitis.
- J1745: Infliximab (Remicade) for Crohn's, Ulcerative Colitis, Rheumatoid Arthritis.
- J2250: Upadacitinib (Rinvoq) for Rheumatoid Arthritis, Ulcerative Colitis, Crohn's.
- J2323: Natalizumab (Tysabri) for Multiple Sclerosis.
- J2350: Ocrelizumab (Ocrevus) for Multiple Sclerosis.
- J3262: Tocilizumab (Actemra) for Scleroderma-associated lung fibrosis.
- J3357: Ustekinumab (Stelara) for Crohn's, Ulcerative Colitis, Psoriatic Arthritis.
- J3380: Vedolizumab (Entyvio) for Crohn's, Ulcerative Colitis.
- J3590: Secukinumab (Cosentyx) for Plaque Psoriasis.
- J7500: Azathioprine (Imuran) for Lupus, Crohn's, Sjögren's.
- J7517: Mycophenolate (Cellcept) for Lupus, Sjögren's.
- J9070: Cyclophosphamide (Cytoxan) for Sjögren's, Vasculitis.
- J9250: Methotrexate for Sjögren's, Rheumatoid Arthritis (unresponsive to other treatment).
- J9302: Ofatumumab (Kesimpta) for Multiple Sclerosis.
- J9312: Rituximab (Rituxan) for Rheumatoid Arthritis, Sjögren's.
- J9332: Efgartigimod (Vyvgart) for Myasthenia Gravis.

Submitters also provided coding information for potential medical services for medical treatment for pulmonary diseases when aspiration of dental pathogens risk or cause the initiation and/or recurrence of complications, such as:

- CPT codes 99212–99215: Evaluation and Management (E/M) Services.
- CPT code 99291: Critical Care Services.
- DRG code 177: Hospitalization for respiratory infections and inflammation.
- DRG code 190: COPD with complications.

Submitters also provided coding regarding medical treatment for dentally sourced dissecting maxillofacial space infections:

- CPT 41000: Intraoral incision and drainage of abscess.
- CPT 87181: Antibiotic susceptibility study.
- CPT 96365: Infusion of antibiotic.
- CPT codes 99281–99285: Emergency department services.
- CPT codes 99291–99292: Critical care services.
- DRG code 135: Sinus procedures with CC/MCC.
- DRG code 141: Major head and neck procedures with CC.
- DRG code 872: Hospitalization for septicemia or severe sepsis.

Submitters providing information through the public submissions process stated that if dental or oral infections are left undetected or untreated in the population of individuals undergoing immunosuppressive therapy for autoimmune disease, serious complications may occur and negatively impact the course and outcome of the covered medical procedures, which submitters state is analogous to previously finalized policies for dental

[232] Ibid.

[233] *https://www.womenshealth.gov/a-z-topics/autoimmune-diseases.*

services inextricably linked to covered cancer treatment for the patient. Several submitters pointed out that we stated in the CY 2024 PFS final rule that proceeding without a dental or oral exam of the mouth prior to chemotherapy could lead to systemic infection or sepsis, among other complications, and that similar outcomes can follow for those receiving immunosuppressive therapy to treat autoimmune diseases.

The submitters noted that in the CY 2024 PFS final rule, we described that AHRQ identified evidence to support that dental evaluation/treatment prior to cancer treatment led to decreased incidence and/or less severity of serious oral infections and complications like oral mucositis and encouraged CMS to explore this connection to confirm that dental evaluations and treatment prior to immunosuppressive therapy would lead to decreased incidence of serious oral infections in a similar fashion. The submitters also stated that they believe it is critical that beneficiaries with an autoimmune disease that requires immunosuppressive therapy have access to necessary dental services, as proper dental care for this population can reduce the incidence of serious infection and improve overall patient outcomes for the covered service.

We appreciate the evidence and information provided by submitters and agree that we should continue to research whether there is a connection between dental and oral evaluations and treatment prior to immunosuppressive therapy and outcomes for said therapies, including the potential decreased incidence of serious oral infections.

However, we seek comment on whether the level of immunosuppression utilized in the treatment of autoimmune diseases is analogous to the immunosuppression levels employed in the treatment of cancer. We believe that the level of immunosuppression for systemic autoimmune disease has different characteristics versus therapies utilized in chemotherapy used in the treatment of cancer. For example, the usage of monoclonal antibodies in the treatment of autoimmune disease may not render the same level of immunosuppression and subsequent susceptibility to infection as chemotherapy used in the treatment of cancer.

We also seek information on the connection between immunosuppressive therapy in the treatment of autoimmune disease and the likelihood of systemic infection and sepsis. Specifically, we seek information regarding the likelihood of dental and oral sources as the locus of the seeding of infection in this patient population. Additionally, we seek information regarding standards of care or clinical guidelines that recommend that a dental infection be addressed before proceeding with the immunosuppressive treatment or the administration of drugs or whether oral antibiotics would be prescribed to resolve the infection and that the therapy would advance without direct dental or oral services to address the infection.

We also seek information regarding whether there is differential impact between drugs that are administered in an office setting or similar versus those medications that are taken in an oral fashion.

We thank submitters for the information they provided through the public submissions process. We believe that additional information is necessary to consider whether there is an inextricable link between dental services and covered services to treat systemic autoimmune disease requiring immunosuppressive therapies and seek comment from the public. We remain open to considering any such services identified by public commenters, and, if sufficient evidence is presented, we may consider adding such services to § 411.15(i)(3) in the final rule.

5. Implementation of Payment for Dental Services Inextricably Linked to Other Specific Covered Services

In the CY 2024 PFS final rule (88 FR 79035 through 79039), we solicited comments on whether we should provide additional guidance that would aid in processing claims for dental services that are inextricably linked to a Medicare-covered medical service. Some commenters suggested the usage of a modifier on the dental claim format that would better identify when dental services are inextricably linked to specific covered medical services. As we continue to consider improvements to our payment policies and have gained experience around the provision of dental services inextricably linked to covered medical services, we have explored tools and resources that may help to facilitate the implementation and coordination of dental services that are currently covered under Medicare, including the possible usage of modifiers and diagnosis codes. The usage of modifiers on a dental claim would seek to identify the dental service as a service the billing practitioner identifies as inextricably linked to a specific covered medical service and for which there was an exchange of information, or integration, between the medical and dental professional (physician, including a dentist, or other non-physician practitioner) as specified in the CY 2023 PFS final rule (87 FR 69663 through 69688). We have explained that if there is no exchange of information, or integration, between the medical professional (physician or other non-physician practitioner) regarding the primary medical service and the practitioner furnishing the dental services, then there would not be an inextricable link between the dental and covered medical service within the meaning of our regulation at § 411.15(i)(3). Furthermore, integration between medical and dental professionals can occur when these professionals coordinate care. This level of coordination can occur in various forms such as, but not limited to, a referral or exchange of information between the medical professional (physician or non-physician practitioner) and the dentist. This coordination should occur between a dentist and another medical professional (physician or other non-physician practitioner) regardless of whether both individuals are affiliated with or employed by the same entity.

Currently, the KX modifier is submitted on a Medicare Part B claim to indicate that the service or item is medically necessary, and that the healthcare provider has included appropriate documentation in the medical record to support or justify the medical necessity of the service or item. We believe that usage of the KX modifier in the context of claims for dental services inextricably linked to covered services would be appropriate and support claims processing and program integrity efforts.

Based on comments received and summarized in the CY 2024 PFS final rule (88 FR 79037), interested parties requested that we provide more guidance on how a practitioner submitting claims for dental services can attest that the dental and medical services are inextricably linked, and that the criteria have been met to support payment. We believe that the use of the KX modifier would allow practitioners to signal that the dental services meet the criteria to support payment. Also, use of the KX modifier may improve the MACs' ability to ascertain the volume of claims that are being submitted for dental services inextricably linked to covered services.

Therefore we are proposing that, effective January 1, 2025, the KX modifier would be required for claims submission for dental services inextricably linked to covered medical services on both the dental claim format 837D and the professional claim format

837P. We are proposing that practitioners who bill for dental services for which they seek payment in accordance with § 411.15(i)(3) must include the KX modifier on the 837D or 837P claim to indicate that they believe that the dental service meets the established payment criteria; that the practitioner has included appropriate documentation in the medical record to support or justify the medical necessity of the service or item and that demonstrates the inextricable linkage to covered medical services; and that coordination of care between the medical and dental practitioners has occurred. To help with this transition to potentially requiring use of the KX modifier for claims submission for dental services inextricably linked to covered medical services beginning in 2025, practitioners now have the option to utilize the KX modifier as proposed, for services with dates of service in CY 2024. This optional usage in CY 2024 would not be mandatory and would serve to support both clinician and MAC claims processing activities. We intend to provide additional instruction and education through subregulatory guidance regarding this voluntary phase of the usage of the KX modifier on claims submitted for dental services inextricably linked to covered medical services. We seek comment on all aspects of this proposal.

While the KX modifier indicates that the services are medically necessary, the GY modifier (along with three other HCPCS denial modifiers) serves to indicate that a service is not covered because it is outside of the scope of Medicare coverage authorized by the statute. We reiterate that denial modifiers should be used when physicians, practitioners, or suppliers want to indicate that the item or service is statutorily non-covered.

Use of the GY modifier could support MAC efforts to adjudicate claims and remove from the claims processing pipeline those claims that do not require further processing. We are seeking comment on whether we should recommend the usage of the GY modifier on the 837D or 837P dental claim format in instances where a Medicare claim denial is sought for purposes of submission to third party payers or when the service does not fit within a Medicare benefit category and is statutorily excluded from coverage.

Additionally, in general, the Act and our regulations mandate the submission of diagnostic coding (for example, ICD–10 codes) on Medicare claims. Section 1842(p)(1) of the Act states that ''each request for payment, or bill submitted, for an item or service furnished by a physician or practitioner specified in subsection (b)(18)(C) for which payment may be made under this part shall include the appropriate diagnosis code (or codes) as established by the Secretary for such item or service.'' Under this section, each bill or request for payment for physicians' services under Medicare Part B must include the appropriate diagnostic code ''as established by the Secretary'' for each item or service for which the Medicare beneficiary received treatment. In the March 4, 1994 final rule entitled *Medicare Program; Diagnosis Codes on Physician Bills,* we codified that each bill or request for payment for a service furnished by a physician under Medicare Part B must include appropriate diagnostic coding for the diagnosis or the symptoms of the illness or injury for which the Medicare beneficiary received care and revised our regulations at § 424.32, *Basic requirements for all claims,* to state specifically that a claim for physician services must include appropriate diagnostic coding using diagnostic information (59 FR 10290).

Additionally, in the CY 2023 PFS final rule, we stated that dentists are included in the statutory definition of physician at section 1861(r)(2) of the Act and would generally be considered and treated as a physician for purposes of enrollment, compliance, and other administrative programs (87 FR 69673). Therefore, dentists, who are physicians for the purposes of the Medicare program, are required to submit diagnosis codes on claims for physician services as described in the statute and regulations. Furthermore, we note that diagnosis code information is currently required on the submission of the professional claim form 837P; professional claims lacking such information are returned to the healthcare provider and are not processed.

In the CY 2023 PFS final rule (87 FR 69679 through 69680), we acknowledged the need to address and clarify certain operational issues related to Medicare payment for dental services inextricably linked to covered services and noted that we were working to address these issues, including claims processing questions raised by the commenters. We stated that we anticipated resolving many of the additional operational issues raised by commenters potentially as soon as CY 2024, including efforts to adopt the dental claim form (837D). Similarly, in the CY 2024 PFS final rule (88 FR 79036), we stated that we continue to work to address issues raised by commenters, such as questions related to claims processing and efforts to accommodate the dental claim form within our claims processing systems, effective 2024. The efforts related to adopting the dental claim form are ongoing, and as efforts advance to address the implementation and functionality of claims processing systems for the dental claim form, we intend to provide appropriate guidance and education to interested parties.

We anticipate that our systems will be able to process claims submitted using the dental claim form 837D (OMB Control No. 0938–1471) by January 1, 2025. Consistent with the statutory and regulatory requirements discussed above, we intend to require a diagnosis code to be included on claims submitted for physicians' services for dental services inextricably linked to covered medical services on both the 837P and 837D formats, beginning on January 1, 2025. However, given the complexities related to the operational launch of and transition to the 837D dental claims format, we are also considering further delaying the requirement to include a diagnosis code on the 837D form. For example, interested parties have indicated that in current dental practice, claims processing systems may not require the submission of a diagnosis code on claims for dental services, and therefore dental practices may need time to adjust to this requirement for the 837D form. We believe that it may be appropriate to delay this requirement for a limited time to support clinicians and billing entities as they seek to change their workflows and transition to using the 837D form. We seek comment on our intention to require the inclusion of a diagnosis code on the 837D form beginning on January 1, 2025. We are particularly interested in any operational challenges that interested parties may face in attempting to comply, as well as other considerations that we should take into account with regard to the timing of this requirement.

In the CY 2023 PFS final rule, we stated that we believed that MACs are appropriately situated to establish contractor prices for dental services inextricably linked to covered services until we have additional pricing data that could enable national pricing (87 FR 69680). Therefore, dental services inextricably linked to covered services are currently contractor priced. However, we have received feedback from the MACs regarding pricing information for dental services inextricably linked to covered services, and the MACs have requested information that would support their efforts to assign payment amounts for such dental services. The MACs retain

broad flexibility with respect to assigning payment amounts to claims for dental services inextricably linked to covered services; however, we seek to facilitate the sharing of available pricing information with the MACs for these purposes. Thus, we seek comment from the public on potential sources of payment information for the pricing of dental services inextricably linked to covered services. We note, for example, that publicly available data (such as Fair Health cost data) are available for purchase; however, we understand that this information may not directly inform payment amounts in a manner useful for the payment of Medicare claims for dental services. According to Fair Health's website, cost estimate information is based on claims for medical and dental services paid for by private insurance plans, including the country's largest insurers.[234] We are also aware of other fee schedules, such as those used by state governments for state employees, or discount fee schedules, such as discount dental programs (for example, *https://www.dentalbenefitprogram.com/groupfees.php?id=NEV*). We aim to support the ongoing efforts by the MACs to price these services and seek any information from the public that may serve to support and inform the MAC development of payment amounts for dental services inextricably linked to covered services.

6. Request for Information: Services Associated With Furnishing Oral Appliances Used for the Treatment of Obstructive Sleep Apnea

Section 1861(s) of the Act defines the term ''medical and other health services'' that may be covered under Medicare, including physicians' services under section 1861(s)(1), services and supplies furnished incident to a physician's professional service under section 1861(s)(2)(A), and durable medical equipment (DME) under section 1861(s)(6) of the Act.[235]

In addition to the statutory definition of DME, § 414.202 of our regulations defines DME as equipment furnished by a supplier or a home health agency that meets the following conditions:

- Can withstand repeated use.
- Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- Is primarily and customarily used to serve a medical purpose.
- Generally is not useful to an individual in the absence of an illness or injury.
- Is appropriate for use in the home.

For items to be considered DME, all five criteria of the definition must be met. The CMS policies for determining whether an item meets the definition of DME are further outlined in the Medicare Benefit Policy Manual (CMS Pub. 100–02), Chapter 15, section 110.1. With respect to the first and second criteria, DME items must be able to withstand repeated use in the home, potentially by successive patients.

Different types of oral appliances are fabricated and furnished by licensed dentists (DDS or DMD) to reposition oral and pharyngeal tissues in an effort to create and maintain a patient's airway during sleep for treatment of obstructive sleep apnea. Obstructive sleep apnea is a medical disorder in which a person frequently stops breathing during sleep. It results from an obstruction of the upper airway during sleep that occurs because of inadequate motor tone of the tongue and/or airway dilator muscles. A treating practitioner may prescribe use of an oral appliance as the first line of treatment for obstructive sleep apnea, or in cases where other treatments, such as use of a continuous positive airway pressure (CPAP) device and/or bi-level positive airway pressure device have been tried and failed.

The following two HCPCS Level II codes were established effective January 1, 2006, for these devices:

- E0485 ''Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment''.
- E0486 ''Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment''.

A very limited subset of custom fabricated oral appliances used to treat obstructive sleep apnea (HCPCS code E0486) have been covered for Medicare beneficiaries by the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) under the DME benefit. These devices are considered durable equipment by the DME MACs because of the presence of a fixed mechanical hinge.

An additional HCPCS code was established effective April 1, 2022, to describe custom fabricated oral appliances without a fixed mechanical hinge:

- K1027 ''Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment''.

The DME MACs have not covered any of the prefabricated devices (HCPCS code E0485) based on a determination that there is insufficient evidence to support that these items are effective therapy for obstructive sleep apnea. The DME MAC Local Coverage Determination for the devices is available at *https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=33611&ver=25*.

For several years, manufacturers of products without fixed mechanical hinges that dentists use in custom fabricating oral appliances have raised concerns regarding why their versions of the custom fabricated oral appliances have not been classified as DME. There have been an increasing number of requests for HCPCS codes and Medicare benefit category determinations from several different manufacturers of these products. Using the public meeting consultation process outlined in regulations at § 414.240, we obtained public consultation regarding these various products. National Medicare benefit category determinations have not been established for these appliances because we have not been able to confirm that any of the custom fabricated devices can withstand repeated use. As indicated above, equipment must be able to withstand repeated use in order to be classified as DME, which means they are items that can normally be rented and used by successive patients (repeated use).

We are not aware of any oral appliances used to treat obstructive sleep apnea, regardless of whether they include a fixed mechanical hinge, that are prefabricated, or custom fabricated, and can withstand repeated use. These are oral appliances that do not seem to be the kind of equipment that could potentially be rented and used by successive patients. In addition, national fee schedule amounts have not been established for the devices with the mechanical hinge because of complexities related to pricing of the professional services of the dentist that are integral to the fabrication and furnishing of the device. The DME MACs have been paying claims for devices they have been covering as DME under code E0486 using local fee schedule amounts. Before making a final determination regarding whether these devices could be classified as DME, we are requesting information that would help us determine if oral appliances used to treat obstructive sleep apnea can withstand repeated use (furnished as rental equipment for use by successive patients).

[234] *https://www.fairhealthconsumer.org/#answer2;* Accessed May 22, 2024.

[235] *https://www.ssa.gov/OP_Home/ssact/title18/1861.htm.*

As described in section II.J.1.a. of this proposed rule, section 1862(a)(12) of the Act generally precludes payment under Medicare Parts A or B for any expenses incurred for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. Oral sleep apnea appliances and similar appliances are used in the direct treatment of sleep apnea. A treating practitioner may prescribe the use of an oral sleep apnea appliance as the first line of treatment for obstructive sleep apnea, a medical condition, or in instances where other treatments, such as use of a CPAP device and/or bi-level positive airway pressure device have been tried and failed. Therefore, we believe that these appliances and related services, while utilized in the mouth and situated on the teeth, would not be considered services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting the teeth. Rather, we believe that oral sleep apnea appliances, when prescribed by a practitioner for the treatment of a medical condition such as obstructive sleep apnea, as medically reasonable and necessary and therefore may be payable by Medicare. Further, we believe that payment for oral sleep apnea appliances would not fall within the payment policy for dental services inextricably linked to covered medical services, as the appliances are not services for dental care, but are instead services and supplies for the purposes of directly treating a medical condition unrelated to teeth or structures directly supporting the teeth (for example, sleep apnea).

The statutory definition of physician includes a doctor of dental surgery or of dental medicine in section 1861(r)(2) of the Act, and, to the extent payment for dental services is not precluded under section 1862(a)(12) of the Act, medically necessary services furnished by a dentist may be covered and paid as physicians' services under section 1861(s)(1) and (2), and section 1848 of the Act.

We are requesting information regarding the types of services furnished by a dentist or other practitioner related to oral sleep apnea appliances. Specifically, we are seeking information regarding details that may inform or support a future proposal regarding a code assignment for services related to oral sleep apnea appliances under the Medicare physician fee schedule.

We are requesting details and information regarding the services related to the furnishment of oral appliances used to treat obstructive sleep apnea, as described in the questions below:

- *Patient eligibility criteria:* to whom is the service related to the furnishing of oral appliances being provided? How is the nuisance snorer differentiated from the medical condition of sleep apnea? What criteria are used to determine whether the provision of these services may be medically reasonable and necessary?
- *Services provided:* What is the service definition for oral sleep apnea appliances? Is a bundle of services provided? If yes, what services are included in the bundle? What does the process for evaluating, furnishing, and fitting of oral sleep apnea appliances involve? What work is involved? Which elements of the services are essential (particularly in terms of what work is essential to the effectiveness of the device)? What are the costs associated with providing these services? What are the payment amounts for these services?
- *Timing of services:* What is the service period? Are the services provided over a period of time? Are services timed in any way?
- *Practitioner type:* Who provides these services? What credentialing is required? Is supervision required? Who would be billing for these services? Would incident to payment policy rules apply?
- *Location of services:* Where and how are services for oral sleep apnea appliances provided? Are all services provided in an in-person setting? Does the patient have to be present for all elements of this service? Does the service involve direct contact with the patient in each instance?
- *Considerations for Telehealth:* Are any of these services provided, or capable of being provided, via telehealth?
- *Site of service:* Can services related to oral sleep apnea appliances be provided by hospital-based physicians?
- *Other considerations:* What billing procedures exist for these oral sleep apnea appliances? What existing and/or additional coding may currently describe these types of services? In addition to the HCPCS Level II codes described above (for example, E0485 and E0486), we believe that the CDT codes D9947 through D9957 may describe both the fabrication of the appliance as well as services provided during and after fabrication.

We will review any information provided by the public and consider potential refinements to PFS payment policy accordingly. We reiterate that we do not believe the evaluation services or fabrication and fitting of oral sleep apnea appliances by dentists or other physicians or non-physician practitioners would be subject to the prohibition on payment for dental services under section 1862(a)(12) or the payment policy for dental services inextricably linked to covered services. However, we seek information regarding the services associated with the provision of these appliances and may consider code creation or other refinements in the context of the Medicare physician fee schedule. Additionally, we note that as described in section II.C. of this proposed rule, individuals and groups may nominate codes that they believe may be potentially misvalued codes through our public nomination process for potentially misvalued codes, which was established in the CY 2012 PFS final rule with comment period (76 FR 73026, 73058 through 73059). Individuals could consider nominating codes related to oral sleep apnea appliances for consideration under this process. Nominations may be submitted to CMS in one of two ways: via email or through postal mail. Email submissions should be sent to the CMS email box at *MedicarePhysicianFeeSchedule@cms.hhs.gov*, with the phrase ''Potentially Misvalued Codes'' and the referencing CPT code number(s) and/or the CPT descriptor(s) in the subject line. Physical letters for nominations should be sent via the U.S. Postal Service to the Centers for Medicare & Medicaid Services, Mail Stop: C4–01–26, 7500 Security Blvd., Baltimore, Maryland 21244. Envelopes containing the nomination letters must be labeled ''Attention: Division of Practitioner Services, Potentially Misvalued Codes.'' Nominations for consideration in our next annual rule cycle should be received by our February 10th deadline.

K. Payment for Skin Substitutes

In the CY 2023 PFS proposed rule (87 FR 46027 through 46029), we outlined several objectives related to refining skin substitute policies under Medicare, including: (1) ensuring a consistent payment approach for skin substitute products across the physician office and hospital outpatient department settings; (2) ensuring that appropriate HCPCS codes describe skin substitute products; (3) using a uniform benefit category across products within the physician office setting, regardless of whether the product is synthetic or comprised of human or animal-based material, to incorporate more consistent payment methodologies; and (4) maintaining clarity for interested parties on CMS skin substitutes policies and procedures. When considering potential changes to policies involving skin

substitutes, we noted that we believe it would be appropriate to take a phased approach over multiple rulemaking cycles to examine how we could appropriately incorporate skin substitutes as supplies under the PFS ratesetting methodology. After receiving feedback from commenters requesting more information on how CMS intends to achieve a consistent payment approach for skin substitute products, we did not finalize any policies in the CY 2023 PFS final rule.

In alignment with our objectives, in the CY 2024 PFS final rule, we solicited comments on different approaches CMS could use to identify appropriate practice expense (PE) direct costs for skin substitute products, such as reviewing various sources for price information, including performing market research, reviewing invoices submitted by interested parties, or cost information on Medicare claims. Discussing these approaches in the CY 2024 PFS final rule provided interested parties with more details about payment mechanisms CMS is considering under our PFS ratesetting methodology.

The CY 2024 PFS proposed rule did not contain a specific proposal for changing how skin substitute products are paid under the PFS; however, we continue to pursue our objectives for refining skin substitute payment policies under Medicare, as mentioned above. More specifically, we continue examining ways to treat skin substitute products as incident-to supplies under the PFS ratesetting methodology. Additionally, we believe continuing this dialogue with interested parties on payment for skin substitute products will help inform potential policy changes for future rulemaking.

We recognize that skin substitute products may vary in composition, size, and applicability and will continue to consider these distinct characteristics in proposing a consistent payment approach and policy. We also note an increase in HCPCS Level II coding request applications for newly developed skin substitute products and are considering broadly all of our relevant payment policies. Such policies, for example, include the discarded drug refund policy and the Part B drug inflation rebate policy and how these policies may align with the usage and payment for skin substitute products. In the CY 2024 PFS final rule (88 FR 79060 through 79061), we finalized that billing and payment codes that describe products currently referred to as skin substitutes are not counted for identifying refundable drugs for calendar quarters during 2023 and 2024. While we continue to consider making changes to the Medicare Part B payment policies for such products, similar to last year, for CY 2025, we are proposing that billing and payment codes that describe products currently referred to as skin substitutes would not be counted for purposes of identifying refundable drugs for calendar quarters in 2025. We plan to revisit discarded drug refund obligations for skin substitutes in future rulemaking. In section III.I. of this proposed rule, CMS is proposing to codify existing policy by including products currently referred to as skin substitutes on the list of product categories that are not considered Part B rebatable drugs in proposed § 427.101(b)(5).

III. Other Provisions of the Proposed Rule

A. Drugs and Biological Products Paid Under Medicare Part B

1. Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs to Provide Refunds with Respect to Discarded Amounts (§§ 414.902 and 414.940)

a. Background

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58, November 15, 2021) (hereinafter referred to as ''the Infrastructure Act'') amended section 1847A of the Act to redesignate subsection (h) as subsection (i) and insert a new subsection (h), which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug (hereinafter referred to as ''refundable drug'') for calendar quarters beginning January 1, 2023.

In the CY 2023 PFS final rule (87 FR 69710 through 69734), we finalized many policies to implement this provision. First, we finalized the requirement that billing providers and suppliers report the JW modifier for all separately payable drugs and biologicals (hereinafter referred to as ''drugs'') with discarded drug amounts from single use vials or single use packages payable under Part B, beginning January 1, 2023 (87 FR 69719). We also finalized the requirement that billing providers and suppliers report the JZ modifier for all such drugs with no discarded amounts beginning no later than July 1, 2023, and we stated that we would begin claims edits for both the JW and JZ modifiers beginning October 1, 2023 (87 FR 69718 through 69719). After the issuance of the CY 2023 PFS final rule, CMS published a JW Modifier and JZ Modifier Policy Frequently Asked Questions (FAQ) document [236] to provide further guidance on the correct use of these modifiers.

Second, we adopted a definition of ''refundable single-dose container or single-use package drug'' at § 414.902, which also specifies exclusions from this definition (87 FR 69724). These three exclusions are: radiopharmaceutical or imaging agents, certain drugs requiring filtration, and drugs approved by FDA on or after November 15, 2021 for which payment has been made under Part B for fewer than 18 months.

Third, regarding reports to manufacturers, we specified that we would send reports (including information described in section 1847A(h)(1) of the Act) for each calendar quarter, on an annual basis, to each manufacturer of a refundable drug (87 FR 69726).

Fourth, we finalized how the refund amount will be calculated, which is specified in regulation at § 414.940 (87 FR 69731). We stated we would issue a preliminary report based on available claims data from the first two quarters of CY 2023 to provide manufacturers information regarding discarded amounts of refundable drugs prior to the initial refund report (87 FR 69725). In these reports, which were sent in December of 2023, we included preliminary information on estimated discarded amounts of refundable drugs for each labeler code based on available claims data from the first 2 quarters of CY 2023 for any refundable drug for which discarded units were billed using the JW modifier. More information about discarded drugs, including the discarded drug refund and the JW and JZ modifier policy, can be found at *https://www.cms.gov/medicare/payment/part-b-drugs/discarded-drugs*.

Fifth, we addressed drugs with unique circumstances for which we can, through notice-and-comment rulemaking, increase the applicable percentage otherwise applicable for determining the refund. Section 1847A(h)(3)(B)(ii) of the Act provides that, in the case of a refundable drug that has unique circumstances involving similar loss of product as that described in section 1847A(h)(8)(B)(ii) of the Act, the Secretary may increase the applicable percentage otherwise applicable as determined appropriate by the Secretary. We adopted an increased applicable percentage of 35 percent for drugs reconstituted with a hydrogel and with variable dosing based on patient-

[236] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf*.

specific characteristics (87 FR 69731). Lastly, we adopted a dispute resolution process through which manufacturers can challenge refund calculations, and we established enforcement provisions, including manufacturer audits, provider audits, and civil money penalties required by statute (87 FR 69732 through 69734).

In the CY 2024 PFS final rule (88 FR 79047 through 79064), we finalized the date of the initial refund report to manufacturers, the date for subsequent reports, method of calculating refunds for discarded amounts in lagged claims data, method of calculating refunds when there are multiple manufacturers for a refundable drug, increased applicable percentages for certain drugs with unique circumstances, and a future application process by which manufacturers may apply for an increased applicable percentage for a drug, which would precede proposals to increase applicable percentages in rulemaking.

We also finalized that drugs separately payable under Part B from single-dose containers that are furnished by a supplier who is not administering the drug are required to be billed with the JZ modifier, since we believe it is unreasonable to collect discarded drug data from beneficiaries. We were concerned that claim rejections may occur in the absence of a claims modifier to designate that a drug was dispensed, but not administered, by the billing supplier.

b. Application for Increased Applicable Percentage

Section 1847A(h)(3)(B)(ii) of the Act permits the Secretary to increase the applicable percentage for a refundable drug that has unique circumstances through notice and comment rulemaking. In the CY 2024 PFS final rule (88 FR 79057 through 79060), we finalized an application process (CMS–10835, OMB 0938–1435) by which manufacturers could apply for an increased applicable percentage for a drug and may request that we consider an individual drug to have unique circumstances for which an increased applicable percentage is appropriate. We explained that manufacturers could benefit from a formal process through which they can provide information, including that which may not be publicly available, in order to request an increase in their refundable drug's applicable percentage and provide justification for why the drug has unique circumstances for which such an increase is appropriate, including in the case of a drug with an applicable percentage that has already been increased by virtue of its unique circumstances. We finalized the application deadline of February 1 of each year, adopted a deadline of August 1 for the FDA-approval of the drug and the deadline for notifying and submitting the FDA-approved label to CMS of September 1 of the year before the year in which the increased applicable percentages would apply. We codified this process in regulation at § 414.940(e). The application process requires the applicant to provide a written request comprising FDA-approved labeling for the drug; justification for the consideration of an increased applicable percentage based on such unique circumstances; and justification for the requested increase in the applicable percentage.

We received one application for increased applicable percentage for CY 2025 from the manufacturer of Leukine® (sargramostim). Leukine® is a leukocyte growth factor that is primarily used in hematological malignancies to increase white blood cell counts. The applicant submitted the information required under § 414.940(e)(1), including its justification for consideration for increased applicable percentage, and justification for the requested applicable percentage of 72 percent. The applicant did not submit FDA-approved labeling for the drug for the particular adjuvant uses described in the application (further described below in this paragraph) due to ongoing cancer vaccine adjuvant trials. The applicant states that there are several manufacturers in late-stage (Phase II and Phase III) development using Leukine® as a vaccine adjuvant in oncology indications, specifically in stimulating the immune response of dendritic cells when used alongside these vaccines. Cancer treatment vaccines are different from the vaccines that work against viruses (for example, influenza). These vaccines try to get the immune system to mount an attack against cancer cells in the body. Instead of preventing disease, they are meant to get the immune system to attack a disease that already exists.[237] The applicant stated that it has no ownership stake in the development of these vaccines and does not possess control or influence over the design and execution of the clinical trials. The estimated completion dates for Phase III clinical trials vary, with the earliest expected in March 2025 [238] and the latest in March 2029.[239] The adjuvant use of Leukine® in predetermined dosage introduces a new use of the drug that is distinct from its six FDA-approved indications, all of which have dosages that are based on body weight or body surface area (BSA). The adjuvant use dosages of Leukine® in clinical trials are generally much smaller than dosages for indications in the FDA-approved labeling. The smallest dose of Leukine® used for vaccine adjuvant purposes of which the applicant is aware (that is, 70 mcg) would lead to as much as 72 percent of the drug being discarded from a single-dose 250 mcg lyophilized vial, which is the only size available commercially. The applicant suggested that if use of these small doses were to become more common, the percentage of discarded units could increase the discarded drug refund amount that could be owed by the applicant, even though the applicant lacks control or knowledge of the potential variability of the discarded amounts that may occur if Leukine® were used for such purposes. If an FDA approval for adjuvant use of Leukine® were to occur by another manufacturer, the available presentations of Leukine® would likely not be optimized for the small doses being studied in these trials.

As part of CMS's review of the application, we analyzed existing claims data from the first quarter of 2023 through the first quarter of 2024 and found the percentage of units discarded for the Healthcare Common Procedure Coding System (HCPCS) code for Leukine® (J2820) ranged from 1.2 percent to 3.8 percent, which is below the applicable percentage of 10 percent. Since we do not yet know the impact of a new adjuvant indication with a type of immunotherapy commonly referred to as cancer vaccines [240] on the current percentage of units discarded, we are not proposing an increased applicable percentage without additional information. Because it is not yet known whether Leukine® will be approved for additional indications with varying dosage requirements and the information provided by the applicant; and available data does not provide enough information for CMS to determine whether Leukine® has unique circumstances that would prompt an increase in the applicable percentage, we are not proposing an increase in the applicable percentage for the drug at this time.

The applicant may reapply in a future application cycle when more information becomes available.

[237] *https://www.cancer.org/cancer/managing-cancer/treatment-types/immunotherapy/cancer-vaccines.html.*

[238] *https://clinicaltrials.gov/study/NCT04229979.*

[239] *https://clinicaltrials.gov/study/NCT05100641.*

[240] *https://www.cancerresearch.org/treatment-types/cancer-vaccines.*

c. Clarifications for the Definition of Refundable Single-Dose Container or Single-Use Package Drug

(1) Exclusions for Drugs for Which Payment Has Been Made Under Part B for Fewer Than 18 Months

Section 1847A(h)(8)(B)(iii) of the Act excludes from the definition of refundable drug a drug approved or licensed by FDA on or after November 15, 2021, and for which payment has been made under Part B for fewer than 18 months. This is codified in the definition of refundable single-dose container or single-use package drug in § 414.902. In the CY 2023 PFS final rule (87 FR 69720 through 69731), we finalized that the 18-month period begins on the first day of the calendar quarter following the date of first sale as reported to CMS for the first National Drug Code (NDC) assigned to the HCPCS code. We expected that the first date of sale would approximate the date of payment of the first Part B claim, and we finalized that we would use the first date of sale because it is more operationally feasible than identifying the date when the first Part B claim was paid for a new drug. We did not receive any opposing comments to this approach when the policy was proposed (87 FR 69719 through 69724). Since then, however, we have found one instance where the date of first sale for a drug, as reported to CMS, does not adequately approximate the first date for which payment was made under Part B.

We propose that, while we would continue to use the first date of sale reported to CMS for most refundable drugs, we would use the date on which the drug is first paid under Part B if the date of first sale as reported to CMS does not adequately approximate the first date of payment under Part B due to an applicable National Coverage Determination (NCD). Under the exception, the first date for which the drug is actually paid under Part B (not the date of first sale) would be used to determine the beginning of the 18-month exclusion period.

For example, in the case of Leqembi® (lecanemab-irmb), the second drug targeting cerebral amyloid-beta plaques in Alzheimer's disease to receive FDA approval, the first date of sale reported to CMS via the Average Sales Price (ASP) portal was in January 2023, as it was marketed and sold under accelerated approval granted on January 6, 2023. However, because Leqembi® is subject to the NCD for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease under coverage with evidence development (CED),[241] and because Leqembi® was initially marketed and sold under accelerated approval, Leqembi® coverage under Part B required the product to be furnished in a randomized controlled trial (RCT) conducted under an investigational new drug (IND) application.[242] In public comments on the CY 2024 proposed rule, the manufacturer of Leqembi® explained that Leqembi®'s Phase III confirmatory trial was already fully enrolled and complete prior to FDA granting accelerated approval, and as such, there was no RCT in which to enroll Medicare beneficiaries. Leqembi® received traditional approval on July 6, 2023. The first Part B payments for Leqembi® did not occur until after traditional FDA approval of the drug on July 6, 2023, and Medicare paid for the drug beginning that month in CED studies using a registry.[243] Under policies finalized in the CY 2023 PFS final rule, the 18-month exclusion period for Leqembi® would begin on April 1, 2023, which marks the first day of the calendar quarter after the drug's first date of sale as reported to CMS in January 2023. We believe that, in this situation, our current policy of using the date of first sale as reported in ASP data does not adequately approximate the beginning of the 18-month period for which payment has been made for the drug under Part B.

Under this proposed rule, the 18-month exclusion for Leqembi® would be October 1, 2023, through March 31, 2025 (that is, six full calendar quarters following the date that the drug was first paid under Medicare Part B).

To maintain operational feasibility of this provision and better align the policy with statutory language when the date of first sale reported to CMS does not adequately approximate the date of first payment under Medicare Part B, we are proposing to amend the exclusions in the definition of refundable single-dose container or single-use package drug at § 414.902. We note that we are also proposing to revise the structure of the definition of *Refundable single-dose container or single-use package drug* and as part of that restructuring, we are proposing that exclusions would be defined at paragraph (2) of the definition. Moreover, we are proposing to add a fourth exclusion to paragraph (2) to address drugs for which the date of first sale does not adequately approximate the first date of payment under Part B due to an applicable NCD. We anticipate that instances of inadequately approximating the date of first payment under Medicare Part B based on the date of first sale due to an applicable NCD will be rare, as coverage of a drug under Part B is not often restricted by an NCD.

(2) Clarification for Identifying Single-Dose Containers

In the CY 2023 PFS final rule (87 FR 69719), we finalized that the definition of refundable drug would apply to drugs paid under Medicare Part B (that is, under any payment methodology) that are described in FDA-approved labeling as being supplied in a ''single-dose'' container or ''single-use'' package. This definition also includes drugs described in FDA-approved labeling as a part of a ''kit'' that is intended for a single dose or single use. We also finalized that for a drug to meet the definition of refundable drug, all NDCs assigned to the drug's billing and payment code must be single-dose containers, as described in each product's labeling.

During our analysis in identifying refundable drugs for the preliminary reports (which are based on available JW modifier data from the first and second quarters of 2023), we learned that some product labeling[244] does not specify the package type terms (for example, whether the product is supplied in a single-dose or single-use package or a multiple-dose preparation). This may occur in drugs that were approved prior to October 2018 because at that time, FDA issued guidance[245] regarding the selection of the appropriate package terms to address bacterial and viral infections among patients resulting from improper use of single-dose containers such as vials, ampules, and prefilled syringes. The guidance defines a single-dose container as a container of a sterile medication for parenteral administration (injection or infusion) that is not required to meet the antimicrobial effectiveness testing requirements. The guidance further states a single-dose container is designed for use with a single patient as a single injection/infusion and, when space permits, the label should include the correct package type term and appropriate discard statements. Discard statements include instruction for

[241] Section 200.3 of the Medicare National Coverage Determinations Manual.

[242] *https://www.cms.gov/medicare/coverage/coverage-evidence-development/monoclonal-antibodies-directed-against-amyloid-treatment-alzheimers-disease-ad.*

[243] *https://www.cms.gov/newsroom/press-releases/statement-broader-medicare-coverage-leqembi-available-following-fda-traditional-approval.*

[244] ''Product labeling'' in this document means the container label, carton labeling, or prescribing information.

[245] *https://www.fda.gov/media/117883/download.*

discarding or, if appropriate, storage guidance for drugs remaining after preparation. The guidance defines a multiple-dose container as a container of sterile medication for parenteral administration that has met antimicrobial effectiveness testing requirements or is excluded from such testing requirements. In addition, the guidance defines the term ''single-patient-use'' container, which describes a package that contains multiple doses of an injectable medical product that is intended to be used in a single patient.

Some drugs approved prior to the release of this guidance (that is, those prior to October 2018) and some Orphan drugs do not include the package type terms and explicit discard statements. Examples of drugs without the package type terms and discard statements include certain manufacturers of digoxin (approved in 1954), oxytocin (approved in 1980), diphenhydramine (approved in 1982), phenobarbital (orphan drug without FDA approval). Several of these drugs are available in small containers with only a few mL of labeled drug in the containers.

In this proposed rule, we are proposing to include injectable drugs with a labeled volume of 2 mL or less and that lack the package type terms and explicit discard statements in their product labeling to be single-dose containers in the definition of refundable single-dose container or single-use package drugs. We identified 2 mL as a threshold for this proposal for several reasons. For intramuscular administration, the maximum volume administered at one time for diphenhydramine and digoxin is less than or equal to 2 mL. We also note that for adults, the maximum volume [246] for intramuscular administration is typically limited to 3 mL. For drugs administered intravenously and supplied in containers containing 2 mL or less, like digoxin and phenobarbital, dosages are calculated based on body weight, potentially leading to discarded amounts. We believe that preparation of these drugs would likely be used for a single dose based on the range of dose sizes for these drugs and the amount of drug in the container. In other words, it is unlikely that more than one dose could be prepared from the amount of drug in the container.

Another category of drugs approved before 2018 that lack discard statements is drugs contained in ampules (also spelled as ampoules or ampuls, hereinafter referred to as ''ampules''). The term ampule is an airtight vial made of glass, plastic, metal, or any combination of these materials.[247] Examples of drugs currently contained in ampules include epinephrine (approved in 1939), lidocaine hydrochloride (1948), dicyclomine (1950), digoxin (1954), chlorpromazine (1957), fentanyl citrate (1968), promethazine (1973), alprostadil (1981), nalbuphine (1993), and tacrolimus (1994). Drugs contained in ampules are accessed by breaking the concaved part (''the neck''), and the content should be passed through a sterile filter to remove any residual glass particles.[248]

Therefore, we are proposing to amend the definition of refundable single-dose container or single-use package drug to include drugs contained in ampules and for which there is no discard statement. We are proposing to classify drugs supplied in ampules to be drugs in single-dose containers for purposes of this discarded drug policy because this approach would be consistent with the description of single-dose container in the October 2018 FDA guidance. We note that some drugs contained in ampules may be excluded from the definition of refundable drug under section 1847A(h)(8)(B)(ii) of the Act because dosage and administration instructions included in the product labeling require filtration during the drug preparation process, prior to dilution and administration, and require that any unused portion of such drug after the filtration process be discarded after the completion of such filtration process. This exclusion would still be applicable for ampules that can demonstrate that they meet that exclusion. However, this is not the case for the product labeling of all drugs contained in ampules.

In summary, we are proposing to amend the definition of *Refundable single-dose container or single-use package drug* at § 414.902 by including ''single-patient-use container'' as a package type term and adding three types of products that may be considered refundable single-dose container or single-use package drugs under paragraph (1). These are:

(1) Product furnished from a single-dose container or single-use package based on FDA-approved labeling or product information.

(2) Product furnished from an ampule for which product labeling does not have discard statement or language indicating the package type term, like ''single-dose container,'' ''single-use package,'' ''multiple-dose container,'' or ''single-patient-use container''.

(3) Product furnished from a container with a total labeled volume 2 ml or less for which product labeling does not have language indicating the package type term, like ''single-dose container,'' ''single-use package,'' ''multiple-dose container,'' or ''single-patient-use container''.

As noted above, we are also revising the organization of this definition in the regulatory text. We welcome comments on these proposals.

(3) Skin Substitutes

As discussed in the CY 2023 PFS final rule (87 FR 69650 through 69655), CMS aims to create a consistent coding and payment approach for the suite of products currently referred to as skin substitutes. In the CY 2024 PFS final rule (88 FR 79060 through 79061), we finalized that billing and payment codes that describe products currently referred to as skin substitutes are not counted for purposes of identifying refundable drugs for calendar quarters during 2023 and 2024. While we continue to consider making changes to the Medicare Part B payment policies for such products, similar to last year, for CY 2025, we are proposing again that billing and payment codes that describe products currently referred to as skin substitutes not be counted for purposes of identifying refundable drugs for calendar quarters in 2025. We plan to revisit discarded drug refund obligations for skin substitutes in future rulemaking. More information regarding the payment of skin substitutes is available in section II.K. of this proposed rule.

d. Discarded Amounts

Effective January 1, 2017, providers and suppliers were required to report the JW modifier on all claims that bill for drugs separately payable under Medicare Part B with unused and discarded amounts (that is, discarded amounts) from single-dose containers or single-use packages. In the CY 2023 PFS, we finalized the requirement to use the JW modifier for single-dose container drugs that are separately payable under Part B, and we finalized the use of the JW modifier (or any successor modifier that includes the same data) to identify discarded billing units of a billing and payment code for the purpose of calculating the refund amount as described in section 1847A(h)(3) of the Act. In that final rule, to align with the JW modifier policy, we

[246] Open Resources for Nursing (Open RN); Ernstmeyer K, Christman E, editors. Nursing Skills [internet]. 2nd edition. Eau Claire (WI): Chippewa Valley Technical College; 2023. Chapter 18 Administration of Parenteral Medications. Available from *https://www.ncbi.nlm.nih.gov/books/NBK596739/*.

[247] 40 CFR 273.9.

[248] Pharmaceutical Compounding—Sterile Preparations. *USP–NF* 2023. November 1, 2023.

also finalized the requirement that, beginning July 1, 2023, the JZ modifier is required when there are no discarded amounts of a single-dose container drug for which the JW modifier would be required if there were discarded amounts.

In the CY 2023 PFS final rule (87 FR 69723), we discussed the applicability of the JW and JZ modifiers to drugs that are not administered by the billing supplier, including drugs furnished through a covered item of DME that may be administered by the beneficiary. In such cases, we stated that the reporting requirement does not apply to drugs that are self-administered by a patient or caregiver in the patient's home. In the JW Modifier and JZ Modifier Policy FAQ document [249] released on January 5, 2023, we reiterated that suppliers who dispense but do not actually administer a separately payable drug are not expected to report the JW or JZ modifier.

Then, in the CY 2024 PFS final rule (88 FR 79062), we finalized a change to this policy, such that drugs separately payable under Part B from single-dose containers that are furnished by a supplier who is not administering the drug be billed with the JZ modifier. This meant that the JW modifier would not be used on these claims. As we stated in that rule, in the absence of a claims modifier to designate that a drug was dispensed, but not administered, by the billing supplier (as finalized in the CY 2023 PFS), we were concerned that claims rejections may occur. Therefore, this change in policy required the JZ modifier on all such claims to ensure claims rejections did not occur unnecessarily. On October 16, 2023, we updated the JW Modifier and JZ Modifier Policy FAQ document to include the requirement of the JZ modifier by the supplier.

However, after this policy was finalized, interested parties have requested further clarification on how to appropriately bill for discarded amounts from single-dose containers when there are amounts discarded during preparation by the billing supplier who is not administering the drug. To provide additional clarity, we are now proposing to require the JW modifier if a billing supplier is not administering a drug, but there are amounts discarded during the preparation process before supplying the drug to the patient. Such a supplier would report the JZ modifier if no amounts were discarded during the preparation process before supplying the drug to the patient.

We believe this proposal is appropriate because drug preparation occurs before supplying a drug to the beneficiary and the billing supplier can determine the discarded amount at the site of drug preparation. These discarded units should be billed using the JW modifier in the same way as a drug that is administered incident-to physician service. In addition, suppliers and other interested parties have expressed that suppliers are accustomed to using the JW modifier in this context already. Therefore, we propose to require the JW modifier if a billing supplier is not administering a drug, but there are amounts discarded during the preparation process before supplying the drug to the patient. For example, if a billing supplier prepares a dose from a single-dose vial labeled as containing a total of 50 billing units such that 45 billing units of the drug are used in the prepared dose and 5 billing units are discarded during preparation, and then the drug is supplied to the patient (but not administered by the supplier), the claim should be submitted on two lines: 45 units (without a modifier) and 5 units with the JW modifier. We reiterate that suppliers who dispense a drug, but do not actually administer the drug, are not expected to monitor or bill for discarded amounts that are discarded after the drug is supplied because they are not at the site of administration to measure discarded amounts. For example, if the patient who was supplied the above dose with 45 billing units subsequently only receives 35 of those billing units, the above billing supplier would not be expected to account for the 10 subsequently discarded billing units on the claim.

We welcome comments on this proposal.

2. Payment Limit Calculation When Manufacturers Report Negative or Zero Average Sales Price (ASP) Data (§ 414.904)

a. Background

Drugs payable under Medicare Part B fall into three general categories: those furnished incident to a physician's service (hereinafter referred to as ''incident to'') (section 1861(s)(2) of the Act), those furnished via a covered item of durable medical equipment (DME) (section 1861(s)(6) of the Act), and other drugs for which coverage is specified by statute (for example, certain vaccines described in sections 1861(s)(10)(A) and (B) of the Act). Payment limits for most drugs separately payable under Medicare Part B are determined using the methodology in section 1847A of the Act, and in many cases, payment is based on the average sales price (ASP) plus a statutorily mandated 6 percent add-on. If CMS determines a payment limit for a drug, it is published in the ASP pricing file or Not Otherwise Classified (NOC) pricing file,[250] which are both updated quarterly.

CMS generally calculates the payment limits for drugs payable under Part B on a quarterly basis using the manufacturer's ASP (as defined in § 414.902). Manufacturers are required to report ASP to CMS pursuant to sections 1847A(f)(2) and 1927(b)(3) of the Act. Manufacturers are instructed to calculate ASP in accordance with section 1847A(c) of the Act and § 414.804(a).

For each NDC, in most cases, the manufacturer's ASP is a positive dollar value, along with a positive number of units sold (hereinafter referred to as ''positive manufacturer's ASP data''). However, sometimes the reported data is not positive manufacturer's ASP data. Specifically, a manufacturer could report that an NDC has a negative or zero-dollar value for the manufacturer's ASP with a positive, negative, or zero number of units sold, or a positive dollar value for the manufacturer's ASP with a negative or zero number of units sold (each of these scenarios is hereinafter referred to as ''negative or zero manufacturer's ASP data''). Such negative or zero manufacturer's ASP data could occur because of lagged discounts, units returned to the manufacturer, drug shortages, discontinuation of a drug, or other reasons that are not known to CMS. Negative or zero manufacturer's ASP data can occur when a manufacturer calculates its ASP in accordance with section 1847A of the Act.

First, section 1847A(c)(3) of the Act requires that the manufacturer's calculation of its ASP for an NDC must include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid drug rebate program or the Medicare Prescription Drug Inflation Rebate Program) (hereinafter referred to as ''price concessions''). Second, section 1847A(c)(5)(A) of the Act requires each manufacturer to apply a methodology based on a 12-month rolling average for the manufacturer to estimate costs attributable to price concessions if there is a lag in the reporting of the information on rebates and chargebacks

[249] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf.*

[250] *https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files.*

under section 1847A(c)(3) of the Act. These provisions may result in the inclusion of large price concessions from a quarter or quarters with a higher sales price prior to price concessions in the ASP calculation for a subsequent quarter with a much lower sales price, which can result in negative dollar value ASP. The same situation could happen in a quarter if more units were returned to the manufacturer than are sold, which can result in a negative dollar value ASP as well as a negative number of units sold. The requirement to use a rolling average for lagged price concessions is codified at § 414.804(a)(3), which states that, to the extent data on price concessions are available on a lagged basis, the manufacturer must estimate its ASP in accordance with the described methodology in that paragraph. In certain instances, as stated above, lagged price concessions can lead to negative or zero manufacturer's ASP data.

In 2022, the U.S. Department of Health and Human Services Office of Inspector General (OIG) issued a report assessing potential inaccuracies in manufacturer reporting of ASP and noted that manufacturers believe additional guidance may be needed to reduce distortions and inconsistencies in the calculation of payment limits.[251] The report found that several manufacturers would like additional guidance regarding reporting of negative ASP data and how CMS uses negative ASP data in payment limit calculations. CMS concurred with the OIG's recommendation to actively review current guidance and determine whether additional guidance would ensure more accurate and consistent ASP calculations.

Accordingly, we reviewed our current guidance and determined that it is appropriate for us to provide additional guidance regarding how CMS will handle payment for drugs separately payable under Part B when the manufacturer's ASP for at least one NDC within the billing and payment code (that is, HCPCS code) of the drug is negative or zero. Currently, when all NDCs assigned to a HCPCS code have negative or zero manufacturer's ASP data, CMS establishes the payment limit in other ways. As appropriate given the data available for a drug, CMS will either calculate a payment limit for a billing and payment code based on other applicable and available pricing data or not include a payment limit for the billing and payment code on the ASP pricing file. When a payment limit for a drug separately payable under Part B is not included in the ASP pricing file, the payment limit is based on either the published or Wholesale Acquisition Cost (WAC) or invoice pricing, as described in section 20.1.3, Chapter 17 of the Medicare Claims Processing Manual.[252]

CMS previously contemplated how to set a payment limit in certain situations in which ASP data is ''not available'' for multiple source drugs. In the CY 2011 PFS final rule (75 FR 73461 through 73465), CMS addressed situations in which ASP data for some, but not all, NDCs in a multiple source drug billing and payment code are not available for the calculation of an ASP payment limit (for example, if a manufacturer's entire submission of data was not received or manufacturer's ASP data for specific NDCs was not reported).[253] In that rule, we finalized a process, consistent with authority in section 1847A(c)(5)(B) of the Act, to update payment limits based on the manufacturer's ASP reported for the most recent quarter for which data is available. We specified that if manufacturer's ASP data is not available for some but not all NDCs in a multiple source drug billing and payment code prior to the publication deadline for quarterly payment limits and such unavailability of manufacturer's ASP data significantly changes the quarterly payment limit for the billing and payment code when compared to the prior quarter's payment limit, CMS will calculate the payment limit by carrying over the most recent available manufacturer's ASP price from a previous quarter for an NDC, adjusted by the weighted average of the change in the manufacturer's ASPs for the NDCs that were reported for both the most recently available previous quarter and the current quarter, and codified this policy in § 414.904(i).[254] In that final rule, we explained that such circumstances are limited to when a manufacturer's data for a multiple source drug product with sales during a quarter is missing, and efforts to obtain manufacturer reported ASP data before Medicare ASP payment limits publication deadlines have not been successful. We continue to believe that this process, which we apply in cases ASP data is ''not available'' for some but not all NDCs associated with a multiple source billing and payment code, is appropriate.

b. Approach to Payment Limit Calculations When Manufacturer's ASP Data is Not Available

As described in the previous section, we determined that it is appropriate for CMS to provide additional guidance regarding how we will handle payment for drugs separately payable under Part B when the reported manufacturer's ASP for at least one NDC within the billing and payment code (that is, HCPCS code) of the drug is negative or zero (that is, has negative or zero manufacturer's ASP data). As detailed below, we are proposing to consider ASP data to be not ''available'' for the purposes of calculating a payment limit in circumstances in which negative or zero manufacturer's ASP data is reported, consistent with section 1847A(c)(5)(B) of the Act. We are also proposing how CMS would calculate a payment limit in these circumstances, consistent with section 1847A(c)(5)(B) of the Act.

Our current policy does not address how payment limits are calculated for several situations in which a drug separately payable under Part B does not have available ASP data. The set of situations in which this might occur include circumstances in which either some or all NDCs for a billing and payment code have a negative or zero manufacturer's ASP data; in which negative or zero manufacturer's ASP data is reported for a drug which has been discontinued; and vary further depending on whether a drug is multiple source or single source (both as defined in § 414.902). In each of these circumstances, there are various other pricing data available that we believe can appropriately be used to calculate a payment limit.

Therefore, we are proposing, consistent with section 1847A(c)(5)(B) of the Act, a methodology for calculating payment limits in certain circumstances based on manufacturer's ASP for the most recent quarter for which data is available. Specifically, we propose to specify that positive manufacturer's ASP data are considered ''available'' and that negative or zero manufacturer's ASP data are considered ''not available'' for purpose of CMS calculating a payment limit under the statute. We believe it is appropriate to consider negative or zero manufacturer's ASP data to be not available because if used to calculate a payment limit, this data can result in a negative or zero payment limit, which would require CMS to collect payment from providers and suppliers for a drug, rather than

[251] OEI–BL–21–00330. *https://oig.hhs.gov/oei/reports/OEI-BL-21-00330.asp.*

[252] *https://www.cms.gov/%E2%80%8BRegulations-and-Guidance/%E2%80%8BGuidance/%E2%80%8BManuals/%E2%80%8BDownloads/%E2%80%8Bclm104c17.pdf.*

[253] *https://www.govinfo.gov/content/pkg/FR-2010-11-29/pdf/2010-27969.pdf.*

[254] *https://www.ecfr.gov/current/title-42/part-414/section-414.904#p-414.904(i).*

make payment for a drug. Negative or zero payment limits for a drug are not reasonable because Medicare does not expect to collect payment from providers and suppliers for their provision of separately payable drugs. Therefore, we are proposing to specify the methodology we will use for calculating the payment limit in such circumstances to ensure reasonable payment amounts based on the best available data for separately payable drugs. Below, we propose how payment limits would be determined using available ASP data for each scenario.

c. Single and Multiple Source Drugs When Negative or Zero Manufacturer's ASP Data Is Reported for Some, But Not All NDCs

In the case that a drug separately payable under Part B has negative or zero manufacturer's ASP data reported for some, but not all, NDCs associated with a billing and payment code for that drug, we are proposing to calculate a payment limit using only NDCs with positive manufacturer's ASP data (and omitting NDCs with negative or zero manufacturer's ASP data) for that drug and propose to codify this at § 414.904(i). We are proposing this policy to apply to both single source drugs, including biosimilar biological products, and multiple source drugs. We believe this is appropriate because it would result in payment limits based on the most recent positive manufacturer's ASP data reported by manufacturers with NDCs associated with a billing and payment code.

However, we note that, as discussed in section III.A.2.a of this proposed rule, CMS already has a policy in place for multiple source drugs for which the absence of ASP data would result in a significant change (that is, a 10 percent or greater change) in the ASP payment limit compared to the payment limit of the previous quarter, as finalized in the CY 2011 PFS final rule (75 FR 73461 through 73465). In that discussion (75 FR 73462), we noted several examples of situations in which data is not available to be included in the calculation of a payment limit, such as when a manufacturer's entire submission was not received or when the manufacturer's ASP data for specific NDCs has not been reported. We do not intend for our proposed policy to override that existing policy; rather, we intend for the proposed policy described above to address circumstances not addressed in that rulemaking (that is, we intend to address circumstances of single source drugs when negative or zero manufacturer's ASP data is reported for some, but not all NDCs, and of multiple source drugs when negative or zero manufacturer's ASP data is reported for some, but not all NDCs and the absence of such data from the calculation of the payment limit does not result in a significant change in the payment limit compared to the payment limit of the previous quarter) and thus fill a policy gap. In addition, the circumstances we provided as examples in which ASP data is not available in the CY 2011 PFS final rule continue to be circumstances we consider manufacturer's ASP data not available under current § 414.904(i) (which we propose to move within § 414.904(i) to fit within the structure of the proposed new set of payment limit methodologies); but, as noted in section III.A.2.b, we are expanding what we consider to be not available to include circumstances in which negative or zero manufacturer's ASP data is reported.

d. Multiple Source Drugs With Only Negative or Zero Manufacturer's ASP Data

In the case of a multiple source drug (as defined in § 414.902) separately payable under Part B that has negative or zero manufacturer's ASP data reported for all NDCs associated with a billing and payment code for that drug (and at least one NDC for the is actively being marketed (that is, not discontinued)), we are proposing to carry over all positive manufacturer's ASP data from the most recently available previous quarter with positive manufacturer's ASP data for at least one NDC until at least one NDC for the drug has positive manufacturer's ASP data for a quarter. Specifically, we are proposing to calculate the payment limit for the applicable quarter using data from the most recent calendar quarter for which data is available, *i.e.,* for which there is positive manufacturer's ASP data. We believe this is appropriate because, similar to the methodology described in section III.A.2.c, it would result in payment limits based on the most recent positive manufacturer's ASP data reported by manufacturers with NDCs associated with a billing and payment code. Similarly, we believe the most recent available positive manufacturer's ASP data from NDCs associated with a billing and payment code are more likely to be reflective of providers' acquisition costs for drugs associated with that billing and payment code in a given quarter than other pricing data, and unlikely to result in challenges to access for these drugs for providers and beneficiaries.

We note that because section 1847A of the Act provides for payment limit calculations that differ between single-source drugs (as defined in section 1847A(c)(6)(D) of the Act and § 414.902) and multiple source drugs (as defined in section 1847A(c)(6)(C) of the Act and § 414.902), we are proposing different ways to determine payment limits for each, in cases in which only negative or zero manufacturer's ASP data is reported, to reflect these differences. Specifically, the payment limit for single source drugs is described in section 1847A(b)(1)(B) of the Act; for multiple source drugs, the payment limit is described in section 1847A(b)(1)(A) of the Act. The payment limit for single source drugs is determined using the lesser of ASP or WAC; but WAC is not used for multiple source drugs whose ASP exceeds WAC. Nonetheless, our proposals for the calculation of the payment limit for single source and multiple source drugs with only negative or zero manufacturer's ASP data are consistent in that, where ASP is used, we propose to use the most recent available positive manufacturer's ASP data from at least one NDC for the drug. We believe using similar input data in our calculation of the payment limit is consistent with our goal to ensure reasonable payment amounts based on the best available data for separately payable drugs.

We are proposing to amend § 414.904(i) to include the above proposal regarding how CMS would calculate the payment limit in circumstances in which only negative or zero manufacturer's ASP data is reported for a multiple source drug.

e. Single Source Drugs With Only Negative or Zero Manufacturer's ASP Data, Excluding Biosimilar Biological Products

In the case of a single source drug, excluding biosimilar biological products (both as defined in § 414.902), separately payable under Part B that has negative or zero manufacturer's ASP data reported for all NDCs associated with a billing and payment code for that drug (and at least one NDC for the drug is actively being marketed (that is, not discontinued)), we are proposing to set the payment limit for the given quarter for the single source drug at the lesser of the following until at least one NDC for the drug has positive manufacturer's ASP data for a quarter:

- 106 percent of the volume-weighted average of the most recent available positive manufacturer's ASP data from a previous quarter in which at least one NDC for the drug has positive manufacturer's ASP data for a quarter. If the payment limit from the quarter with the most recent available positive manufacturer's ASP data was based on

106 percent of the WAC because of the application of § 414.904(d)(1), that payment limit would be carried over; or

• 106 percent of the WAC for the given quarter. If there is more than one WAC per billing unit for the drug, the payment limit would be set using the lowest WAC per billing unit.

We would only use the lesser of the positive manufacturer's ASP or WAC data from that previous quarter or the WAC data from the given quarter until positive manufacturer's ASP data is available for a future quarter. Once positive manufacturer's ASP data for a drug is available again in a future quarter, CMS will have data available to input into the routinely used methodologies described in section 1847A(b) of the Act and § 414.904.

As discussed above, we believe it is appropriate to propose different policies for determining payment limits for single and multiple source drugs when negative or zero manufacturer's ASP data is reported because of statutory differences in the payment limit calculations.

f. Biosimilars With Only Negative or Zero Manufacturer's ASP Data

In circumstances in which negative or zero manufacturer's ASP data is reported for all NDCs for a biosimilar biological product (defined at § 414.902) (hereinafter referred to as a ''biosimilar'') for a given quarter (and at least one NDC for the biosimilar is actively being marketed (that is, not discontinued)), and positive manufacturer's ASP data is available for another biosimilar(s) with the same reference biological product (hereinafter referred to as a ''reference product'') for the given quarter, we are proposing to set the payment limit for the given quarter equal to the sum of the following until at least one NDC for the particular biosimilar for which all NDCs report negative or zero manufacturer's ASP data has positive manufacturer's ASP data for a quarter:

• The volume-weighted average of the positive manufacturer's ASP data from all other biosimilars with the same reference product, and

• 6 percent (or 8 percent for qualifying biosimilar biologicals as defined in § 414.902, as appropriate) of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in § 414.902) for the given quarter.

We believe this is appropriate because Section 351(i)(2) of the Public Health Service Act defines the terms biosimilar and biosimilarity to mean that a biosimilar is highly similar to its reference product, notwithstanding minor differences in clinically inactive components, and that there are no clinically meaningful differences between the biosimilar and the reference product in terms of the safety, purity, and potency of the product. In addition, biosimilars with the same reference product likely compete in the marketplace since both rely on FDA's previous determination of safety, purity, and potency for the reference product clinical data for approval. For these reasons, we believe that when a biosimilar has only negative or zero manufacturer's ASP data, the volume-weighted average of positive manufacturer's ASP data of biosimilars with the same reference product would be an appropriate payment limit for a biosimilar that, under this proposal, would be considered to have ASP data that is not available. As such, we are proposing to calculate the payment limit for a biosimilar with only negative or zero manufacturer's ASP data based on the positive manufacturer's ASP data of other biosimilars with the same reference product.

We note that in the CY 2016 PFS final rule (80 FR 71096 through 71101), we finalized that we would group all biosimilars with a common reference product in a single billing and payment code with a single payment rate, in a manner similar to how we price multiple source or generic drugs because of the significant similarities between each biosimilar and its reference product. In the CY 2018 PFS final rule (82 FR 53182 through 53187), we changed the initial policy and finalized separate coding and payment for biosimilars. In that final rule, we stated that that there is a program need for assigning Part B biosimilars into separate billing and payment codes; specifically, that this policy change addressed concerns about the public interest in a stronger marketplace, access to these drugs in the United States marketplace, and provider and patient choice and competition. Our proposal for biosimilars with negative or zero manufacturer's ASP data reported for all NDCs is consistent with the CY 2018 PFS rulemaking, as it would not result in grouping biosimilars with a shared reference product in a single billing and payment code. Rather, it would allow CMS to calculate an operationally reasonable payment limit using positive manufacturer's ASP data for highly similar products in limited instances.

This proposal would also provide payment limit stability that could help avoid potential access issues for providers and beneficiaries that could otherwise occur if we were to calculate a payment limit for a drug with negative or zero manufacturer's ASP data that is far below the provider's cost for acquiring the drug. If a biosimilar's ASP falls below zero only after several quarters of declining but still positive manufacturer's ASP data, the most recent positive manufacturer's ASP data from a previous quarter for a drug may be significantly lower than the volume-weighted average of the biosimilars with the same reference product as the biosimilar with negative ASP data. In such a case, the payment limit based on the ASPs of competitor biosimilars would be higher than if we were constrained to use ASP data only from the biosimilar that has most recently reported negative or zero manufacturer's ASP data. We note that under the methodology proposed in section III.A.2.c, in circumstances in which some, but not all NDCs of a single or multiple source drug are negative or zero, we would similarly calculate the payment limit using only NDCs with positive manufacturer's ASP data from the given quarter and omitting those that had declined to zero or a negative value in ASP or sales. Likewise, we believe that such an approach would likely result in a payment limit reflective of providers' acquisition costs of biosimilars and be helpful in avoiding access issues for providers and beneficiaries.

In circumstances in which negative or zero manufacturer's ASP data is reported for all NDCs for a biosimilar for a given quarter and either no other biosimilars have been approved for the same reference product or no other biosimilars with the same reference product report positive manufacturer's ASP data for the given quarter, we propose that we would set the payment limit for the given quarter equal to the sum of the following until at least one NDC for the biosimilar has positive manufacturer's ASP data for a quarter:

• The volume-weighted average of the most recent available positive manufacturer's ASP data from a previous quarter, and

• 6 percent (or 8 percent for qualifying biosimilar biologicals, as appropriate) of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in § 414.902) for the given quarter.

In situations in which CMS would use the volume-weighted average of the most recent available positive manufacturer's ASP data from a previous quarter, we would only use positive manufacturer's ASP data from that previous quarter until positive manufacturer's ASP data is available for

a future quarter. This proposed methodology is similar to the proposed methodology for multiple source drugs and single source drugs that are not biosimilars when manufacturers report negative or zero manufacturer's ASP for all NDCs.

In addition to the payment approaches we are proposing for biosimilars with only negative or zero manufacturer's ASP data, we considered two alternatives for which we are seeking public comment. Under the first alternative, the volume-weighted ASP calculation would include the ASP data and billing units sold of its reference product for a given quarter along with those of the other biosimilars that reference the same reference product in the volume-weighted average calculation. We believe including the reference product's data in the blended calculation for a biosimilar's payment limit in the limited circumstance described could be appropriate in determining an operationally reasonable payment limit because the FDA approval for the biosimilar relies in part on FDA's previous determination of safety, purity, and potency for the reference product, and the biosimilar and reference product are necessarily approved for at least one shared condition of use, as required under the 351(k) approval pathway; [255] therefore, the case that the two are comparable is at least as strong as that for any two biosimilars with the same reference product. If it is preferable, as we propose, to base the payment limit on the available positive manufacturer's ASP data submitted by manufacturers of market competitor biosimilars (in this context, biosimilars that reference the same reference product), then including the ASP data and billing units sold of the reference product would also increase the likelihood that positive data in such a group is available, particularly in the case that a reference product only has one biosimilar. Under this alternative, the payment limit would be set equal to the sum of the volume-weighted average of the positive manufacturer's ASP data from all other biosimilars with the same reference product and the reference product plus 6 or 8 percent, as appropriate, of the amount determined under section 1847A(b)(4) of the Act for the reference biological product for the given quarter. We are seeking public comments about whether including ASP data from the reference product in a variant of the proposed calculation would produce a more appropriate payment limit for a biosimilar with only negative or zero manufacturer's ASP data.

Under the second alternative, we would calculate payment limits for all biosimilars with only negative or zero manufacturer's ASP data in the manner described above for biosimilars when either no other biosimilars have been approved for the same reference product or no other biosimilars with the same reference product report positive manufacturer's ASP data for the given quarter. That is, under this alternative we would not consider the manufacturer's ASP data of other biosimilars with the same reference product; rather, we would base the payment limit of the biosimilar on the volume-weighted average of the its own most recent available positive manufacturer's ASP data from a previous quarter and either 6 or 8 percent, as appropriate, of the amount determined under section 1847A(b)(4) of the Act for the reference biological product for the given quarter. We are interested in comments from interested parties about whether, and if so, why, it is preferable for the payment limit to be calculated only using manufacturer's ASP data from the biosimilar that reports negative or zero manufacturer's ASP data in a given quarter.

g. Discontinued Drugs

Generally, for single source drugs and multiple source drugs for which negative or zero manufacturer's ASP data is reported for all NDCs and for which all relevant applications (for example, new drug applications (NDAs), biologics license applications (BLAs), or abbreviated new drug applications (ANDAs)) have a marketing status of ''discontinued'' on the FDA website,[256] [257] we propose that the drug be priced by MACs consistent with section 20.1.3 in Chapter 17 of the Medicare Claims Processing Manual for developing payment limits for covered drugs when CMS does not supply the payment allowance limit on the ASP drug pricing file.[258]

Once a drug is discontinued, as indicated by the marketing status on the FDA website (either at Drugs@FDA [259] for drugs or the Purple Book [260] for biologicals), the manufacturer might not have sales to calculate an ASP and, therefore, the manufacturer often reports zero sales for the drug or a negative number for its calculated ASP or number of sales. However, even if a drug has a marketing status of discontinued on the FDA website, there may theoretically be available product that could be billed by the provider until the expiration date of the last lot sold for the drug. Relatedly, we have observed that very few claims are paid for drugs following their discontinuation. For these reasons, setting a payment limit for drugs with a marketing status of discontinued on the FDA website is not expected to be practically useful for claims processing and is not a prudent use of CMS resources.

h. Summary

We are proposing to amend § 414.904(i) to reflect CMS's approach to setting a payment limit in circumstances in which negative or zero manufacturer's ASP data is reported by a manufacturer for a drug. Specifically, we are proposing to codify that in cases where negative or zero manufacturer's ASP data is reported for some, but not all, NDCs of a multiple source drug, we would calculate the payment limit using the positive manufacturer's ASP data reported for the drug, except for the existing carryover policy for multiple source drugs that we would apply when unavailable data results in a significant change in the ASP payment limit. We are proposing to move this carryover policy for multiple source drugs within § 414.904(i) to fit within the structure of the proposed new set of payment limit methodologies. We are also proposing to codify that in the case of a multiple source drug for which negative or zero manufacturer's ASP data is reported for all NDCs, we would set the payment limit using the most recent available positive manufacturer's ASP data from a previous quarter until at least one NDC for the drug has positive manufacturer's ASP data for a quarter.

We are proposing to codify that in cases where negative or zero manufacturer's ASP data is reported for some, but not all, NDCs of a single source drug that is not a biosimilar, we would calculate the payment limit using the positive manufacturer's ASP data reported for the drug. We are proposing to codify that for single source drugs that are not biosimilars with all negative or zero manufacturer's ASP data for a given quarter, the payment limit would

[255] *https://www.fda.gov/science-research/fda-stem-outreach-education-and-engagement/development-biosimilar-351k-bla-clinical-pharmacology-study-database.*

[256] *https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm.*

[257] *https://purplebooksearch.fda.gov/.*

[258] Medicare Claims Processing Manual Chapter 17, section 20.1.3: *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf.*

[259] *https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm.*

[260] *https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or.*

be, until at least one NDC for the drug has positive manufacturer's ASP data for a quarter, the lesser of 106 percent of the volume-weighted average of the most recent available positive manufacturer's ASP data for at least one NDC from a previous quarter and 106 percent of the WAC, and we would use 106 percent of the lowest WAC per billing unit if there is more than one WAC per billing unit available.

We are also proposing to codify that in cases where negative or zero manufacturer's ASP data is reported for some, but not all, NDCs of a biosimilar, we would calculate the payment limit using the positive manufacturer's ASP data reported for the biosimilar. Lastly, we are proposing to codify two scenarios when the manufacturer reports negative or zero manufacturer's ASP for all NDCs for a biosimilar for a given quarter:

- When positive manufacturer's ASP data is available for another biosimilar(s) with the same reference product for the given quarter, we are proposing to set the payment limit equal to the sum of the volume-weighted average of the positive manufacturer's ASP data from all other biosimilars with the same reference product plus 6 percent (or 8 percent for a qualifying biosimilar biological) of the amount determined under section 1847A(b)(4) of the Act for the reference biological product for the given quarter; and
- When either no other biosimilars have been approved for the same reference product or no other biosimilars with the same reference product report positive manufacturer's ASP data for the given quarter, we are proposing to set the payment limit equal to the sum of the volume-weighted average of the most recent available positive manufacturer's ASP data from a previous quarter plus 6 percent (or 8 percent for a qualifying biosimilar biological) of the amount determined under section 1847A(b)(4) of the Act for the reference biological product for the given quarter.

We welcome comments on these proposals.

3. Payment of Radiopharmaceuticals in the Physician Office

Section 303(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted December 8, 2003) revised the payment methodology for most Medicare-covered Part B drugs by adding section 1847A to the Act, which established a new average sales price (ASP) drug payment methodology for separately payable Medicare Part B drugs, beginning January 1, 2005. Specifically, section 303(h) of the MMA states, ''Nothing in the amendments made by this section [303 of the MMA] shall be construed as changing the payment methodology under [Medicare] Part B . . . for radiopharmaceuticals, including the use by carriers of invoice pricing methodology.''

In accordance with the law, radiopharmaceuticals are not required to be paid using payment methodology under section 1847A of the Act, as currently described in the Medicare Claims Processing Manual (MCPM) Chapter 17, section 20.1.3. The manual instructs MACs to determine payment limits for radiopharmaceuticals based on the methodology in place as of November 2003, before the passage of the MMA, in the case of radiopharmaceuticals furnished in settings other than the hospital outpatient department. Currently, payment can vary by MAC. For example, payment can be based on 95 percent of Average Wholesale Price (AWP), invoices, or other reasonable payment methods/data made available when the product is contractor priced.[261] [262] [263] [264] [265] [266]

CMS has heard from MACs and other interested parties that there is confusion about which exact methodologies are available to MACs for pricing of radiopharmaceuticals in the physician office setting, as different MACs had different methodologies in place as of November 2003. MACs are uncertain whether they can use *any* of these payment policies that were in place, or only the policy that was in place for their jurisdiction as of November 2003.

Accordingly, while we evaluate our broader policies in this space for future rulemaking, we are proposing to clarify that *any* payment methodology that was being used by *any* MAC prior to the enactment of the MMA can continue to be used by any MAC, including the use of invoice pricing. That is, we are proposing to clarify that any methodology that was in place to set pricing of radiopharmaceuticals in the physician office setting prior to November 2003 can be used by any MAC, whether or not that specific MAC used the methodology prior to November 2003.

Thus, we are proposing to codify in regulations at § 414.904(e)(6) that, for radiopharmaceuticals furnished in a setting other than the hospital outpatient department, MACs shall determine payment limits for radiopharmaceuticals based on any methodology used to determine payment limits for radiopharmaceuticals in place on or prior to November 2003. Such methodology may include, but is not limited to, the use of invoice-based pricing.

We welcome comments on these proposals.

4. Immunosuppressive Therapy (§§ 410.30 and 414.1001)

a. Background

Medicare Part B coverage of drugs used in immunosuppressive therapy was established by section 9335(c) of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99–509) (OBRA '86). OBRA '86 added subparagraph (J) to section 1861(s)(2) of the Act to provide Medicare Part B coverage for immunosuppressive drugs, furnished to an individual who receives an organ transplant for which Medicare payment is made, for a period not to exceed 1 year after the transplant procedure. Coverage of these drugs under Medicare Part B began January 1, 1987. Section 4075 of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100–203) (OBRA '87) revised section 1861(s)(2)(J) of the Act so that the scope of coverage was expanded from coverage of ''immunosuppressive drugs'' to coverage of ''prescription drugs used in immunosuppressive therapy.'' For the purposes of this proposed rule, we refer to this benefit as the immunosuppressive drug benefit.

In the Medicare Coverage of Prescription Drugs Used in Immunosuppressive Therapy final rule (60 FR 8951 through 8955), we finalized policies for the scope of drugs for which payment may be made under this benefit. We finalized that payment may be made for prescription drugs used in immunosuppressive therapy that have

[261] How Does Palmetto GBA Price Drugs and Biologics?, Palmetto GBA. *https://www.palmettogba.com/palmetto/jjb.nsf/DIDC/8EELKH2211~Specialties~DrugsandBiologicals.*

[262] Radiopharmaceutical Fee Schedule 2024 Update, Noridian. *https://med.noridianmedicare.com/web/jeb/fees-news/fee-schedules/radiopharmaceutical-fees.*

[263] Radiopharmaceutical Drugs—Billing Instructions, A Celerian Group Company. *https://www.cgsmedicare.com/partb/pubs/news/2013/0313/cope21543.html.*

[264] Reimbursement Guidelines for Radiopharmaceuticals HCPCS Level II Codes, Novitas Solutions. *https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00231502.*

[265] Reimbursement Guidelines for Radiopharmaceuticals Procedure Codes (Prior to January 2023), First Coast Service Options, Inc. *https://medicare.fcso.com/Coverage_News/0494780.asp.*

[266] Radiopharmaceutical Reimbursement, National Government Services. *https://www.ngsmedicare.com/web/ngs/fee-schedule-lookup-details?lob=93617&state=97256&rgion=93623&selectedArticleId=4920515.*

been approved for marketing by the U.S. Food and Drug Administration (FDA) and meet one of the following conditions:

(1) The approved labeling includes the indication for preventing or treating the rejection of a transplanted organ or tissue.

(2) The approved labeling includes the indication for use in conjunction with immunosuppressive drugs to prevent or treat rejection of a transplanted organ or tissue.

(3) Have been determined by a Part B carrier, in processing a Medicare claim, to be reasonable and necessary for the specific purpose of preventing or treating the rejection of a patient's transplanted organ or tissue, or for use in conjunction with immunosuppressive drugs for the purpose of preventing or treating the rejection of a patient's transplanted organ or tissue. (In making these determinations, the carriers may consider factors such as authoritative drug compendia, current medical literature, recognized standards of medical practice, and professional medical publications.)

We also finalized the period of coverage eligibility for a transplant patient.[267] Lastly, we established the policy that drugs are covered under this provision irrespective of whether they can be self-administered. We codified these policies at § 410.31 (later redesignated as § 410.30).

We note that we do not maintain a list of drugs covered under this benefit; rather, MACs are expected to maintain a list of these drugs, as stated in section 80.3, Chapter 17 of the *Medicare Claims Processing Manual.* MACs are expected to keep informed of FDA approvals of immunosuppressive drugs and update guidance as applicable.

While the eligibility timeframe has been extended and eligibility has been expanded since the immunosuppressive drug benefit under Medicare Part B was revised by OBRA '87, the scope of drugs payable under this benefit has not changed. Some examples of how the benefit has been extended and expanded include: section 13565 of the Omnibus Reconciliation Act of 1993 (OBRA '93) (Pub. L. 103–66), amended section 1861(s)(2)(J) of the Act to extend the duration of coverage for the immunosuppressive drug benefit to 36 months from the hospital discharge date following a covered transplant procedure for drugs furnished after CY 1997; section 113 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554) (BIPA) revised section 1861(s)(2)(J) of the Act to eliminate the time limits for coverage of prescription drugs used in immunosuppressive therapy under the Medicare program; and most recently, section 402 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260) amended section 226A(b)(2) to allow certain individuals whose Medicare entitlement based on ESRD would otherwise end 36 months after a kidney transplant to continue enrollment under Medicare Part B only for the coverage of immunosuppressive drugs described in section 1861(s)(2)(J) of the Act.

After reviewing our longstanding policies for the immunosuppressive drug benefit and engaging with interested parties about current practices and challenges, we are proposing policies aimed to reduce barriers faced by beneficiaries receiving immunosuppressive drugs under this benefit, as described below.

b. Compounded Immunosuppressive Drugs With Oral or Enteral Routes of Administration

As discussed in the previous section, the immunosuppressive drug benefit currently includes immunosuppressive therapies that have been approved for marketing by the FDA (and meet other regulatory requirements at § 410.30). Interested parties have expressed concern that compounded formulations of immunosuppressive drugs (for example, a liquid formulation of an immunosuppressive drug not commercially available from a manufacturer but prepared by a pharmacist) are not included in the immunosuppressive therapy benefit because these formulations are not approved by the FDA (that is, FDA does not review these drugs to evaluate their safety, effectiveness, or quality before they reach patients),[268] which is a regulatory requirement under the current benefit. These interested parties communicated that compounded formulations are frequently used in the treatment of transplant recipients who cannot swallow oral capsules or tablets due to age or oral-motor dysfunction. Some examples of drugs compounded for preventing or treating the rejection of a transplanted organ or tissue include, but are not limited to, azathioprine,[269] cyclophosphamide,[270] and tacrolimus.[271]

We recognize certain patient groups, such as those with dysphagia, those with enteral feeding tubes (for example, a nasogastric feeding tube or a percutaneous endoscopic gastrostomy (PEG) tube), and many pediatric patients [272] [273] covered under Medicare rely on compounded immunosuppressive drugs for maintenance therapy and believe that their inclusion in the immunosuppressive drug benefit would help to ensure that each beneficiary is able to access the most clinically appropriate formulation of an immunosuppressive drug.[274] [275] [276] Nonadherence to lifelong maintenance immunosuppressive therapy contributes to unfavorable post-transplant outcomes, with obstacles to accessing medication being a prominent risk factor for such nonadherence.[277]

[267] Since the establishment of the benefit by the enactment of OBRA '86, the period of coverage for a transplant patient under section 1861(s)(2)(J) of the Social Security Act has been subsequently amended by section 202 of the Medicare Catastrophic Coverage Act of 1988 (Pub. L. 100–360), the Medicare Catastrophic Coverage Repeal Act of 1989 (Pub. L. 101–234), section 13565 of the Omnibus Reconciliation Act of 1993 (OBRA '93) (Pub. L. 103–66), section 160 of the Social Security Act Amendments of 1994 (Pub. L. 103–432), section 113 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554) (BIPA 2000). The last of these statutory changes eliminates the time limits for coverage of prescription drugs used in immunosuppressive therapy under the Medicare program, effective with immunosuppressive drugs furnished on or after December 21, 2000.

[268] *https://www.fda.gov/drugs/human-drug-compounding/compounding-laws-and-policies.*

[269] United States Pharmacopeia (2024). USP Monographs, Azathioprine Compounded Oral Suspension. USP–NF. Rockville, MD: United States Pharmacopeia.

[270] United States Pharmacopeia (2024). USP Monographs, Cyclophosphamide Compounded Oral Suspension. USP–NF. Rockville, MD: United States Pharmacopeia.

[271] United States Pharmacopeia (2024). USP Monographs, Tacrolimus Compounded Oral Suspension. USP–NF. Rockville, MD: United States Pharmacopeia.

[272] In the United States, children under 18 years of age comprise only 0.14 percent of the total Medicare ESRD population. Source: CY 2024 End-Stage Renal Disease Prospective Payment System final rule (88 FR 76374).

[273] Lentine, K, Smith, JM, Lyden, GR, Miller, JM, Dolan, TG, Bradbrook, K, Larkin, L, Temple, K, Handarova, DK, Weiss, S, Israni, AK, Snyder, JJ (2024). OPTN/SRTR 2022 Annual Data Report: Kidney. *American Journal of Transplantation,* 24(2), S19–S118. *https://doi.org/10.1016/j.ajt.2024.01.012.*

[274] Silva RME, Portela RDP, da Costa IHF, et al. Immunosuppressives and enteral feeding tubes: An integrative review. J Clin Pharm Ther. 2020;45:408–418. *https://doi.org/10.1111/jcpt.13093.*

[275] Goorhuis JF, Scheenstra R, Peeters PM, Albers MJ. Buccal vs. nasogastric tube administration of tacrolimus after pediatric liver transplantation. Pediatr Transplant. 2006 Feb;10(1):74–7. doi: 10.1111/j.1399–3046.2005.00402.x. PMID: 16499591.

[276] Liverman, R, Chandran, MM, Crowther, B. Considerations and controversies of pharmacologic management of the pediatric kidney transplant recipient. Pharmacotherapy. 2021 Jan;41(1): 77–102. *https://doi.org/10.1002/phar.2483.*

[277] Fine RN, Becker Y, De Geest S, et al. Nonadherence consensus conference summary

Therefore, we are proposing revisions at § 410.30 to include orally and enterally administered compounded formulations with active ingredients derived only from FDA-approved drugs where approved labeling includes an indication for preventing or treating the rejection of a transplanted organ or tissue, or for use in conjunction with immunosuppressive drugs to prevent or treat rejection of a transplanted organ or tissue, or have been determined by a MAC, in processing a Medicare claim, to be reasonable and necessary for this specific purpose as outlined in the immunosuppressive drug benefit. As we intend this proposal to enhance access and address adherence concerns for patients who are not able to swallow capsules or tablets and we do not believe there are access concerns with other types of formulations, we propose to limit the included compounded formulations to those products with oral and enteral routes of administration (for example, oral suspensions or solutions).

We solicit comment on these proposals.

c. Immunosuppressive Refill Policy and Supplying Fee

Section 303(e)(2) of the MMA added section 1842(o)(6) of the Act which requires the Secretary to pay a supplying fee (less applicable deductible and coinsurance) to pharmacies for certain Medicare Part B drugs and biologicals, as determined appropriate by the Secretary, including for immunosuppressive drugs described in section 1861(s)(2)(J) of the Act.

In the CY 2005 PFS, we established a supplying fee of $50 for the initial oral immunosuppressive prescription supplied in the first month after a transplant (69 FR 66312 through 66313). In the CY 2006 Physician Fee Schedule, we established a supplying fee of $16 for all subsequent prescriptions after the initial prescription supplied during a 30-day period (70 FR 70233 through 70236).

Following the CY 2006 rulemaking, we issued program instruction [278] to the MACs that prohibits payment for refills of immunosuppressive drug prescriptions in most circumstances and limits payment for prescriptions to 30-day supplies. We state in Chapter 17 of the Medicare Claims Processing Manual that contractors should limit payment for prescriptions to those of 30-day supplies, except in special circumstances, because dosage frequently diminishes over time; it is not uncommon for the provider to change the prescription from one drug to another; and coinsurance liability on unused drugs could be a financial burden to the beneficiary.

We have heard from interested parties that both the 30-day limit on supplies and prohibition on payment for refills no longer align with current practice for treating patients on maintenance immunosuppression regimens who are prescribed a stable dosage for months or years and receive refillable supplies for several months' use at a time. Frequent dosage adjustments for some immunosuppressive drugs that require therapeutic drug monitoring and dose titration based on blood concentrations, such as tacrolimus, tend to occur more often in newly transplanted recipients, and less frequently once patients are on stable regimens.[279] Other immunosuppressive drugs, such as mycophenolate mofetil, do not require routine therapeutic drug monitoring and have fixed recommended dosages per labeling where patients may be maintained on stable dosages for several months unless patients experience complications.[280] Transplant recipients must take immunosuppressive drugs on a lifelong basis to prevent rejection, maintain allograft function, and, for some transplanted organs, prevent death. Most patients are eventually prescribed stable maintenance immunosuppressive drug dosages post-transplant for extended periods of time. For example, liver transplant guidelines recommend review of the immunosuppressive drug regimen at least every 6 months.[281] For transplant beneficiaries, we believe that the limitation on payment to a maximum 30-day supply of immunosuppressive therapy by our program instruction is an unnecessary burden that poses a greater risk to adherence than does the potential for a sudden change in dosage needs. There is considerable concern among providers and advocates that interrupted access to immunosuppressive drugs caused by running out of or having insufficient medication supply can decrease medication adherence, increase risk of organ transplant rejection, and ultimately decrease the rate of survival of transplant recipients.[282] [283] We agree with interested parties that it would be beneficial to patients to reduce barriers that complicate access to immunosuppressive medication and reasonable for CMS to make programmatic changes consistent with this objective.

Accordingly, we are proposing two changes regarding supplying fees and refills for immunosuppressive drugs. First, we are proposing to allow payment of a supplying fee for a prescription of a supply of up to 90 days. To reflect this proposal, we are proposing to revise § 414.1001 to allow payment of a supplying fee to a pharmacy for first prescriptions and for prescriptions following the first prescription for greater than a 30-day supply. We are proposing additional modifications at § 414.1001 to combine paragraphs (a) (for supplying fees) and (b) (for supplying fees following a transplant). Accordingly, we are also proposing to remove paragraph (b) and redesignate paragraphs (c) and (d) as paragraphs (b) and (c), respectively. We intend to further study the supplying fee schedule for immunosuppressive drugs and are not proposing to make any changes to the supplying fee amounts at this time (meaning the current 30-day supplying fees would apply to any amount of days' supply). The dispensing and supplying fees under Part B (§ 414.1001) have been shown to be higher than dispensing fees paid in the commercial market.[284] So, until additional study is done regarding input costs for dispensing drugs billed to Medicare Part B and subsequent notice-and-comment rulemaking can be done, if appropriate, in response to such information, we aim to continue the current fee schedule regardless of the days' supply dispensed. Second, we are proposing to allow payment of refills for

report. *Am J Transplant.* 2009; 9(1): 35–41. *doi: 10.1111/j.1600–6143.2008.02495.x.*

[278] Section 80.3, Chapter 17 of the Medicare Claims Processing Manual.

[279] Tacrolimus [package insert]. Northbrook, IL: Astellas Pharma, Inc.; 2022. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/050708s055,010115s007lbl.pdf.*

[280] Cellcept [package insert]. San Francisco, CA: Genentech USA, Inc.; 2022. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/050722s050,050723s050,050758s048,050759s055lbl.pdf.*

[281] Lucey MR, Terrault N, Ojo L, et al. Long-term management of the successful adult liver transplant: 2012 practice guideline by the American Association for the Study of Liver Diseases and the American Society of Transplantation. Liver Transpl. 2013 Jan;19(1):3–26. doi: 10.1002/lt.23566.

[282] Nelson J, Alvey N, Bowman L, et al. Consensus recommendations for use of maintenance immunosuppression in solid organ transplantation: Endorsed by the American College of Clinical Pharmacy, American Society of Transplantation, and the International Society for Heart and Lung Transplantation. *Pharmacotherapy.* 2022; 42:599–633. *doi: 10.1002/phar.2716.*

[283] Chisholm MA, Lance CE, Williamson GM, Mulloy LL. Development and validation of an immunosuppressant therapy adherence barrier instrument. *Nephrol Dial Transplant.* 2005 Jan;20(1): 181–188. *https://doi.org/10.1093/ndt/gfh576.*

[284] *https://www.pcmanet.org/rx-research-corner/mandating-pharmacy-reimbursement-increase-spending/08/31/2021/#:~:text=The%20average%20dispensing%20fee%20in,the%20state's%20Medicaid%20FFS%20rate.*

these immunosuppressive drugs. Under our proposal, if finalized, the prescribing healthcare provider may adjust the days' supply up to 90 days and allow refills for an immunosuppressive drug based on the individual circumstance of the beneficiary in accordance with applicable state laws.

We welcome comments on these proposals.

5. Blood Clotting Factors (§ 410.63)

a. Background

Hemophilia is a genetic bleeding disorder resulting in a deficiency of coagulation Factor VIII (hemophilia A) or coagulation Factor IX (hemophilia B) due to mutations in the respective clotting factor genes.[285] [286] Prophylactic use of clotting factors has been proven to improve quality of life by preventing joint bleeds but requires maintenance therapy, usually throughout the life of the patient. Preventing joint damage early is crucial because the initial damage will progress, irrespective of whether further bleeds occur in the affected joints.[287] Currently, clotting factor treatments include: plasma-derived products, which are virally inactivated and made from human donor plasma; recombinant products, such as recombinant Factors VIIa, VIII, IX, X, XIII, which are created using genetically engineered cells and recombinant technology; and a monoclonal antibody product that binds to specific receptor sites of missing clotting factor, which is needed for effective hemostasis.[288] [289] Individuals with hemophilia generally self-infuse clotting factor at home, often learning to do so in childhood.[290] [291] [292]

Section 2324 of the Deficit Reduction Act of 1984 (Pub. L. 98–369) added subparagraph (I) to section 1861(s)(2) of the Act to provide Medicare Part B coverage of blood clotting factor treatments for hemophilia patients who are competent to use such factors to control bleeding without medical supervision (that is, self-administered), and items related to the administration of such factors; this is codified at § 410.63(b). As set forth in 1842(o)(1)(C) of the Act, payment for clotting factor product is the amount provided for under section 1847A of the Act.

In January of 2003, the Comptroller General of the United States published a report entitled ''Payment for Blood Clotting Factor Exceeds Providers Acquisition Cost'' [293] (hereinafter referred to the January 2003 report). Among other things, the report found that ''providers incur additional costs associated with delivering clotting factor that are not separately reimbursed by Medicare.'' Specifically, the report cited delivery costs generated in inventory management, specialized refrigerated storage, shipping, and the provision of ancillary supplies such as needles, syringes, and tourniquets to patients that were not accounted for by Medicare payment for the clotting factor product alone.

After the release of the January 2003 report, section 303I(1) of the MMA amended section 1842(o) of the Act by adding a new paragraph (5), requiring the Secretary to establish a furnishing fee for the items and services associated with the furnishing of blood clotting factor. Specifically, section 1842(o)(5) of the Act requires that for clotting factors furnished on or after January 1, 2005, the Secretary shall provide for a separate payment to the entity which furnishes blood clotting factors for items and services related to the furnishing of such factors in an amount that the Secretary determines to be appropriate. Accordingly, the clotting factor furnishing fee was codified at § 410.63(c), which states that the furnishing fee is added on a per unit basis to the clotting factor.

In 2005, CMS established a furnishing fee of $0.14 per unit of clotting factor. The clotting factor furnishing fee is increased by the percentage increase in the Consumer Price Index (CPI) for Medical Care for the 12-month period ending with June of the previous year, as required by Section 1842(o)(5)(C) of the Act, and updated annually in chapter 17, section 80.4.1 of the Medicare Claims Processing Manual. For 2024, the clotting factor furnishing fee is $0.250 per unit. Chapter 17 of the Medicare Claims Processing Manual, section 80.4.1 indicates that ''CMS includes this clotting factor furnishing fee in the nationally published payment limit for clotting factor billing codes'' along with the pricing file, which denotes which HCPCS codes have the furnishing fee added. The payment limit in the pricing file includes the payment limit for the clotting factor product (under methodology in section 1847A of the Act) plus furnishing fee.

As was the case at the time the clotting factor furnishing fee regulations were originally finalized, we continue to believe the products eligible for payment of the clotting factor furnishing fee and those eligible for payment as clotting factor products are the same subset of products: that is, self-administered clotting factor products, as described above. Similar to section 1861(s)(2)(I) of the Act, section 1842(o)(5) of the Act specifically contemplates that clotting factors are self-administered. In particular, section 1842(o)(5)(A)(ii) of the Act specifies that the furnishing fee can take into account ''ancillary supplies and patient training for the self-administration of such factors.'' As stated in the CY 2005 PFS final rule, the furnishing fee accounts for the costs associated with supplying the clotting factor, including patient training necessary for self-administration of such factors (69 FR 47523; 69 FR 66311). Thus, the clotting factor furnishing fee, as implemented, pays for services and supplies in connection with the patient's self-administration of the product.

We note that section 1842(o)(5)(A) of the Act directed the Secretary to ''review [. . .] the January 2003 report'' when establishing the separate payment for entities which furnish blood clotting factors to the patient. The January 2003 report refers to self-administration of clotting factor and the benefits beneficiaries receive from home-use of the product throughout the report. For example, the report states, ''Individuals with hemophilia generally self-infuse clotting factor. Clotting factor can be infused on demand, when a bleeding episode occurs, or for prevention, known as prophylactic use. By self-infusing, individuals can avoid waiting for care at a medical facility.''

Most notably, for purposes of understanding the Medicare clotting factor payment inadequacy that was addressed by Congress by adding the furnishing fee, the report states ''[t]he method of delivery of clotting factor has implications for Medicare payment. Most outpatient drugs covered by Medicare are administered in a

[285] *https://www.hemophilia.org/bleeding-disorders-a-z/types/hemophilia-a*, accessed April 9, 2024.

[286] *https://www.hemophilia.org/bleeding-disorders-a-z/types/hemophilia-b*, accessed April 9, 2024.

[287] Aledort LM, Haschmeyer RH, Pettersson H. A longitudinal study of orthopaedic outcomes for severe factor-VIII-deficient haemophiliacs. The Orthopaedic Outcome Study Group. J Intern Med. 1994 Oct;236(4):391–9.

[288] Srivastava A, et al. Haemophilia. 2020;26(suppl 6):1–158.

[289] *https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=2483adba-fab6-4d1b-96c5-c195577ed071.*

[290] GAO–03–184 Medicare: Payment for Blood Clotting Factor. *www.gao.gov/assets/gao-03-184.pdf.*

[291] Valentino, L.A., Baker, J.R., Butler, R., Escobar, M., Frick, N., Karp, S., . . . Skinner, M. (2021). Integrated Hemophilia Patient Care via a National Network of Care Centers in the United States: A Model for Rare Coagulation Disorders. Journal of Blood Medicine, 12, 897–911. *https://doi.org/10.2147/JBM.S325031.*

[292] *https://www.hemophilia.org/bleeding-disorders-a-z/treatment/current-treatments*, accessed April 9, 2024.

[293] *https://www.gao.gov/assets/gao-03-184.pdf.*

physician's office. When a beneficiary visits a physician in order to receive a drug, the physician receives one payment from Medicare for the drug and another payment through the physician fee schedule for administering the drug. Clotting factor, however, is generally not administered in a physician's office.'' That is, the report highlighted that Medicare payment for clotting factor, in particular, was inadequate because there are costs associated with supplying the clotting factor, but because it is self-administered, the furnishing of clotting factor was generally not eligible for the administration fee. Generally, the report noted that payment for supplying other outpatient drugs covered by Medicare Part B were adequate because they are eligible for the administration fee. Again, as stated above, Congress addressed this issue by creating the furnishing fee for these self-administered clotting factor products in the MMA.

More recently, gene therapies have been FDA-approved for the treatment of hemophilia. These gene therapies introduce a functional gene to the patient, which provides the genetic information needed for the patient to produce the missing or nonfunctional protein. A viral vector in the gene therapies, engineered with adeno-associate virus, delivers the functional copy of the clotting factor gene into the patient's liver cells. The viral vector then releases the functional gene which integrates into the cell's DNA and starts producing the missing clotting factor protein (that is, Factor VIII or Factor IX) to restore normal clotting function.

In the case of hemophilia A or B, the gene therapy introduces the functional gene that enables the patient to produce Factor VIII or Factor IX, respectively, on their own. Unlike clotting factors, which promptly restore balance in the coagulation cascade at the point of deficiency or bridge activated Factor IX and Factor X to restore the function of missing activated Factor VIII,[294] allowing for stable blood clot formation and hemostasis, the gene therapies do not directly integrate into the coagulation cascade.[295] [296] In the coagulation cascade, clotting factors become activated in response to damaged tissues or exposure to collagen at the injury site. This activation initiates the conversion of prothrombin to thrombin. Thrombin then converts fibrinogen into fibrin strands, forming the blood clot. Clotting factors restore normal clotting function by replacing deficient factors through repeated, dose-adjustable infusions or injections. In contrast, a single administration of gene therapies maintains a consistent and adequate level of clotting factors over the long term by enabling the self-production of the clotting factor proteins—an indirect method that relies on the patient's cells to increase clotting factor levels. However, as the self-production of clotting factor proteins takes time, the sustained outcomes of gene therapies may take several weeks to fully manifest. Interested parties have asked if CMS considers these gene therapies to be clotting factors for which the clotting factor furnishing fee would be paid.

Gene therapies for hemophilia are administered via a one-time, single-dose intravenous infusion in a setting where personnel and equipment are immediately available to treat infusion-related reactions. They are not typically administered by the patient in his or her home, and close monitoring is required for at least three hours after the end of the infusion.[297] While these gene therapy products may have a similar goal to clotting factor products, in that both products are designed to improve outcomes for patients with hemophilia, gene therapy products prompt the body to make clotting factors, but are not clotting factors themselves. Given that the administration would occur incident to a physician service (that is, the product is not self-administered), the differing mechanism of action from replacing deficient factors (that is, triggering the body to make clotting factors rather than infusing clotting factors into the body), and the requirement of close monitoring by a healthcare professional post-infusion, these gene therapies do not have the characteristics described in the January 2003 report that is referenced in section 1842(o)(5) of the Act, which the Secretary relied on in drafting § 410.63(c). Therefore, they do not constitute ''clotting factors'' for purposes of Medicare payment.

Accordingly, gene therapies for hemophilia are eligible for payment as drugs or biologicals under Part B as part of (or incident to) a physician's service. The ''incident to'' coverage is limited to drugs that are not usually self-administered and the physician generally must incur a cost for the drug and must bill for it. Furnishing entities will bill for its administration, and the administration fees will reflect the resources necessary to furnish the drug. For example, certain CPT codes for administering drugs include preparation of the dose and patient monitoring. Specifically, CPT codes 96401–96549 (chemotherapy administration and nonchemotherapy injections and infusions) include clinical labor activities such as clinical staff preparation of chemotherapy agent(s) as well as evaluation and management services.[298]

For the reasons explained above, we do not believe gene therapies for hemophilia meet the definition of a clotting factor for purposes of Medicare payment, but even if they did, they still would not be eligible for the furnishing fee because the costs associated with furnishing these gene therapies would already be reflected in applicable administration codes paid under the Physician Fee Schedule. In accordance with § 410.63(c)(1), a clotting factor furnishing fee is not payable when the costs associated with furnishing a clotting factor are paid through another payment system. In this case, the payment system is the payment system established under the Physician Fee Schedule. Furnishing fees for drugs that are physician administered would result in physicians being paid twice for incidental costs of administering the drug because the furnishing fee is intended to compensate for supplies like needles, syringes, and tourniquets as well as storage costs, and so is the Part B payment for administering the drug. We do not believe this double payment is appropriate, nor do we believe this is what Congress intended in directing CMS to establish a clotting factor furnishing fee.

Accordingly, in this proposed rule, we are proposing to update § 410.63(b) to clarify existing CMS policy that blood clotting factors must be self-administered to be considered clotting factors for which the furnishing fee applies. Additionally, we are proposing to clarify at § 410.63(c) that the furnishing fee is only available to entities that furnish blood clotting factors, unless the costs associated with furnishing the clotting factor are paid though another payment system, including the Physician Fee Schedule. That is, we are proposing to clarify through revisions to § 410.63 that

[294] Genentech, Inc. Hemlibra (emicizumab-kxwh) injection, for subcutaneous use. South San Francisco, CA: Genentech, Inc.; 2023. Package insert.

[295] Hoffman, M., & Monroe, D.M. (2001). A cell-based model of hemostasis. *Thrombosis and Haemostasis,* 85(6), 958–965.

[296] Schenone M, Furie BC, Furie B. The blood coagulation cascade. *Curr Opin Hematol.* 2004 Jul;11(4):272–7.

[297] Carvalho M, Sepodes B, Martins APPatient access to gene therapy medicinal products: a comprehensive reviewBMJ Innovations 2021;7:123–134.

[298] Section 30.5, Chapter 12 of the Medicare Claims Processing Manual.

clotting factors (as specified in section 1861(s)(2)(I) of the Act) and those eligible to receive the clotting factor furnishing fee (as specified in section 1842(o)(5) of the Act) are the same subset of products.

B. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Background on RHC and FQHC Payment Methodologies

As provided in 42 CFR part 405, subpart X, of our regulations, RHC and FQHC visits generally are defined as face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which one or more RHC or FQHC qualifying services are furnished. RHC and FQHC practitioners are physicians, NPs, PAs, CNMs, clinical psychologists (CPs), licensed marriage and family therapists, mental health counselors, and clinical social workers, and under certain conditions, a registered nurse or licensed practical nurse furnishing care to a homebound RHC or FQHC patient in an area verified as having shortage of home health agencies. Transitional Care Management (TCM) services can also be paid by Medicare as an RHC or FQHC visit. In addition, Diabetes Self-Management Training (DSMT) or Medical Nutrition Therapy (MNT) sessions furnished by a certified DSMT or MNT program may also be considered FQHC visits for Medicare payment purposes. Only medically necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner are RHC or FQHC billable visits. Services furnished by auxiliary personnel (for example, nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered incident to the visit and are included in the per-visit payment.

RHCs generally are paid an all-inclusive rate (AIR) for all medically necessary medical and mental health services and qualified preventive health services furnished on the same day (with some exceptions). The AIR is subject to a payment limit, meaning that an RHC will not receive any payment beyond the specified limit amount. As of April 1, 2021, all RHCs are subject to upper payment limits determined in accordance with section 1833(f) of the Act.

FQHCs were paid under the same AIR methodology until October 1, 2014. Beginning on that date, in accordance with section 1834(o) of the Act (as added by section 10501(i)(3) of the Patient Protection and Affordable Care Act (Pub. L. 111–148)), FQHCs began to transition to the FQHC PPS system, in which they are paid based on the lesser of the FQHC PPS rate or their actual charges. The FQHC PPS rate is adjusted for geographic differences in the cost of services by the FQHC PPS geographic adjustment factor (GAF). The rate is increased by 34 percent when an FQHC furnishes care to a patient that is new to the FQHC, or to a beneficiary receiving an initial preventive physical examination (IPPE) or has an annual wellness visit (AWV).

Both the RHC AIR and FQHC PPS payment rates were designed to reflect the cost of all services and supplies that an RHC or FQHC furnishes to a patient in a single day. The rates are not adjusted at the individual level for the complexity of individual patient health care needs, the length of an individual visit, or the number or type of practitioners involved in the patient's care. Instead for RHCs, all costs for the facility over the course of the year are aggregated and an AIR is derived from these aggregate expenditures. The FQHC PPS base rate is updated annually by the percentage increase in the FQHC market basket reduced by a productivity adjustment. For CY 2025, CMS is proposing to rebase and revise the FQHC market basket to reflect a 2022 base year; see section III.B.7 of this proposed rule.

2. General Care Management Services in RHCs and FQHCs

a. Background

We have been engaged in a multi-year examination of coordinated and collaborative care services in professional settings, and as a result established codes and separate payment in the PFS to independently recognize and pay for these important services. The care coordination included in services, such as office visits, does not always adequately describe the non-face-to-face care management work involved in primary care and similar care relationships. Payment for office visits may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries, such as those who are returning to a community setting following discharge from a hospital or skilled nursing facility (SNF) stay.

Before we get into the detailed background of our RHC and FQHC payment policies for care coordination services, we want to acknowledge that we have used several terms to describe these services and are providing clarification. We use the terms ''care coordination'' services interchangeably with the term ''care management'' services in preamble and manual guidance to describe the type of work discussed above. We began to use the term ''general care management'' when we established the HCPCS code G0511 for CY 2018. Use of ''general care management'' is meant to describe certain non-face-to-face care management work involved in primary care that we have identified as appropriate for separate payment as discussed in the following paragraphs.

As we discussed in the CY 2016 PFS final rule (80 FR 71081 through 71088), to address the concern that the non-face-to-face care management work involved in furnishing comprehensive, coordinated care management for certain categories of beneficiaries is not adequately paid for as part of an office visit, beginning on January 1, 2015, practitioners billing under the PFS are paid separately for chronic care management (CCM) services when CCM service requirements are met. We explained that RHCs and FQHCs cannot bill under the PFS for RHC or FQHC services and individual practitioners working at RHCs and FQHCs cannot bill under the PFS for RHC or FQHC services while working at the RHC or FQHC. Although many RHCs and FQHCs pay for coordination of services within their own facilities and may sometimes help to coordinate services outside their facilities, the type of structured care management services that are now payable under the PFS for patients with multiple chronic conditions, particularly for those who are transitioning from a hospital or SNF back into their communities, are generally not included in the RHC or FQHC payment. Therefore, separate payment was established in the CY 2016 PFS final rule (80 FR 71080 through 71088) for RHCs and FQHCs that furnish CCM services. We believe the non-face-to-face time required to coordinate care is not captured in the RHC AIR or the FQHC PPS payment, particularly for the rural and/or low-income populations served by RHCs and FQHCs. Allowing separate payment for CCM services in RHCs and FQHCs is intended to reflect the additional resources necessary for the unique components of CCM services.

In the CY 2018 PFS final rule (82 FR 53169 through 53180), we finalized revisions to the payment methodology for CCM services furnished by RHCs and FQHCs and established requirements for general behavioral health integration (BHI) and psychiatric collaborative care management (CoCM)

services furnished in RHCs and FQHCs, beginning on January 1, 2018. We also initiated the use of HCPCS codes G0511 and G0512. HCPCS code G0511 is a general care management code for use by RHCs or FQHCs when at least 20 minutes of qualified CCM or general BHI services are furnished to a patient in a calendar month. HCPCS code G0512 is for psychiatric CoCM and can be billed by RHCs or FQHCs when at least 60 minutes of qualified psychiatric CoCM services are furnished to a patient in a calendar month.

For CY 2018 the payment amount for HCPCS code G0511 was set at the average of the 3 national non-facility PFS payment rates for the CCM and general BHI codes and updated annually based on the PFS amounts. That is, for CY 2018 the 3 codes that comprised HCPCS code G0511 were CPT code 99490 (*20 minutes or more of CCM services*), CPT code 99487 (*60 minutes or more of complex CCM services*), and CPT code 99484 (*20 minutes or more of BHI services*).

In the CY 2019 PFS final rule (83 FR 59683), we explained that another CCM code was introduced for practitioners billing under the PFS, CPT code 99491, which would correspond to 30 minutes or more of CCM furnished by a physician or other qualified health care professional and is similar to CPT codes 99490 and 99487. Therefore, for RHCs and FQHCs, we added CPT code 99491 as a general care management service and included it in the calculation of HCPCS code G0511. Starting on January 1, 2019, RHCs and FQHCs were paid for HCPCS code G0511 based on the average of the national non-facility PFS payment rates for CPT codes 99490, 99487, 99484, and 99491 (83 FR 59687).

In the CY 2021 PFS final rule (85 FR 84697 through 84699), we explained that the requirements described by the codes for principal care management (PCM) services were similar to the requirements for the services described by HCPCS code G0511; therefore, we added HCPCS codes G2064 and G2065 to HCPCS code G0511 as general care management services for RHCs and FQHCs. Consequently, effective January 1, 2021, RHCs and FQHCs are paid when a minimum of 30 minutes of qualifying PCM services are furnished during a calendar month. The payment rate for HCPCS code G0511 for CY 2021 was the average of the national non-facility PFS payment rate for the RHC and FQHC care management and general behavioral health codes (CPT codes 99490, 99487, 99484, and 99491), and PCM codes (HCPCS codes G2064 and G2065). We noted that in the CY 2022 PFS final rule (86 FR 65118), HCPCS codes G2064 and G2065 were replaced by CPT codes 99424 and 99435. Therefore, for CY 2022 the payment rate for HCPCS code G0511 was the average of the national non-facility PFS payment rate for CPT codes 99490, 99487, 99484, 99491, 99424, and 99425).

In the CY 2023 PFS final rule (87 FR 69735 through 69737), we included chronic pain management (CPM) services described by HCPCS code G3002 in the general care management HCPCS code G0511 when at least 30 minutes of qualifying non-face-to-face CPM services are furnished during a calendar month. We explained since HCPCS code G3002 is valued using a crosswalk to the PCM CPT code 99424, which is currently one of the CPT codes that comprise HCPCS code G0511, there was no change made to the average used to calculate the HCPCS code G0511 payment rate to reflect CPM services.

Most recently, in the CY 2024 PFS final rule (88 FR 79071 through 79073) we included the CPT codes that are associated with the suite of services that comprise remote physiologic monitoring (RPM) and remote therapeutic monitoring (RTM) in the general care management HCPCS code G0511 when these services are furnished by RHCs and FQHCs. In addition, we included community heath integration (CHI), principal illness navigation (PIN), and PIN—peer support services in HCPCS code G0511 when these services are furnished by RHCs and FQHCs (88 FR 79073 through 79081). We noted that for each of these newly included services that they must be medically reasonable and necessary, meet all requirements, and not be duplicative of services paid to RHCs and FQHCs under the general care management code for an episode of care in a given calendar month. We also clarified RHCs and FQHCs may bill HCPCS code G0511 multiple times in a calendar month, as long as all of the requirements are met and resource costs are not counted more than once (88 FR 79075).

Additional information on care management requirements is available on the CMS Care Management web page and on the CMS RHC and FQHC web pages.[299] [300] [301]

[299] *https://www.cms.gov/medicare/payment/fee-schedules/physician/care-management.*

[300] *https://www.cms.gov/center/provider-type/rural-health-clinics-center.*

[301] *https://www.cms.gov/medicare/payment/prospective-payment-systems/federally-qualified-health-centers-fqhc-center.*

b. Proposed Regulatory Update (§ 405.2464(c))

During our development of the proposals discussed in section III.B.2.c. and III.B.2.d. of this proposed rule, we determined that the language located in § 405.2464(c) could use additional information to streamline and provide clarity on our payment policy for care coordination services. For example, using consistent terms, effective dates, and the description of the basis of payment. Therefore, we propose technical changes to § 405.2464(c) to accurately reflect the iterations of our payment policy for care coordination services as detailed in this background section.

c. Proposed Payment Policy for General Care Management Services

As discussed previously, in the last few years of PFS payment rules we have expanded the scope of care management services billable using HCPCS code G0511. Prior to CY 2024, HCPCS code G0511 was based on the national average non-facility PFS payment rate for each base code identified as billable general care management services. That is, we added each payment rate divided by the total number of codes to arrive at the payment amount for HCPCS code G0511. This payment amount was a flat rate that was not subsequently adjusted for locality.

In the CY 2024 PFS final rule (88 FR 79076 through 79079), we explained continuing to calculate the value of HCPCS code G0511 using an approach based on an average may no longer be appropriate payment for those services since we are simply dividing by the number of codes that comprise HCPCS code G0511 and as that number of services with lower payment rates increases, the payment rate decreases. We noted that while the policy may address providing a payment for furnishing non-face-to-face services, the magnitude of the value may not appropriately account for the costs. Therefore, we finalized a revised methodology for the calculation of HCPCS code G0511 by looking at the actual utilization of the services. We used a weighted average of the services that comprise HCPCS code G0511. For the utilization data of the services, we used the most recently available utilization data from the services paid under the PFS in the physician office setting. We explained that the physician office setting may provide an appropriate proxy for utilization of these services in the absence of actual data because this setting most closely aligns with the types of services

furnished in RHCs and FQHCs since they typically furnish primary care.

To ensure we accounted for payments accurately, we explained that we looked at PFS utilization of the base code for the service and any applicable add-on codes used in the same month as well as any base codes reported alone in a month for all of the services comprising general care management (that is, the array of services that made up HCPCS code G0511). We believed we needed to account for the payment associated with the base code along with an applicable add-on code in our calculation as this demonstrates a complete encounter. Then to arrive at the payment rate for HCPCS code G0511 for CY 2024, we took the weighted average of the base code and add-on code pairs, in addition to the individual base codes for all of the services that comprise HCPCS code G0511 by using the CY 2021 PFS utilization.

We determined that this approach was a more accurate representation of the payment since it is consistent with practitioners billing under the PFS, and it accounts for the additional time spent in care coordination.

Subsequent to the issuance of the CY 2024 PFS final rule, interested parties have requested that CMS give them the ability to bill Medicare for each of the care management services that comprise HCPCS code G0511 when they are furnished in RHCs and FQHCs. RHCs, FQHCs, and associations supporting access to health care for rural populations have expressed concerns regarding the transparency of the services being billed with HCPCS code G0511. We note, in the CY2024 PFS final rule we stated that HCPCS code G0511 could be billed multiple times in a calendar month for each care management code that comprised HCPCS code G0511 as long as all requirements were met, there was no overlapping of resource time and services were furnished in accordance with CPT coding guidelines and conventions. However, providing this guidance triggered questions on how CMS tracks which general care management service is being furnished if the bundled code is reported so they would know when it was appropriate to bill multiple care management services on a single claim. RHCs and FQHCs have also requested the ability to bill the add-on codes that describe additional minutes spent on furnishing care management services and often ask for guidance on how to account for additional time spent.

We have also heard from interested parties that RHCs and FQHCs would not find it burdensome to report the actual HCPCS code that describes the care management service furnished, which was the main concern we had when we implemented HCPCS code G0511 (82 FR 53172). We understand that RHCs and FQHCs have become more sophisticated with billing and therefore reporting multiple codes has become less burdensome than in CY 2018 when we implemented G0511. In addition, we have heard that RHCs and FQHCs are interested in having more exposure and recognition in playing their part the delivery of quality primary care and believe that this could be achieved with data that shows their utilization of services which could also be used in future payment refinements.

Due to these concerns, we have reevaluated our payment policy for care management services. We agree with interested parties that it is important to identify the actual services being furnished and understand the utilization of these services, especially given our strong interest in their volume and their contribution to initiatives on health equity and social needs of services in the care coordination space. Therefore, we are proposing to require RHCs and FQHCs to bill the individual codes that make up the general care management HCPCS code, G0511. The current list of base and add-on codes that make-up G0511 are listed in Table 24, titled ''General Care Management HCPCS Codes and Descriptors.'' Under this proposal, HCPCS code G0511 would no longer be payable when billed by RHCs and FQHCs. We note that the payment amounts for some services that made up G0511 are less than the payment amount for G0511 and if an RHC or FQHC mostly furnishes these services, they could see a potential decline in payment. We are also proposing to allow RHCs and FQHCs to bill the add-on codes for additional time spent once the minimum threshold of time was met to account for a complete encounter. This could potentially offset any decrease in payments. Payment for these services would be the national non-facility PFS payment rate when the individual code is on an RHC or FQHC claim, either alone or with other payable services and the payment rates are updated annually based on the PFS amounts for these codes. We believe that these proposals promote transparency in billing and payment and allowing RHCs and FQHCs to bill the individual care management codes would take into account the complexity of the service and the time spent furnishing the service.

BILLING CODE P

TABLE 24: General Care Management HCPCS Codes and Descriptors

HCPCS code	Short Descriptors	Long Descriptors
99091	Collj & interpj data ea 30 d	Collection and interpretation of physiologic data (e.g. Blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days
99424	Prin care mgmt phys 1st 30	Principal care management services, for a single high-risk disease, with the following required elements: one complex chronic condition expected to last at least 3 months, and that places the patient at significant risk of hospitalization, acute exacerbation/ decompensation, functional decline, or death, the condition requires development, monitoring, or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities, ongoing communication and care coordination between relevant practitioners furnishing care; first 30 minutes provided personally by a physician or other qualified health care professional, per calendar month
99425	Prin care mgmt phys ea addl	Principal care management services, for a single high-risk disease, with the following required elements: one complex chronic condition expected to last at least 3 months, and that places the patient at significant risk of hospitalization, acute exacerbation/ decompensation, functional decline, or death, the condition requires development, monitoring, or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen and/or the management of the condition is unusually complex due to comorbidities, ongoing communication and care coordination between relevant practitioners furnishing care; each additional 30 minutes provided personally by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)
99426	Prin care mgmt staff 1st 30	Principal care management services, for a single high-risk disease, with the following required elements: one complex chronic condition expected to last at least 3 months, and that places the patient at significant risk of hospitalization, acute exacerbation/ decompensation, functional decline, or death, the condition requires development, monitoring, or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen and/or the management of the condition is unusually complex due to comorbidities, ongoing communication and care coordination between relevant practitioners furnishing care; first 30 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month
99427	Prin care mgmt staff ea addl	Principal care management services, for a single high-risk disease, with the following required elements: one complex chronic condition expected to last at least 3 months, and that places the patient at significant risk of hospitalization, acute exacerbation/ decompensation, functional decline, or death, the condition requires development, monitoring, or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen and/or the management of the condition is unusually complex due to comorbidities,

HCPCS code	Short Descriptors	Long Descriptors
		ongoing communication and care coordination between relevant practitioners furnishing care; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional per calendar month (List separately in addition to code for primary procedure)
99437	Chrnc care mgmt phys ea addl	Chronic care management services, provided personally by a physician or other qualified health care professional, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/ decompensation, or functional decline, comprehensive care plan established, implemented, revised or monitored; each additional 30 minutes by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)
99439	Chrnc care mgmt staf ea addl	Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month
99453	Rem mntr physiol param setup	Remote monitoring of physiologic parameter(s) (e.g. Weight, blood pressure, pulse oximetry, respiratory flow rate) initial set-up and patient education on use of equipment
99454	Rem mntr physiol param dev	Remote monitoring of physiologic parameter(s) (e.g. Weight, blood pressure, pulse oximetry, respiratory flow rate) initial device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days
99457	Rem physiol mntr 1st 20 min	Remote physiologic monitoring treatment services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes
99458	Rem physiol mntr ea addl 20	Remote physiologic monitoring treatment services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (list separately in addition to code for primary procedure)
99474	Self-meas bp 2 readg bid 30d	Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient
99484	Care mgmt svc bhvl hlth cond	Care management services for behavioral health conditions, at least 20 minutes of clinical staff time, directed by a physician or other qualified health care professional time, per calendar month, with the following required element: initial assessment or follow-up monitoring, including using applicable validated rating scales, behavioral health care planning about behavioral or psychiatric health problems, including revision for patients not progressing or whose status changes, facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling, or psychiatric consultation, continuity of care with an appointed member of the care team
99487	Cplx chrnc care 1st 60 min	Complex chronic care management services, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the

HCPCS code	Short Descriptors	Long Descriptors
		patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, establishment or substantial revision of comprehensive care plan, moderate or high complexity medical decision making; first 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month
99489	Cplx chrnc care ea addl 30	Complex chronic care management services, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, establishment or significant revision of comprehensive care plan, moderate or high complexity medical decision making; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)
99490	Chrnc care mgmt staff 1st 20	Chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; first 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month
99491	Chrnc care mgmt phys 1st 30	Chronic care management services, provided personally by a physician or other qualified healthcare professional, at least 30 minutes of physician or other qualified healthcare professional time, per calendar month, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored
98975	Rem ther mntr 1st setup&edu	Remote therapeutic monitoring (e.g. therapy adherence, therapy response); initial set-up and patient education on use of equipment
98976	Rem ther mntr dev sply resp	Remote therapeutic monitoring (e.g. therapy adherence, therapy response); device(s) supply with scheduled (e.g. daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days
98977	Rem ther mntr dv sply mscskl	Remote therapeutic monitoring (e.g. therapy adherence, therapy response); device(s) supply with scheduled (e.g. daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days
98980	Rem ther mntr 1st 20 min	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes
98981	Rem ther mntr ea addl 20 min	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the

HCPCS code	Short Descriptors	Long Descriptors
		calendar month; each additional 20 minutes (list separately in addition to code for primary procedure)
G0140	Nav srv peer sup 60 min pr m	Principal Illness Navigation – Peer Support by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a certified peer specialist; 60 minutes per calendar month, for specified activities
G0146	Nav srv peer sup add 30 pr m	Principal Illness Navigation—Peer Support, additional 30 minutes per calendar month (List separately in addition to G0140)
G3002	Chronic pain mgmt 30 mins	Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care, e.g. physical therapy and occupational therapy, and community-based care, as appropriate. Required initial face-to- face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month. (when using G3002, 30 minutes must be met or exceeded)
G3003	Chronic pain mgmt addl 15m	Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calenda month. (List separately in addition to G3002. When using G3003, 15 minutes mut be met or exceeded).
G0323	Care manage beh svs 20mins	Care management services for behavioral health conditions, at least 20 minutes of clinical psychologist or clinical social worker time, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, coordination with an/or referral to physicians and practitioners who are authorized by Medicare law to prescribe medications and furnish E/M services counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team)
G0019	Comm hlth intg svs sdoh 60 mn	Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that are significantly limiting the ability to diagnose or treat problem(s) addressed in an initiating visit.
G0022	Comm hlth intg svs add 30 m	Community health integration services, each additional 30 minutes per calendar month (List separately in addition to G0019)
G0023	Pin srv 60 min pr m	Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other

HCPCS code	Short Descriptors	Long Descriptors
		practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities: • Person-centered assessment, performed to better understand the individual context of the serious, high risk condition. ++ Conducting a person-centered assessment to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors. ++ Facilitating patient-driven goal setting and establishing an action plan. ++ Providing tailored support as needed to accomplish the practitioner's treatment plan. • Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services.
G0024	Pin srv add 30 min pr m	Principal Illness Navigation services, additional 30 minutes per calendar month (List separately in addition to G0023).

BILLING CODE C

We are proposing revisions at § 405.2464(c) to reflect the proposed payment method for care management services furnished in RHCs and FQHCs beginning January 1, 2025. We welcome comments on this proposed payment methodology.

d. New Codes for Advanced Primary Care Management (APCM) Services

As discussed in section II.G of this proposed rule, HHS and CMS have been analyzing opportunities to strengthen and invest in primary care in alignment with the goals of the HHS Initiative to Strengthen Primary Care.[302] Research has demonstrated that greater primary care physician supply is associated with improved population-level mortality and reduced disparities,[303] and also that establishing a long-term relationship with a primary care provider leads to reduced emergency department (ED) visits,[304] improved care coordination, and increased patient satisfaction.[305] HHS recognizes that effective primary care is essential for improving access to healthcare, for the health and wellbeing of individuals, families, and communities, and for achieving health equity. The first coordinated set of HHS-wide actions to strengthen primary care, as part of the Initiative, is in primary care payment; for example, adjusting payment to ensure it supports delivery of advanced primary care. CMS Innovation Center models, described in section II.G.2.a.(1) of this proposed rule, reflect the ongoing work within HHS and the unified, comprehensive approach to HHS primary care activities that we are accomplishing through our current statutory authorities and funding.

In recent years, CMS has implemented significant changes aimed at better capturing the resources required for care management services, including chronic care management (CCM), principal care management (PCM), and transitional care management (TCM) and more recently, community health integration (CHI), principal illness navigation (PIN) and PIN-peer support services. For RHCs and FQHCs, we have established payment for these suites of care management services outside of the RHC AIR and FQHC PPS. The policy requirements for RHCs and FQHCs furnishing these various care coordination services are consistent with those finalized under the PFS.

In section II.G.2.b. of this proposed rule, we are proposing to establish coding and make payment under the PFS for a newly defined set of APCM services described and defined by three new HCPCS G-codes. This new coding would reflect the recognized effectiveness and growing adoption of the advanced primary care approach to care. It would also encompass a broader range of services and simplify the billing and documentation requirements, as compared to existing care management codes. The proposed coding for APCM incorporates elements of several existing care management services into a bundle that we have already considered to be care coordination services paid separately to RHCs and FQHCs using HCPCS code G0511. For example, CCM and PCM. In addition, the coding for APCM incorporates elements of communication technology-based services (CTBS) into a bundle that we have already considered to be virtual communications paid separately to RHCs and FQHCs using HCPCS code G0071. For example, remote evaluation of patient videos/images, virtual check-in, and e-visits. Therefore, to allow RHCs and FQHCs the ability to simplify the billing and documentation requirements associated with furnishing APCM services we are proposing to allow RHCs and FQHCs to bill for these services and receive separate payment. Consistent with section II.G.2.b. of this proposed rule, the APCM code sets vary by the degree of complexity of patient conditions (that is, non-complex and complex CCM for multiple chronic conditions or PCM for a single high-risk condition), and whether the number of minutes spent by clinical staff or the physician or non-physician practitioner (NPP) is used to meet time thresholds for billing. The proposed HCPCS codes are described below:

HCPCS code GPCM1 (*Advanced primary care management services provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar*

[302] U.S. Department of Health and Human Services. (2023). Primary Care: Our First Line of Defense. *https://www.hhs.gov/sites/default/files/primary-care-issue-brief.pdf.*

[303] Basu S, Berkowitz SA, Phillips RL, Bitton A, Landon BE, Phillips RS. Association of Primary Care Physician Supply With Population Mortality in the United States, 2005–2015. *JAMA Intern Med.* 2019;179(4):506–514. doi:10.1001/jamainternmed.2018.7624. *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2724393.*

[304] Willemijn L.A. Schäfer et al, ''Are People's Health Care Needs Better Met When Primary Care Is Strong? A Synthesis of the Results of the QUALICOPC Study in 34 Countries,'' Primary Health Care Research and Development 20 (2019): e104. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6609545/.*

[305] Michael J. van den Berg, Tessa van Loenen, and Gert P Westert, ''Accessible and Continuous Primary Care May Help Reduce Rates of Emergency Department Use: An International Survey in 34 Countries,'' Family Practice 33, no. 1 (Feb. 2016): 42–50. *https://academic.oup.com/fampra/article/33/1/42/2450446.*

month, with the following elements, as appropriate:

- *Consent*;

++ Inform the patient of the availability of the service; that only one practitioner can furnish and be paid for the service during a calendar month; of the right to stop the services at any time (effective at the end of the calendar month); and that cost sharing may apply.

++ Document in patient's medical record that consent was obtained.

- *Initiation during a qualifying visit for new patients or patients not seen within 3 years;*
- *Provide 24/7 access for urgent needs to care team/practitioner, including providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent needs regardless of the time of day or day of week;*
- *Continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments;*
- *Deliver care in alternative ways to traditional office visits to best meet the patient's needs, such as home visits and/or expanded hours;*
- *Overall comprehensive care management;*

++ Systematic needs assessment (medical and psychosocial).

++ System-based approaches to ensure receipt of preventive services.

++ Medication reconciliation, management and oversight of self-management.

- *Development, implementation, revision, and maintenance of an electronic patient-centered comprehensive care plan;*

++ Care plan is available timely within and outside the billing practice as appropriate to individuals involved in the beneficiary's care, can be routinely accessed and updated by care team/practitioner, and copy of care plan to patient/caregiver;

- *Coordination of care transitions between and among health care providers and settings, including referrals to other clinicians and follow-up after an emergency department visit and discharges from hospitals, skilled nursing facilities or other health care facilities as applicable;*

++ Ensure timely exchange of electronic health information with other practitioners and providers to support continuity of care.

++ Ensure timely follow-up communication (direct contact, telephone, electronic) with the patient and/or caregiver after an emergency department visit and discharges from hospitals, skilled nursing facilities, or other health care facilities, within 7 calendar days of discharge, as clinically indicated.

- *Ongoing communication and coordinating receipt of needed services from practitioners, home- and community-based service providers, community-based social service providers, hospitals, and skilled nursing facilities (or other health care facilities), and document communication regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors, in the patient's medical record;*
- *Enhanced opportunities for the beneficiary and any caregiver to communicate with the care team/practitioner regarding the beneficiary's care through the use of asynchronous non-face-to-face consultation methods other than telephone, such as secure messaging, email, internet, or patient portal, and other communication-technology based services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with patients, as appropriate;*

++ Ensure access to patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits).

- *Analyze patient population data to identify gaps in care and offer additional interventions, as appropriate;*
- *Risk stratify the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients;*
- *Be assessed through performance measurement of primary care quality, total cost of care, and meaningful use of Certified EHR Technology.*).

HCPCS code GPCM2 (*Advanced primary care management services for a patient with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the elements included in GPCM1, as appropriate*) and HCPCS code GPCM3 (*Advanced primary care management services for a patient that is a Qualified Medicare Beneficiary with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the elements included in GPCM1, as appropriate*).

As we've established previously, care coordination services are RHC/FQHC services and as such, we are proposing to align once again with the PFS and adopt the new codes for APCM services. Additionally, allowing separate payment for APCM services in RHCs and FQHCs is intended to reflect the additional time and resources necessary for the unique components of care coordination services.

Further, in alignment with our proposal earlier in this section to require RHCs and FQHCs to utilize the same coding as when billing under the PFS and no longer use HCPCS code G0511, which described many care coordination services, we are proposing to require RHCs and FQHCs when furnishing APCM to use the codes created for the PFS, that is, the three HCPCS G-codes described above. We would pay for these services in addition to the RHC AIR or FQHC PPS because we consider these services as non-face-to-face services and similar to other care management services such as chronic care management, principal care management, and remote physiological monitoring, where these services are not captured in the RHC AIR or FQHC PPS payment. Similarly, we are proposing that payment for these services would be paid at the PFS non-facility rate.

It is important to note that if RHCs and FQHCs report these new codes, they are per calendar month bundles. If the RHC/FQHC decides to bill for APCM then they would not bill for individual services. For further discussion on duplicative services and concurrent billing restrictions with regard to APCM policies, we refer readers to section II.G.2.d. of this proposed rule.

e. Request for Information—Aligning With Services Paid Under the PFS

As we discuss in section III.B.2.a. of this proposed rule, over the last several years we have been increasing our focus on care coordination. These services have evolved to focus on preventing and managing chronic disease, improving a beneficiary's transition from the hospital to the community setting, or on integrative treatment of patients with

behavioral health conditions. We have acknowledged that the care coordination included in services such as office visits does not always describe adequately the non-face-to-face care management work involved and may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries. Therefore, under the PFS we have proposed new services over the years that practitioners billing under the PFS can be paid separately under the PFS. We have noted previously that RHCs and FQHCs cannot bill under the PFS for RHC or FQHC services and individual practitioners working at RHCs and FQHCs cannot bill under the PFS for RHC or FQHC services while working at the RHC or FQHC. Therefore, we have proposed payment policies for RHCs and FQHCs that complement the new services for care coordination under the PFS to align the RHC and FQHC resource cost for those services with payment.

The increase in frequency of this complementary rulemaking has triggered us to consider operational efficiencies internally that we believe could result in more transparency and clarity for interested parties. Since RHCs and FQHCs are generally paid under encounter-based payment systems, we have not systematically analyzed all services paid under the PFS (nor do we analyze all new services proposed) to determine if they are included as a part of the visit versus are eligible for additional payment. Another reason that we do not analyze every code is because frequently codes created under the PFS for billing practitioners are to more appropriately account for resources paid under the PFS. Codes for these purposes are not applicable for RHCs and FQHCs since they are not paid under the PFS.

Generally, for PFS services that are a part of the office visit, there is no separate payment under the RHC AIR or FQHC PPS methodologies. On the contrary, care coordination services where the focus is on care management, coordination, or certain activities needed to manage chronic illnesses or adapt to new models of care, we have allowed separate payment for RHCs and FQHCs.

We are seeking comment on how we can improve the transparency and predictability regarding which HCPCS codes are considered care coordination services. Our goal is to classify care coordination services on the PFS in a way that makes it automated in the downstream effect on RHCs and FQHCs. We believe establishing a streamlined policy regarding which services are separately paid for RHCs and FQHCs versus included as part of the visit is more transparent. In addition, a policy where codes are communicated and updated through sub-regulatory guidance may be more efficient.

3. Telecommunication Services

a. Background

Section 3704 of the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) (Pub. L. 116–136, March 27, 2020) directed the Secretary to establish Medicare payment for telehealth services provided by RHCs and FQHCs serving as a distant site (that is, where the practitioner is located) during the PHE for COVID–19. Separately, section 3703 of the CARES Act expanded CMS' emergency waiver authority to allow for a waiver of any of the statutory telehealth payment requirements under section 1834(m) of the Act for telehealth services furnished during the PHE. Specifically, section 1834(m)(8)(B) of the Act, as added by the CARES Act, requires that the Secretary develop and implement payment methods for FQHCs and RHCs that serve as a distant site during the PHE for the COVID–19 pandemic. The payment methodology outlined in the CARES Act requires that rates shall be based on rates that are similar to the national average payment rates for comparable telehealth services under the Medicare PFS. CMS established rates based on the average amount for all PFS telehealth services on the telehealth list, weighted by volume.

In the CY 2022 PFS final rule with comment (86 FR 65211), we revised the regulatory requirement that an RHC or FQHC mental health visit must be a face-to-face (that is, in-person) encounter between an RHC or FQHC patient and an RHC or FQHC practitioner. We revised the regulations under § 405.2463 to state that an RHC or FQHC mental health visit can also include encounters furnished through interactive, real-time, audio/video telecommunications technology or audio-only interactions in cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder. We noted that these changes aligned with similar mental health services furnished under the PFS. We also noted that this change allows RHCs and FQHCs to report and be paid for mental health visits furnished via real-time, telecommunication technology in the same way they currently do when these services are furnished in-person.

In addition, we revised the regulation under § 405.2463 to state that there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record (86 FR 65210 and 65211).

As discussed in the CY 2023 PFS final rule (87 FR 69738), the Consolidated Appropriations Act, 2022 (CAA, 2022) (Pub. L. 117–103, March 15, 2022) included the extension of several Medicare telehealth flexibilities established during the public health emergency (PHE) for COVID–19 for a limited 151-day period beginning on the first day after the end of the PHE for COVID–19. Specifically, Division P, Title III, section 304 of the CAA, 2022, delayed the in-person requirements under Medicare for mental health services furnished through telehealth under the PFS and for mental health visits furnished by RHCs and FQHCs via telecommunications technology until the 152nd day after the end of the PHE for COVID–19. Therefore, in the CY 2023 PFS final rule (87 FR 69737), we revised the regulations under §§ 405.2463 and 405.2469 again to reflect these provisions.

Further, in the CY 2024 PFS final rule (88 FR 79065), we discussed that the CAA, 2023 (Pub. L. 117–328, December 29, 2022) further extended the Medicare telehealth flexibilities enacted in the CAA, 2022 for a period beginning on the first day after the end of the PHE for COVID–19 and ending on December 31, 2024, if the PHE ends prior to that date. Specifically related to RHCs and FQHCs, section 4113(c) of the CAA, 2023 amended section 1834(m)(8) of the Act to extend payment for telehealth services furnished by FQHCs and RHCs for the period beginning on the first day after the end of the COVID–19 PHE and ending on December 31, 2024, if the PHE ends prior to that date. We noted that payment continued to be made under the methodology established for

telehealth services furnished by FQHCs and RHCs during the PHE, which is based on payment rates that are similar to the national average payment rates for comparable telehealth services under the PFS.

We explained that section 4113(d) of the CAA, 2023 continues to delay the in-person requirements under Medicare for mental health services furnished through telehealth under the PFS and for mental health visits furnished by RHCs and FQHCs via telecommunications technology. That is, for RHCs and FQHCs, in-person visits will not be required until January 1, 2025, or, if later, the first day after the end of the PHE for COVID–19. Therefore, we stated that we will continue to apply the delay of the in-person requirements under Medicare for mental health services furnished by RHCs and FQHCs. We noted that the Department of Health and Human Services declared an end to the Federal PHE for COVID–19 under section 319 of the Public Health Service Act on May 11, 2023.[306] Therefore, we revised the regulations under §§ 405.2463 and 405.2469 again to reflect these provisions (88 FR 79066 through 79067).

b. Direct Supervision Via Use of Two-Way Audio/Video Communications Technology

Under Medicare Part B, certain types of services are required to be furnished under specific minimum levels of supervision by a physician or practitioner. See section II.D.2.a. for the discussion regarding direct supervision for services provided using telecommunications technologies under the PFS.

In the CY 2024 PFS final rule (88 FR 79067), we explained that extending this definition of direct supervision for RHCs and FQHCs under our regulations at §§ 405.2413, 405.2415, 405.2448, and 405.2452 through December 31, 2024, would align the timeframe of this policy with many of the previously discussed PHE-related telehealth policies that were extended under provisions of the CAA, 2023. In addition, we were concerned about an abrupt transition to the pre-PHE policy of requiring the physical presence of the supervising practitioner beginning after December 31, 2023, given that RHCs and FQHCs have established new patterns of practice during the PHE for COVID–19. We also believed that RHCs and FQHCs would need time to reorganize their practices established during the PHE to reimplement the pre-PHE approach to direct supervision without the use of audio/video technology. Similar to services furnished in physician office setting, RHC and FQHC services and supplies furnished incident to physician's services are limited to situations in which there is direct physician supervision of the person performing the service, except for certain care coordination services which may be furnished under general supervision. For CY 2024, we continued to define ''immediate availability'' as including real-time audio and visual interactive telecommunications through December 31, 2024, and solicited comment on whether we should consider extending the definition of ''direct supervision'' to permit virtual presence beyond December 31, 2024.

(1) Proposal for CY 2025

In the CY 2024 PFS proposed rule, we solicited comment on potential patient safety or quality concerns when direct supervision occurs virtually in RHCs and FQHCs; for instance, if certain types of services are more or less likely to present patient safety concerns, or if this flexibility would be more appropriate when certain types of auxiliary personnel are performing the supervised service. We were also interested in potential program integrity concerns such as overutilization or fraud and abuse that interested parties may have in regard to this policy.

Comments provided were overall supportive of our proposal to continue to define ''immediate availability'' to include availability through virtual means, stating that it will benefit healthcare providers while greatly enhancing patient access to quality care, particularly in underserved areas. Commenters also noted that direct supervision has become increasingly challenging and the option to provide virtual direct supervision has enhanced the quality and provision of healthcare services beneficiaries have received in medically underserved, rural communities.

We note that in section II.D.2.a. of this proposed rule, there is a proposal to permanently adopt a definition of direct supervision that allows ''immediate availability'' of the supervising practitioner using audio/video real-time communications technology (excluding audio-only), but only for the following subset of incident-to services described under § 410.26, (1) services furnished incident to a physician or other practitioner's service when provided by auxiliary personnel employed by the billing practitioner and working under their direct supervision, and for which the underlying HCPCS code has been assigned a Professional Component/Technical Component indicator of '5'; and (2) services described by CPT code 99211 (*Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of* a physician or *other qualified health care* professional). In addition, under the PFS we are proposing for all other services required to be furnished under the direct supervision of the supervising physician or other practitioner, to continue to define ''immediate availability'' to include real-time audio and visual interactive telecommunications technology only through December 31, 2025.

After evaluating the information gathered through the comment solicitation, we believe that we should maintain the current flexibility in RHCs and FQHCs as it continues to support access and preserve workforce capacity. We believe that there is value in allowing RHC and FQHC services to be furnished under direct supervision where virtual presence meets the definition of ''immediately available'' as status quo, so that we may further evaluate the services along with the analysis occurring for the remaining services that we are contemplating under the PFS. We note that there may be nuances in the RHC and FQHC settings since generally payment is at the AIR or PPS rate and not at the individual service code level to carve out services limited/obvious services from other services. We could seek to establish a final policy in RHCs and FQHCs once a final policy is determined under the PFS, to avoid confusion since they are taking an incremental approach at the code level for CY 2025.

Therefore, we are proposing to maintain the virtual presence flexibility on a temporary basis, that is, the presence of the physician (or other practitioner) would include virtual presence through audio/video real-time communications technology (excluding audio-only) through December 31, 2025.

c. Telecommunications Technology

As discussed above, section 3704 of the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) (Pub. L. 116–136, March 27, 2020) directed the Secretary to establish Medicare payment for telehealth services provided by RHCs and FQHCs serving as a distant site (that is, where the practitioner is located) during the PHE for COVID–19. Separately, section 3703 of the CARES Act expanded CMS' emergency waiver authority to allow for a waiver of any of the statutory

[306] *https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html.*

telehealth payment requirements under section 1834(m) of the Act for telehealth services furnished during the PHE. Specifically, section 1834(m)(8)(B) of the Act, as added by the CARES Act, required that the Secretary develop and implement payment methods for FQHCs and RHCs that serve as a distant site during the PHE for the COVID–19 pandemic. The payment methodology outlined in the CARES Act requires that rates shall be based on rates that are similar to the national average payment rates for comparable telehealth services under the Medicare PFS. Therefore, CMS established rates based on the average amount for all PFS telehealth services on the telehealth list, weighted by volume. RHCs and FQHCs bill for these Medicare telehealth services using HCPCS code G2025.

In the CY 2022 PFS final rule with comment (86 FR 65211), we revised the regulatory requirement that an RHC or FQHC mental health visit must be a face-to-face (that is, in person) encounter between an RHC or FQHC patient and an RHC or FQHC practitioner. We revised the regulations under § 405.2463 to state that an RHC or FQHC mental health visit can also include encounters furnished through interactive, real-time, audio/video telecommunications technology or audio-only interactions in cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder. We noted that these changes aligned with similar mental health services furnished under the PFS. We also noted that this change allows RHCs and FQHCs to report and be paid for mental health visits furnished via real-time, telecommunication technology in the same way they currently do when these services are furnished in-person.

The temporary authority under section 1834(m)(8) of the Act was extended by statute through the end of CY 2024, meaning under current law, and absent additional changes in regulation, RHCs and FQHCs could not be paid for non-behavioral health services furnished remotely to beneficiaries enrolled in fee-for-service Medicare after December 31, 2024.

(1) Payment Proposal for Non-Behavioral Health Telecommunication Technology Services

Widespread use of telecommunications technology to furnish services during the PHE has illustrated interest within the medical community and among Medicare beneficiaries in furnishing and receiving care through the use of technology beyond the PHE. During the PHE, RHCs and FQHCs, much like other provider types, have had to change how they furnish care in order to meet the needs of their patients, and use of the temporary authority to bill Medicare for PFS telehealth services has been widely utilized by RHCs and FQHCs during the PHE. Eliminating flexibilities under which RHC and FQHC services have been furnished to beneficiaries via telecommunication technologies for over four years and resuming solely in-person, face-to-face medical visits after December 31, 2024, would cause disruptions in access to services from RHC and FQHC practitioners. This would be particularly problematic for the underserved populations that these settings furnish services to since it could fragment care. We believe that we need to preserve the flexibilities under which RHC and FQHC services have been furnished to beneficiaries via telecommunication technologies temporarily and to do so through an approach that these settings are familiar with in order to mitigate burden. Technologies used in this space and the quality of care associated with them continue to evolve. We believe that it would be prudent to allow time to engage interested parties while we consider how to incorporate telecommunication technology services on a more permanent basis.

For these reasons, we propose, on a temporary basis, to allow payment for non-behavioral health visits furnished via telecommunication technology. We propose to facilitate payments using an approach that closely aligns with the mechanisms mandated by the statute but ends December 31, 2024. That is, RHCs and FQHCs would continue to bill for RHC and FQHC services furnished using telecommunication technologies by reporting HCPCS code G2025 on the claim, including services furnished using audio-only communications technology. Since the costs associated with non-behavioral health visits furnished via telecommunication technology are not included in the calculations for the RHC AIR methodology and FQHC PPS, we believe that we need to propose a proxy that would represent such resources used when furnishing these services. Therefore, we propose to continue to calculate the payment amount based on the average amount for all PFS telehealth services on the telehealth list, weighted by volume for those services reported under the PFS. We believe that using this weighted average is appropriate during this interim while we contemplate permanent policies for these services since there is a wide range of values for the telehealth services under the PFS. We believe that RHCs and FQHCs generally furnish services that are similar to and at a frequency the same as physicians and other practitioners paid under the PFS. While we do not have actual cost information, we believe that this weighted average is an appropriate proxy since it addresses certain resource costs experienced by professionals and would mitigate any potential over or under payments. Costs associated with these services would continue to not be used in determining payments under the RHC AIR methodology or the FQHC PPS.

We believe that these proposals would preserve the telecommunication technology flexibility under which RHC and FQHC services have been furnished for over 4 years and would not impact access to care for Medicare beneficiaries who currently benefit from these services while CMS contemplates next steps. We solicit comment on whether there may be other payment methodologies that may be a proxy for costs associated with non-behavioral health visits furnished via telecommunication technology and why those payment methodology may be more appropriate than the weighted average of the telehealth services list under PFS.

We propose to amend § 405.2464 by adding new paragraph (g) to reflect our proposed payment policy for non-behavioral health services furnished in RHCs and FQHCs via telecommunication technology for CY 2025.

(2) Alternative Proposal Considered for Payment of Medical Visits Furnished Via Telecommunication Technology

We considered reevaluating the regulations regarding face-to-face visit requirements for encounters between a beneficiary and an RHC or FQHC practitioner in light of contemporary medical practices. That is, we considered proposing a revision to the regulatory requirement that an RHC or FQHC medical visit must be a face-to-face (that is, in-person) encounter between a beneficiary and an RHC or FQHC practitioner to also include encounters furnished through interactive, real-time, audio and video telecommunications technology. This would result in payment for services furnished via telecommunication technology to be made under the RHC AIR methodology and under the FQHC PPS, similar to how we revised the

regulations for mental health visits. We believe interested parties may prefer the per visit payment that aligns with the RHC AIR or FQHC PPS. However, we did not propose this alternative because we determined that it would have unintended consequences, especially in cases where the RHC AIR or FQHC PPS per-visit rates would be significantly higher than the PFS rate that would apply if other entities furnished the same service to the same beneficiary in the same location.

We believe that continuing to pay temporarily for RHC and FQHC services furnished via telecommunication technologies in the same manner as we have done over the past several years preserves the flexibility for RHCs and FQHCs to continue access to care, mitigates administrative burden, and mitigates potential program integrity concerns. However, we solicit comment on the alternative proposal we considered. That is, revising the definition of a visit to include interactive, real-time, audio/video telecommunication technology which would result in a capitated payment under the RHC AIR methodology or FQHC PPS.

d. In-Person Visit Requirements for Remote Mental Health Services Furnished by RHC and FQHCs

The CAA, 2021, stipulated that the beneficiary needed to receive an in person, non-telehealth service 6 months prior to initiation of the telehealth mental health services and that the Secretary should determine an appropriate frequency for provision of subsequent periodic in person, non-telehealth services.

In the CY 2022 PFS final rule with comment (86 FR 65210), we revised the regulation under § 405.2463 to state that there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record.

As discussed in the CY 2023 PFS final rule (87 FR 69738), the CAA, 2022 included the extension of a number of Medicare telehealth flexibilities established during the PHE for COVID–19 for a limited 151-day period beginning on the first day after the end of the PHE. Division P, Title III, section 304 of the CAA, 2022, delayed the in-person requirements under Medicare for mental health services furnished through telehealth under the PFS and for mental health visits furnished by RHCs and FQHCs via telecommunications technology until the 152nd day after the end of the PHE for COVID–19.

The CAA, 2023 (Pub. L. 117–328, December 29, 2022) extended the Medicare telehealth flexibilities enacted in the CAA, 2022 for a period beginning on the first day after the end of the PHE for COVID–19 and ending on December 31, 2024, if the PHE ended prior to that date. While the CAA, 2021 only applied to the PFS, we implemented similar policies for RHCs, FQHCs, and hospital outpatient departments. The in-person visit requirements are currently set to take effect for services furnished on or after January 1, 2025.

However, given concerns from interested parties on the impact of enforcing these requirements after multiple years of delay, we are proposing an additional extension. We are proposing to continue to delay the in-person visit requirement for mental health services furnished via communication technology by RHCs and FQHCs to beneficiaries in their homes until January 1, 2026.

4. Intensive Outpatient Program Services (IOP)

a. Background

As we discussed in the CY 2024 OPPS final rule (88 FR 81838) section 4124 of Division FF of the CAA, 2023 established Medicare coverage for intensive outpatient program (IOP) services furnished by a hospital to its outpatients, or by a community mental health center (CMHC), a FQHC or a RHC, as a distinct and organized intensive ambulatory treatment service offering less than 24-hour daily care in a location other than an individual's home or inpatient or residential setting, effective January 1, 2024.

IOP is a distinct and organized outpatient program of psychiatric services provided for individuals who have an acute mental illness, which includes, but is not limited to conditions such as depression, schizophrenia, and substance use disorders. We noted an IOP is thought to be less intensive than a partial hospitalization program (PHP).

This new provision mandated several areas of policy to implement an IOP program, including scope of benefits and services, certification and plan of care requirements, and special payment rules for IOP services in RHCs and FQHCs, all of which are discussed in the CY2024 OPPS final rule (88 FR 81838 through 81845). We made corresponding regulation changes for IOP services at §§ 405.2400, 405.2401, 405.2410, 405.2411, 405.2446, 405.2462, 405.2463, 405.2464, 405.2468, and 405.2469.

b. Update to Special Payment Rules for Intensive Outpatient Services

As we discussed in the CY 2024 OPPS final rule (88 FR 81841), section 4124(c) of the CAA, 2023 further amended section 1834(o) of the Act and section 1834(y) of the Act, to provide special payment rules for both FQHCs and RHCs, respectively, for furnishing IOP services. Section 4124(c)(1) of the CAA, 2023 amended section 1834(o) of the Act to add a new paragraph (5)(A) to require that payment for IOP services furnished by FQHCs be equal to the amount that would have been paid under Medicare for IOP services had they been covered outpatient department services furnished by a hospital. In addition, section 4124(c)(2) of the CAA, 2023 amended section 1834(y) of the Act to add a new paragraph (3)(A) to require that payment for IOP services furnished by RHCs be equal to the amount that would have been paid under Medicare for IOP services had they been covered outpatient department services furnished by a hospital.

In the CY 2024 OPPS final rule (88 FR 81841), we provided a detailed discussion of the final CY 2024 payment rate methodology for IOP. CMS finalized two payment rates, a 3- and a 4- or more services per day, for IOP services for hospitals and CMHCs. However, for RHCs and FQHCs we established a 3-service per day payment rate. We stated that we believed it was appropriate to establish the payment rate where the utilization is typically structured to be days with 3 or fewer services and solicited comment on whether the hospital-based IOP payment rate for 4-service days would be appropriate for RHCs and FQHCs. Although we previously stated that we would review the data and consider a 4 or more services per day for future rulemaking, we have since considered this further. We believe that we should provide parity for IOP services across the various settings with site neutral payments while continuing to monitor access to these services. Therefore, we

are proposing to provide a payment rate for 4 or more services per day in an RHC/FQHC setting. Additionally, as required in section 4124(c)(2) of the CAA, 2023 we would align with the 4 or more-services per day payment rate for hospital outpatient departments. As with the 3-services per day, the 4 or more services per day payment rates will be updated annually.

c. Technical Correction (§§ 405.2410 and 405.2462)

In the CY 2024 Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems final rule with comment (88 FR 81844) we finalized revisions to §§ 405.2410, 405.2462, and 405.2464 in the regulations to reflect the payment amount for IOP services and how the Medicare Part B deductible and coinsurance are applied in RHC's and FQHC's. For RHCs, the beneficiary is responsible for the Medicare Part B deductible and coinsurance amounts at an amount not to exceed 20 percent of the clinic's reasonable charges for IOP services. For FQHC's, the beneficiary is responsible for a coinsurance amount of 20 percent of the lesser of the FQHC's actual charge for the service or the IOP rate. We revised the regulatory requirements at § 405.2410, Application of Part B deductible and coinsurance and § 405.2462, Application of deductible and coinsurance for RHCs and FQHCs paid on the basis of the special payment rule under § 405.2462(j) to reflect how the Medicare Part B deductible and coinsurance are applied.

During a recent review of our regulations at §§ 405.2410(c) and 405.2462(j), we noticed that both sections had errors. That is, § 405.2410(c) does not reflect the correct policy that is applicable for beneficiary coinsurance when they receive IOP services in RHCs and FQHCs. With regard to the error at § 405.2462(j), we inadvertently left language specific to RHCs in the introductory text when it should have been its own paragraph. Therefore, we propose revisions to § 405.2410 to reflect the correct policy applicable for beneficiary coinsurance as described above in the previous paragraph. We also propose revisions to § 405.2462(j) to accommodate the new paragraph (j)(1).

5. Payment for Preventive Vaccine Costs in RHCs and FQHCs

a. Background

Section 1833(a)(3)(A) of the Act specifies that services described in section 1861(s)(10)(A)—pneumococcal, influenza and COVID–19 vaccines and their administration—are exempt from the RHC and FQHC payment limit of 80 percent of reasonable costs. Therefore, payment for pneumococcal, influenza and COVID–19 vaccines and their administration in RHCs and FQHCs is governed by the statute at Section 1833(b) of the Act, which requires payment at 100 percent of reasonable cost. For RHCs, this means that costs associated with these vaccines and their administration are not included in determining the AIR or subject to the payment limit, and for FQHCs, these costs are not included under the FQHC PPS. We note that the hepatitis B vaccine, which is described at section 1861(s)(10)(B) of the Act, is not specified at 1833(a)(3)(A) as exempt from the RHC/FQHC payment limit of 80 percent of reasonable costs, and therefore, payment for a hepatitis B vaccine and its administration is included in the FQHCs PPS rate and the RHC AIR. However, since hepatitis B vaccines and their administration are considered a Part B preventive service, no coinsurance or deductible is charged when a hepatitis B vaccine is administered in an RHC or FQHC. Please see section III.H.2.c. of this proposed rule for more information on hepatitis B vaccines in RHCs and FQHCs.

In the April 3, 1996 FQHC final rule (61 FR 14657), we codified at § 405.2466(b)(1)(iv) that, for RHCs and FQHCs, payment for pneumococcal and influenza vaccine and their administration is 100 percent of Medicare reasonable cost, which is paid as part of the annual reconciliation through the cost report. In the CY 2022 PFS final rule (86 FR 65207), we made conforming changes in that section to include the COVID–19 vaccine and its administration.

b. Revisions to Current Policy

In the May 2, 2014 RHC/FQHC PPS final rule (79 FR 25449), we addressed commenters' recommendations that CMS apply a consistent approach to payment for Part B vaccines. One commenter specifically recommended that CMS allow RHCs and FQHCs to bill for Part B vaccines at the time of service, either with or without an encounter for a visit. The commenter stated that those bills could be paid using national Part B rates, to be followed by an annual reconciliation on the cost report between the payments and the reasonable costs of the vaccines and their administration. This commenter wished to reduce the time between vaccine administration and payment, and to enable the documentation on individual patient claims that these vaccines were furnished. Commenters generally asserted that streamlining Part B vaccine payment would help ensure broad vaccine access for Medicare beneficiaries.

In response to these comments, we responded that we did not believe that any changes in our billing policies were necessary. We stated that RHCs and FQHCs are accustomed to reporting and receiving payment for the reasonable costs of Part B vaccines and their administration through the annual cost report, and we believed that an annual reconciliation between vaccine payments and reasonable costs would create an additional administrative burden for FQHCs and MACs. We also noted that as of January 1, 2011, FQHCs have been required to report pneumococcal and influenza vaccines and their administration on a patient claim with the appropriate HCPCS and revenue codes when furnished during a billable visit. Please note that this is not a requirement for RHCs.

In the CY 2022 PFS final rule (86 FR 65207), in which we made conforming regulatory changes at § 405.2466(b)(1)(iv) to include the COVID–19 vaccine, we received several comments regarding the timing of vaccine payments for RHCs and FQHCs. These comments echoed the sentiments expressed by the commenters on the same topic in the 2014 final rule mentioned above, and while they were out of the scope of our proposals for CY2022, we will elaborate on them here. These commenters expressed appreciation for measures taken by CMS in April 2021 to make lump-sum payments for COVID–19 vaccine administration available to RHCs and FQHCs in advance of cost report settlement, but commenters emphasized that those payments were only a temporary solution. Commenters urged CMS to update the RHC and FQHC cost report to ensure adequate, permanent reimbursement for COVID–19 vaccines. Commenters added that RHCs and FQHCs have experienced challenges with burdensome reporting requirements and data collection, as well as slow distribution of payments from MACs. Another commenter stated that RHCs and FQHCs should not have to wait until settlement of cost report to be reimbursed for other preventive vaccines, and that delayed payment may hinder them from immunizing Medicare beneficiaries.

While we did not respond directly to those comments in the CY 2022 PFS final rule, as they were out of scope of the policies that were finalized at the time, we did make clarifications

regarding payment for preventive vaccines and their administration in the RHC and FQHC Frequently Asked Questions (FAQs) that accompanied the publication of the CY 2022 PFS final rule.[307] In those FAQs, we clarified that the conforming change made to § 405.2466(b)(1)(iv) to reflect coverage and payment for COVID–19 vaccines in RHCs and FQHCs did not reflect any other payment policy changes regarding payment for Part B vaccines and administration in those settings. We reiterated that RHCs and FQHCs are paid 100 percent of reasonable cost through their cost report for Part B vaccines and their administration. Since there is a gap in time from when costs are incurred in RHCs and FQHCs for furnishing vaccines and when payment is received, the Medicare Administrative Contractors (MACs) could provide early payments in the form of lump sum payments to RHCs and FQHCs in March of 2021 to facilitate COVID–19 vaccinations. RHCs and FQHCs can request additional lump sum payments from their MAC at any time.

Since the publication of the CY 2022 PFS final rule, we have given additional consideration to the comments discussed above. During and since the COVID–19 PHE, CMS has especially promoted efforts aimed at facilitating increased access to vaccinations for both Medicare enrollees and all Americans. Vaccination promotion efforts also dovetail with CMS' overarching strategic priorities of expanding health care access and advancing health equity. For CY 2025, CMS has identified the issue of vaccination in RHCs and FQHCs as an area where payment policy can be updated to improve access to preventive vaccines for Medicare enrollees.

We are proposing to allow RHCs and FQHCs to bill for the administration of Part B preventive vaccines at the time of service. Based on the proposed changes in section III.M. and III.H.2.c. of this proposed rule, this revision in policy would include all four Part B preventive vaccines: pneumococcal, influenza, hepatitis B, and COVID–19 vaccines. These claims would initially be paid like other Part B vaccine and vaccine administration claims, whose payments are discussed at section III.H.1. of this proposed rule: vaccine products would be paid at 95 percent of their Average Wholesale Price (AWP), and vaccine administration would be paid according to the National Fee Schedule for Medicare Part B Vaccine Administration. The fee schedule's locality-adjusted payment rate files for CY 2024 can be found on the CMS Vaccine Pricing website *at https://www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/vaccine-pricing.* Payment rate files for influenza, pneumococcal and hepatitis B vaccine administration can be found under the ''Seasonal Flu Vaccine'' tab, and payment rate files for COVID–19 vaccines can be found under the ''COVID–19 Vaccines & Monoclonal Antibodies'' tab. The CY 2025 payment rates for Part B vaccine HCPCS codes G0008, G0009, G0010 and 90480, with the annual update applied for CY 2025, will be made available at the time of publication of the CY 2025 PFS final rule, and Tables 45 and 46 in section III.H.1.f. of this proposed rule provide the CY 2025 projected payment rates for those amounts.

We are also clarifying that RHC or FQHC providers are eligible to bill HCPCS code M0201 for an in-home additional payment for Part B preventive vaccine administration, provided that a home visit meets all the requirements of both part 405, subpart X, for RHCs and FQHCs services provided in the home, and § 410.152(h)(3)(iii) for the in-home additional payment for Part B preventive vaccine administration. More information regarding the in-home additional payment can be found at section III.H.1.d of this proposed rule, and current and projected payment rates for M0201 can be found together with Part B vaccine administration payment rates mentioned above.

We emphasize that the statute at section 1833(b) of the Act requires that RHCs and FQHCs be paid at 100 percent of reasonable cost for Part B vaccines and their administration. Therefore, payments for these services received at the time they are furnished in RHCs and FQHCs will need to be annually reconciled with the facilities' actual vaccine and vaccine administration costs, including the in-home additional costs, on their cost reports. Due to the operational systems changes needed to facilitate payment through claims, we propose that RHCs and FQHCs begin billing for preventive vaccines and their administration at the time of service, for dates of service beginning on or after July 1, 2025. This will also allow ample time for CMS to release cost reporting instructions and sub-regulatory guidance with additional billing instructions for RHCs and FQHCs to bill Medicare Part B for preventive vaccines and their administration at the time of service.

We believe that this proposal addresses the comments and requests of stakeholders who have suggested this payment approach over the last several years. We note that this payment approach was mentioned in the Senate Appropriations Committee's ''Explanatory Statement For Departments Of Labor, Health And Human Services, And Education, And Related Agencies Appropriations Bill, 2021.'' [308] That report referenced a December 2019 white paper by the National Association of Community Health Centers, which noted that ''FQHCs can face significant delays in reimbursement for influenza and pneumococcal vaccines.'' [309] The Committee thus encouraged CMS to promote the ability of FQHCs to bill Part B directly for vaccinations at the time of service, with reconciliation of payments at the time of cost report settlement.

We invite public comment on these proposals. We would especially appreciate comments on the benefits of payments for vaccine costs billed at the time of service, weighed against the potential additional burdens of annual reconciliation of vaccine claims payments against actual vaccine costs.

6. Productivity Standards

a. Background

Productivity standards for RHCs were first established on March 1, 1978 (43 FR 8260), and updated on December 1, 1982 (47 FR 54163–54165), to help determine the average cost per patient for Medicare reimbursement in RHCs. These productivity screening guidelines were intended to identify situations where costs would not be allowed without acceptable justification by the clinic and limits on the amount of payment (57 FR 24967). Physicians, nurse practitioners (NPs), physician assistants (PAs), and certified nurse midwives (CNMs) are held to a minimum number of visits per full time employee (FTE), as discussed in section 80.4, chapter 13 of the Medicare Benefit Policy Manual. The productivity standards policy requires 4,200 visits per full-time equivalent (FTE) physician and 2,100 visits per FTE non-physician practitioner (*e.g.,* nurse practitioner, physician assistant, or certified nurse midwife). Physician and non-physician practitioner productivity may be combined and if so, the number of visits

[307] RHCs CY 2022 PFS Final Rule Fact Sheet: *https://www.cms.gov/files/document/rhcs-pfs-faqs.pdf*; FQHCs CY 2022 PFS Final Rule Fact Sheet: *https://www.cms.gov/files/document/fqhcs-pfs-faqs.pdf.*

[308] *https://www.appropriations.senate.gov/imo/media/doc/LHHSRept.pdf.*

[309] *https://www.nachc.org/wp-content/uploads/2023/10/adult-imm-fqhc-white-paper-11–01–2019.pdf.*

per full-time equivalent team is 6,300. If actual visits are less than the productivity standards, the average cost per visit will be computed based on the productivity standards rather than actual visits, which would result in the cost per visit to be lower than if actual visits were used. In other words, if the current productivity standards are not met, the results would be a reduction in the cost per visit, which could negatively impact the RHC AIR and reduce payments. There are exceptions to the productivity standards that can be made based on individual circumstances that is at the discretion of the MAC. We note that these standards of 4,200 visits per FTE physician and 2,100 visit per FTE nonphysician practitioner and 6,300 visits per combined FTE have not been updated since 1982. We also note similar requirements to contain costs in this way were not required in FQHCs or other settings paid on reasonable cost.

Interested parties have requested that CMS re-evaluate or remove the productivity standards policy for RHCs because they believe that the environment today is very different than when the RHC benefit began and that the ''visit per FTE'' is too high for practitioners to meet and results in reducing the AIR. They also shared that the productivity standards matter even less now since the implementation of the CAA, 2021 established payment limits for all RHCs.

During the COVID–19 PHE, CMS issued a combination of emergency authority waivers, regulations, enforcement discretion, and subregulatory guidance to ensure and expand access to care and to give health care providers the flexibilities needed to help keep people safe. RHCs expressed concerns about how the productivity standards might impact them during the PHE. For example, many RHCs had trouble meeting the productivity standards due to a change in the way they staffed their clinics and billed for RHC services with increased telecommunications services. RHCs claimed that they were negatively impacted even more so than other health care settings because of these requirements. We have long standing guidance in the Medicare Benefit Policy Manual, chapter 13, section 80.4 that describes the MAC's role in providing flexibility to grant productivity exceptions to RHCs who experienced disruptions in staffing and services to minimize the burden on RHCs. During the PHE we reminded RHCs of the exception process in FAQs,[310] and provided instructions to MACs to proactively reach out to RHCs reminding them of the exception process and to proactively grant exceptions as necessary.

Section 130 of the CAA, 2021 restructured the payment limits for RHCs beginning April 1, 2021. That is, independent RHCs, provider-based RHCs in a hospital with 50 or more beds, and RHCs enrolled under Medicare on or after January 1, 2021, will receive a prescribed national statutory payment limit per visit increase over an 8-year period for each year from 2021 through 2028. This provision also established payment limits for provider-based RHCs in a hospital with less than 50 beds. See CY 2022 PFS final rule (86 FR 65199 through 65202) for more detailed discussion.

Since the CAA, 2021 restructured the payment limits for RHCs, and in some cases established payment limits for RHCs beginning April 1, 2021, we believe that applying productivity standards may no longer be necessary with the payment limits set out by Congress. We believe that the productivity standards are outdated and redundant with the CAA, 2021 provisions. Therefore, we are proposing to remove productivity standards for RHCs.

7. Proposed Rebasing of the FQHC Market Basket

a. Background

Section 10501(i)(3)(A) of the Affordable Care Act added section 1834(o) of the Act to establish a payment system for the costs of FQHC services under Medicare Part B based on prospectively set rates. In the Prospective Payment System (PPS) for FQHC final rule published in the May 2, 2014 **Federal Register** (79 FR 25436), we implemented a methodology and payment rates for the FQHC PPS. Beginning on October 1, 2014, FQHCs began to transition to the FQHC PPS based on their cost reporting periods, and as of January 1, 2016, all FQHCs have been paid under the FQHC PPS.

Section 1834(o)(2)(B)(ii) of the Act requires that the payment for the first year after the implementation year be increased by the percentage increase in the Medicare Economic Index (MEI). Therefore, in CY 2016, the FQHC PPS base payment rate was increased by the MEI. The MEI at that time was based on 2006 data from the American Medical Association (AMA) for self-employed physicians and was used in the PFS sustainable growth rate (SGR) formula to determine the conversion factor for physician service payments. (See the CY 2014 PFS final rule (78 FR 74264) for a complete discussion of the 2006-based MEI.) Section 1834(o)(2)(B)(ii) of the Act also requires that beginning in CY 2017, the FQHC PPS base payment rate will be increased by the percentage increase in a market basket of FQHC goods and services, or if such an index is not available, by the percentage increase in the MEI.

Beginning with CY 2017, FQHC PPS payments were updated using a 2013-based market basket reflecting the operating and capital cost structures for freestanding FQHC facilities (hereafter referred to as the FQHC market basket). A complete discussion of the 2013-based FQHC market basket can be found in the CY 2017 PFS final rule (81 FR 80393 through 80403). In the CY 2021 PFS final rule (85 FR 84699 through 84710), we rebased and revised the FQHC market basket to reflect a 2017 base year.

For this CY 2025 PFS proposed rule, we are proposing to rebase and revise the 2017-based FQHC market basket to reflect a 2022 base year, which would maintain our historical frequency of rebasing the market basket every four years. The proposed 2022-based FQHC market basket is primarily based on Medicare cost report data for FQHCs for 2022, which are for cost reporting periods beginning on and after October 1, 2021, and prior to October 1, 2022. We propose to use data from cost reports beginning in FY 2022 because these data are the latest available complete set of Medicare cost report data for purposes of calculating cost weights for the FQHC market basket at the time of rulemaking.

In the following discussion, we provide an overview of the proposed FQHC market basket, describe the methodologies for developing the proposed 2022-based FQHC market basket, and provide information on the proposed price proxies. We then present the CY 2025 FQHC market basket update based on the proposed 2022-based FQHC market basket.

b. Overview of the Proposed 2022-Based FQHC Market Basket

Similar to the 2017-based FQHC market basket, the proposed 2022-based FQHC market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix (that is, intensity) of

[310] *https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf.*

goods and services purchased over time are not measured. The index itself is constructed using three steps. First, a base period is selected (we propose to use 2022 as the base period) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive expenditure categories, with the proportion of total costs that each category represents being calculated. These proportions are called cost weights. Second, each cost category is matched to an appropriate price or wage variable, referred to as a ''price proxy.'' In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the cost weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the cost weights multiplied by their price index levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket index levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe. As previously noted, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish FQHC services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a FQHC hiring more nurse practitioners to accommodate the needs of patients would increase the volume of goods and services purchased by the FQHC but would not be factored into the price change measured by a fixed-weight FQHC market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect recent changes in the mix of goods and services that FQHCs purchase (FQHC inputs) to furnish care between base periods.

c. Development of the Proposed 2022-Based FQHC Market Basket Cost Categories and Weights

We are inviting public comments on our proposed methodology, discussed in this section of this rulemaking, for deriving the proposed 2022-based FQHC market basket.

(1) Use of Medicare Cost Report Data

The major types of costs underlying the proposed 2022-based FQHC market basket are derived from the Medicare cost reports (CMS Form 224–14, OMB Control Number 0938–1298) for freestanding FQHCs. Specifically, we use the Medicare cost reports for eleven specific costs: FQHC Practitioner Wages and Salaries, FQHC Practitioner Employee Benefits, FQHC Practitioner Contract Labor, Clinical Staff Wages and Salaries, Clinical Staff Employee Benefits, Clinical Staff Contract Labor, Non-Health Staff Compensation, Medical Supplies, Pharmaceuticals, Fixed Assets, and Movable Equipment. A residual category is then estimated and reflects all remaining costs not captured in the 11 types of costs identified previously (such as non-medical supplies and utilities).

The resulting proposed 2022-based FQHC market basket cost weights reflect Medicare allowable costs. We propose to define Medicare allowable costs centers for freestanding FQHC facilities as the expenses reported on: Worksheet A, lines 1 through 7, lines 9 through 12, lines 23 through 36, and line 66. For the proposed 2022-based FQHC market basket, we are proposing to include data from the cost center from Worksheet A, line 66 (Telehealth) as effective for CY 2022 since CMS finalized a proposal to revise the current regulatory language for RHC or FQHC mental health visits to include visits furnished using interactive, real-time telecommunications technology and for RHCs and FQHCs to report and be paid for mental health visits furnished via real-time, telecommunication technology in the same way they currently do when these services are furnished in-person (86 FR 65208 through 62511). As done with the 2017-based FQHC market basket, we are proposing to continue to exclude Professional Liability Insurance (PLI) costs from the total Medicare allowable costs because FQHCs that receive section 330 grant funds also are eligible to apply for medical malpractice coverage under Federally Supported Health Centers Assistance Act (FSHCAA) of 1992 (Pub. L. 102–501) and FSHCAA of 1995 (Pub. L. 104–73 amending section 224 of the Public Health Service Act).

Later in this section, we explain in more detail how the costs for each of the 11 categories are derived. Prior to estimating any costs, we apply three basic edits. First, we only include the last submitted cost report so there is no double counting of a FQHC provider. Second, we exclude providers that have less than half a year of reported cost data; this edit excludes 175 FQHC providers for 2022. Finally, we remove any providers that did not report net direct patient care expenses on the FQHC cost report Worksheet A, line 37, column 7; this edit excludes 717 FQHC cost reports, or about 29 percent of FQHC providers. If a provider does not have reported costs, then we are unable to use that provider's costs to calculate cost weights. We encourage providers to report net direct patient care expenses when reporting the data. After the three edits, there are 1,713 remaining FQHC providers in the 2022 data set that we use to estimate cost expenditures for, or roughly two-thirds of the total FQHCs in the original Medicare cost report data set.

(a) FQHC Practitioner Wages and Salaries Costs

A FQHC practitioner is defined as one of the following occupations: physicians; nurse practitioners (NPs); physician assistants (PAs); certified-nurse midwife (CNMs); clinical psychologist (CPs); and clinical social workers (CSWs). We propose to calculate FQHC Practitioner Wages and Salaries Costs using three steps. First, we propose to calculate FQHC Practitioner Compensation Costs as equal to the net expenses (that is, costs after reclassifications and adjustments) as reported on Worksheet A, column 7, lines 23, 25, 26, 29, 30, and 31. These lines represent the total net costs (after reclassifications and adjustments) for physicians, PAs, NPs, CNMs, CPs, and CSWs.

Second, we propose to further divide the FQHC Practitioner Compensation Costs for these occupations into wages and salaries, employee benefits, and contract labor costs based on the ratios of practitioner wages and salaries, practitioner employee benefits, and practitioner contract labor costs to the sum of these three groups of costs. We do this by applying the ratios of practitioner wages and salaries, practitioner employee benefits, and practitioner contract labor to the net expense FQHC Practitioner Compensation Costs, and the determination of these ratios is described below. We propose to derive the practitioner wages and salaries costs as the sum of direct care wages and salaries reported on Worksheet A, column 1, lines 23, 25, 26, 29, 30, and 31. These lines represent the wages and salaries costs for physicians, PAs, NPs, CNMs, CPs, and CSWs. We propose to derive the practitioner employee benefits costs for these occupations as the sum of costs reported on Worksheet

S–3, part II, column 2, lines 2, 3, 4, 7, 8, and 9. These lines represent the employee benefits costs for physicians, PAs, NPs, CNMs, CPs, and CSWs. We propose to derive the practitioner contract labor costs for these occupations as the costs reported on Worksheet S–3, part II, column 1, lines 2, 3, 4, 7, 8, and 9. These lines represent the contract labor costs for physicians, PAs, NPs, CNMs, CPs, and CSWs. This was the same method used to calculate the ratios to split the FQHC Practitioner Compensation Costs as was done for the 2017-based FQHC market basket. Approximately 56 percent of FQHCs that reported direct patient care wages and salaries costs also reported employee benefits costs data and approximately 99 percent of FQHCs that reported direct patient care wages and salaries costs also reported contract labor cost data on Worksheet S–3, part II for 2022. This is higher reporting than the percent of FQHCs reporting the same data compared to the 2017-based FQHC market basket, which had a 45 percent and 66 percent reporting incidence for the 2017 cost report data. We are encouraged by this improvement in the data and continue to encourage all providers to report these data on the Medicare cost report.

The final step in the process to derive the FQHC Practitioner Wages and Salaries costs is to apply the ratio of practitioner wages and salaries to the sum of practitioner wages and salaries costs, practitioner employee benefits costs, and practitioner contract labor costs times the FQHC Practitioner Compensation costs (representing the net expenses for each occupation as reported on Worksheet A column 7) as described above. This calculation is done for each occupation individually (physicians, PAs, NPs, CNMs, CPs, and CSWs). The resulting proposed FQHC Practitioner Wages and Salaries costs are equal to the sum of each occupation's wages and salary costs. This is the same methodology that was used for the 2017-based FQHC market basket.

As stated in the CY 2022 PFS final rule (86 FR 65209), effective for CY 2022 FQHC mental health visits furnished using interactive, real-time telecommunications technology are paid for at the same rate as other FQHC visits when these services are furnished in-person; therefore, we propose to include telehealth wages and salaries costs in the FQHC Practitioner Wages and Salaries cost category. We propose to derive telehealth wages and salaries by multiplying the net telehealth costs (as reported on Worksheet A, column 7, line 66) times the ratio of telehealth wages and salaries (as reported on Worksheet A, column 1, line 66) to the sum of telehealth costs (the sum of Worksheet A, column 1 and 2, line 66).

(b) FQHC Practitioner Employee Benefits Costs

To calculate FQHC Practitioner Employee Benefits costs, we propose to use a similar methodology as used to calculate the FQHC Practitioner Wages and Salaries costs. We propose to apply the ratio of practitioner employee benefits as described above to the FQHC Practitioner Compensation costs (representing the net expenses for each occupation as reported on Worksheet A column 7) as defined in the section III.B.7.(c)(1)(a). This calculation is done for each occupation individually (physicians, PAs, NPs, CNMs, CPs, and CSWs). The FQHC Practitioner Employee Benefits costs are equal to the sum of each occupation's employee benefits costs. This is the same methodology that was used for the 2017-based FQHC market basket. As stated previously, effective for CY 2022, telehealth services are covered under the FQHC PPS; therefore, we propose to also include in the FQHC Practitioner Employee Benefits the telehealth employee benefits. We propose to estimate telehealth employee benefits by multiplying telehealth wages and salaries (as described in section III.B.7.(c)(1)(a)) times the ratio of total direct patient care facility benefits (Worksheet S3 Part II, column 2, line 1) to total facility direct patient care salaries (the sum of Worksheet A, columns 1 and 2, lines 23 and 25 through 36), which is estimated to be 21 percent on average. This ratio is referred to as the overall employee benefit share and represents the ratio of employee benefits to wages and salaries for all patient care costs reported by FQHCs.

(c) FQHC Practitioner Contract Labor Costs

To calculate FQHC Practitioner Contract Labor Costs, we propose to use a similar methodology as used to calculate FQHC Practitioner Wages and Salaries and FQHC Practitioner Employee Benefit Costs. We propose to multiply the ratio of practitioner contract labor, as described above, by the FQHC Practitioner Compensation costs (representing the net expenses for each occupation as reported on Worksheet A column 7) as defined in section III.B.7.(c)(1)(a). This calculation is done for each occupation individually (physicians, PAs, NPs, CNMs, CPs, and CSWs). The FQHC Practitioner Contract Labor costs are equal to the sum of each occupation's contract labor costs plus all net expenses reported for Physicians Services Under Agreement from Worksheet A, column 7, line 24. This is the same methodology used for the 2017-based FQHC market basket.

(d) Clinical Staff Wages and Salaries Costs

We propose to calculate Clinical Staff Wages and Salaries Costs using three steps. First, we propose to define Clinical Staff Compensation costs as the sum of net expenses (that is, costs after reclassifications and adjustments) as reported on Worksheet A, column 7, lines 27, 28, 32, 33, 34, 35, and 36. Clinical Staff Compensation includes any health-related clinical staff who do not fall under the definition of a FQHC Practitioner. These lines represent the net expenses for visiting RNs, visiting LPNs, laboratory technicians, registered dietician/Certified DSMT/MNT educators, PTs, OTs, and other allied health personnel.

Second, we propose to further divide the Clinical Staff Compensation costs for these occupations into wages and salaries, employee benefits, and contract labor costs based on the ratio of clinical staff wages and salaries, clinical staff employee benefits, and clinical staff contract labor costs to the sum of these three groups of costs. We do this by applying the ratio of clinical staff wages and salaries, clinical staff employee benefits, and clinical staff contract labor to the net expense Clinical Staff Compensation costs, and the determination of these ratios is described later in this section. We propose to derive clinical staff wages and salaries costs as the sum of direct care cost salaries as reported on Worksheet A, column 1, lines 27, 28, 32, 33, 34, 35, and 36. These lines represent the wages and salaries costs for visiting registered nurses (RNs), visiting licensed practical nurses (LPNs), laboratory technicians, registered dietician/Certified DSMT/MNT educators, physical therapists (PTs), occupational therapists (OTs), and other allied health personnel. We propose to derive the clinical staff employee benefits costs for these occupations as the sum of costs reported on Worksheet S–3, part II, column 2, lines 5, 6, 10, 11, 12, 13, and 14. These lines represent the employee benefits costs for visiting RNs, visiting LPNs, laboratory technicians, registered dietician/Certified DSMT/MNT educators, PTs, OTs, and other allied health personnel. Similarly, we propose to calculate clinical staff contract labor costs for these occupations as the costs reported on Worksheet S–3, part II, column 1, lines 5, 6, 10, 11, 12, 13, and 14. These lines

represent the contract labor costs for visiting RNs, visiting LPNs, laboratory technicians, registered dietician/ Certified DSMT/MNT educators, PTs, OTs, and other allied health personnel. This was the same method used to calculate the ratios to split the Clinical Staff Compensation net expenses as was done for the 2017-based FQHC market basket.

The final step in the process to derive the Clinical Staff Wages and Salaries costs is to apply the ratio of clinical staff wages and salaries calculated in the prior step to the Clinical Staff Compensation costs (representing the net expenses for each occupation as reported on Worksheet A column 7) as described above. This calculation is done for each occupation individually (visiting RNs, visiting LPNs, laboratory technicians, registered dietician/ Certified DSMT/MNT educators, PTs, OTs, and other allied health personnel). The Clinical Staff Wages and Salaries costs is equal to the sum of each occupation's wages and salary costs. This is the same methodology that was used for the 2017-based FQHC market basket.

(e) Clinical Staff Employee Benefits Costs

To calculate Clinical Staff Employee Benefit costs, we propose to use a similar methodology as used to calculate the Clinical Staff Wages and Salaries costs. We propose to multiply the ratio of clinical staff employee benefits, as described above by the Clinical Staff Compensation costs (representing the net expenses for each occupation as reported on Worksheet A column 7) as defined in the section III.B.7.(c)(1)(d). This calculation is done for each occupation individually (visiting RNs, visiting LPNs, laboratory technicians, registered dietician/ Certified DSMT/MNT educators, PTs, OTs, and other allied health personnel). The Clinical Staff Employee Benefits costs are equal to the sum of each occupation's Employee Benefits costs. This is the same methodology that was used for the 2017-based FQHC market basket.

(f) Clinical Staff Contract Labor Costs

To calculate Clinical Staff Contract Labor costs, we propose to use a similar methodology as used to calculate Clinical Staff Wages and Salaries Costs and Clinical Staff Benefit Costs. We propose to multiply the ratio of clinical staff contract labor costs, as described above, by the Clinical Staff Compensation costs (representing the net expenses for each occupation as reported on Worksheet A column 7) as defined in the section III.B.7.(c)(1)(d). This calculation is done for each occupation individually (visiting RNs, visiting LPNs, laboratory technicians, registered dietician/Certified DSMT/ MNT educators, PTs, OTs, and other allied health personnel). The Clinical Staff Contract Labor costs are equal to the sum of each occupation's contract labor costs. This is the same methodology that was used for the 2017-based FQHC market basket.

(g) Non-Health Staff Compensation Costs

We propose to define Non-Health Staff Compensation costs using net expenses (that is, costs after reclassifications and adjustments) as the estimated share of compensation costs from Worksheet A, column 7 for lines 3, 4, 5, 6, 7, 9, 10, 11, and 12. These lines represent the net expenses for the employee benefits department, administrative & general services, plant operations & maintenance, janitorial, medical records, pharmacy, medical supplies, transportation, and other general services. Since the net expenses for the General Service Cost centers include both compensation and other costs, we estimate the share of net expenses for each general service cost center that reflects compensation costs. First, we estimate a share of non-health staff wages and salaries costs for each general service cost center as reported on Worksheet A, column 1 for lines 3, 4, 5, 6, 7, 9, 10, 11, and 12 divided by Worksheet A, column 1 and 2 for lines 3, 4, 5, 6, 7, 9, 10, 11, and 12. Then, we multiply the Non-Health Staff net expenses (that is, costs after reclassifications and adjustments) by the non-health staff wages and salaries share to derive estimated Non-Health Staff Wages and Salaries costs for each general service cost center (lines 3–7 and lines 9–12). Second, we estimate Non-Health Staff Employee Benefit costs by multiplying the Non-Health Staff Wages and Salaries costs (step one) by the overall employee benefit share as described in section III.B.7.(c)(1)(b), or 21 percent. Finally, we sum the derived Non-Health Staff Wages and Salaries costs and the derived Non-Health Staff Employee Benefits costs for each general service cost center (lines 3–7 and lines 9–12) to calculate Non-Health Staff Compensation costs. This is the same methodology used for the 2017-based FQHC market basket.

(h) Pharmaceutical Costs

We propose to calculate Pharmaceutical costs as the non-compensation costs for the Pharmacy cost center. We define this as Worksheet A, column 7, line 9 less derived pharmacy compensation costs. Derived pharmacy compensation costs are included in the Non-health Staff Compensation costs described in section III.B.7.(c)(1)(g). We note that the only pharmaceutical costs eligible for inclusion in the FQHC PPS market basket are those reported on line 9 of Worksheet A. These pharmaceutical costs would include only the costs of routine drugs (both prescription and over the counter), pharmacy supplies, and pharmacy services, provided incident to an FQHC visit. Other types of drugs and pharmacy supplies costs not included in this category are those reported on line 67 (drugs charged to patients), line 77 (retail pharmacy), line 48 (pneumococcal vaccine), and line 49 (influenza vaccine, COVID–19, and monoclonal antibody products for treatment of COVID–19), as these costs are reimbursed to FQHC providers outside of the FQHC PPS payment. The derived pharmacy compensation costs are equal to the sum of the estimated pharmacy wages and salaries and pharmacy employee benefits costs. This is the same methodology used for the 2017-based FQHC market basket.

(i) Medical Supplies Costs

We propose to calculate Medical Supplies costs as the non-compensation costs for the Medical Supplies costs center. We define this as Worksheet A, column 7, line 10 less derived medical supplies compensation costs. Derived medical supplies compensation costs are included in the Non-health Staff Compensation costs described in section III.B.7.(c)(1)(g). The derived medical supplies compensation costs are equal to the sum of the estimated medical supplies wages and salaries and medical supplies benefits costs. This is the same methodology used for the 2017-based FQHC market basket.

(j) Fixed Assets Costs

We propose to define Fixed Asset costs to be equal to costs reported on Worksheet A, line 1, column 7 of the Medicare cost report. This is the same methodology used for the 2017-based FQHC market basket.

(k) Movable Equipment Costs

We propose to define Movable Equipment costs to be equal to the capital costs as reported on Worksheet A, line 2, column 7. This is the same methodology used for the 2017-based FQHC market basket.

(2) Proposed Major Cost Category Computation

After we derive costs for the major cost categories for each provider using the Medicare cost report data as previously described, we propose to trim the data for outliers. For each of the 11 major cost categories, we propose to divide the calculated costs for the category by total Medicare allowable costs calculated for the provider to obtain cost weights for the universe of FQHC providers after basic trims described in section III.B.7.(c). For the proposed 2022-based FQHC market basket, total Medicare allowable costs would be equal to total net expenses (after reclassifications and adjustments) reported on: Worksheet A, column 7, for lines 1 through 7, lines 9 through 12; lines 23 through 36, and line 66. This is the same method used to derive total Medicare allowable costs for the 2017-based FQHC market basket with the only difference being that we now include the net expenses for line 66, telehealth because as previously described, effective for CY 2022 CMS finalized the policy for mental health visits furnished using interactive, real-time telecommunications technology to be paid in the same way they currently do when these services are furnished in-person (86 FR 65208 through 62511).

For the FQHC Practitioner Wages and Salaries, FQHC Practitioner Employee Benefits, FQHC Practitioner Contract Labor, Clinical Staff Wages and Salaries, Clinical Staff Employee Benefits, Clinical Staff Contract Labor, Non-Health Staff Compensation, Pharmaceuticals, Medical Supplies, Fixed Assets, and Movable Equipment cost weights, after excluding cost weights that are less than or equal to zero, we propose to then remove those providers whose derived cost weights fall in the top and bottom 5 percent of provider-specific derived cost weights to ensure the exclusion of outliers. A 5 percent trim is the standard trim applied to the mean cost weights in most CMS market baskets and is consistent with the trimming used in the 2017-based FQHC market basket. After the outliers have been excluded, we sum the costs for each category across all remaining providers. We propose to then divide this by the sum of total Medicare allowable costs across all remaining providers to obtain a cost weight for the proposed 2022-based FQHC market basket for the given category. This trimming process is done for each cost weight separately.

Finally, we propose to calculate the residual ''All Other'' cost weight that reflects all remaining costs that are not captured in the 11 major cost categories listed. Table 25 provides the resulting cost weights for these major cost categories derived from the Medicare cost reports.

Table 25 displays the proposed 2022-based FQHC market basket cost weights compared to the 2017-based FQHC market basket cost weights.

TABLE 25: Major Cost Categories as Derived from Medicare Cost Reports

Major Cost Categories	Proposed 2022-Based FQHC Cost Report Weights (Percent)	2017-Based FQHC Cost Report Weights (Percent)
FQHC Practitioner Compensation	24.8	28.4
FQHC Practitioner Wages and Salaries	17.1	19.4
FQHC Practitioner Employee Benefits	3.6	4.5
FQHC Practitioner Contract Labor	4.1	4.6
Clinical Staff Compensation	15.3	16.8
Clinical Staff Wages and Salaries	11.8	12.9
Clinical Staff Employee Benefits	2.8	3.1
Clinical Staff Contract Labor	0.6	0.9
Non-Health Staff Compensation	28.4	27.2
Pharmaceuticals	3.2	2.4
Medical Supplies	2.4	2.2
Fixed Assets	5.0	4.4
Movable Equipment	2.2	2.0
All Other (Residual)	18.7	16.5

Note: Totals may not sum to 100.0 due to rounding

As we did for the 2017-based FQHC market basket, we propose to allocate the Contract Labor cost weight to the Wages and Salaries and Employee Benefits cost weights based on their relative proportions under the assumption that contract labor costs comprise both wages and salaries and employee benefits for both FQHC Practitioners and Clinical Staff. The contract labor allocation proportion for Wages and Salaries is equal to the Wages and Salaries cost weight as a percent of the sum of the Wages and Salaries cost weight and the Employee Benefits cost weight. This percentage based on the proposed 2022-based FQHC cost weights is 82.5 percent for FQHC practitioners and 80.8 percent for clinical staff. Therefore, we propose to allocate 82.5 percent of the FQHC Practitioner Contract Labor cost weight to the FQHC Practitioner Wages and Salaries cost weight and 17.5 percent to the FQHC Practitioner Employee Benefits cost weight. Similarly, we propose to allocate 80.8 percent of the Clinical Staff Contract Labor cost weight to the Clinical Staff Wages and Salaries cost weight and 19.2 percent to the Clinical Staff Employee Benefits cost weight. Table 26 shows the FQHC Practitioner and Clinical Staff Wages and Salaries and Employee Benefits proposed 2022-based cost weights after the contract labor cost weight has been allocated. Table 26 also includes the comparison of the weights to the 2017-

based cost weights for the same categories.

TABLE 26: Wages and Salaries and Employee Benefits Cost Weights After Contract Labor Allocation

Major Cost Categories	Proposed 2022-Based FQHC Practitioner	Proposed 2022-Based Clinical Staff	2017-Based FQHC Practitioner	2017-Based Clinical Staff
Compensation	**24.8**	**15.3**	**28.4**	**16.8**
Wages and Salaries	20.5	12.4	23.1	13.6
Employee Benefits	4.3	2.9	5.4	3.3

*Totals may not sum due to rounding

(3) Derivation of the Detailed Operating Cost Weights

To further divide the ''All Other'' residual cost weight estimated from the 2022 Medicare cost report data into more detailed cost categories, we propose to use the 2017 Benchmark Input-Output (I–O) ''Use Tables/Before Redefinitions/Purchaser Value'' for NAICS 621100, Offices of Physicians, published by the Bureau of Economic Analysis (BEA). We note that the BEA benchmark I–O data is used to further disaggregate residual costs in other CMS market baskets. Therefore, we note that we believe the data from this industry are the most technically appropriate for disaggregation of the residual net expenses since both physician offices and FQHCs provide similar types of care. These data are publicly available at *https://www.bea.gov/industry/input-output-accounts-data*. For the 2017-based FQHC market basket, we used the 2012 Benchmark Input-Output (I–O) ''Use Tables/Before Redefinitions/Purchaser Value'' for NAICS 621100, Offices of Physicians, published by the BEA.

The BEA Benchmark I–O data are scheduled for publication every 5 years with the most recent data available for 2017. The 2017 Benchmark I–O data are derived from the 2017 Economic Census and are the building blocks for BEA's economic accounts. Therefore, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.[311] BEA also produces Annual I–O estimates. However, while based on a similar methodology, these estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data become available. Instead of using the less detailed Annual I–O data, we propose to inflate the 2017 Benchmark I–O data forward to 2022 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2017 Benchmark I–O data. We repeat this practice for each year. We then calculate the cost shares that each cost category represents of the 2017 data inflated to 2022. These resulting 2022 cost shares were applied to the ''All Other'' residual cost weight to obtain the detailed cost weights for the proposed 2022-based FQHC market basket. For example, the cost for Medical Equipment represents 7.8 percent of the sum of the ''All Other'' 2017 Benchmark I–O Offices of Physicians Expenditures inflated to 2022. Therefore, the proposed Medical Equipment cost weight represents 7.8 percent of the proposed 2022-based FQHC market basket's ''All Other'' cost category (18.7 percent), yielding a Medical Equipment cost weight of 1.5 percent in the proposed 2022-based FQHC market basket (0.078×18.7 percent = 1.5 percent).

Using this methodology, we propose to derive six detailed FQHC market basket cost category weights from the proposed 2022-based FQHC market basket residual cost weight (18.7 percent). These categories are: (1) Utilities; (2) Medical Equipment; (3) Miscellaneous Products; (4) Professional, Scientific, and Technical Services; (5) Administrative and Facilities Support Services; and (6) All Other Services.

(4) Proposed 2022-Based FQHC Market Basket Cost Categories and Weights

Table 27 shows the cost categories and cost weights for the proposed 2022-based FQHC market basket compared to the 2017-based FQHC market basket. The Total Compensation cost weight of 68.5 percent (sum of FQHC Practitioner Compensation, Clinical Staff Compensation, and Non-health Staff Compensation) calculated from the Medicare cost reports for the proposed 2022-based FQHC market basket is 4.1 percentage points lower than the total compensation cost weight for the 2017-based FQHC market basket (72.6 percent). The decrease in the compensation cost weight between the 2017-based and the proposed 2022-based market basket is stemming from the decreasing FQHC Practitioner and Clinical Staff Compensation cost weights. The proposed 2022-based cost weights for FQHC Practitioner and Clinical Staff Compensation are 5.3 percentage points lower compared to the 2017-based FQHC market basket, while the Non-Health Staff Compensation cost weight is 1.2 percentage points higher. Analysis of the cost report data shows that the decline in the health-related compensation cost weights is stemming from a change in the mix of health-related workers from higher-paid to lower-paid occupations. Specifically, there has been a shift in full time equivalents (FTEs) from physicians to nurse practitioners and a shift from registered and licensed practical nurses to other allied health personnel. Additionally, the proposed 2022-based Pharmaceuticals cost weight, Non-Health Staff Compensation costs weight, and the Capital cost weight, are each roughly 1 percentage point higher than the cost weight in the 2017-based FQHC market basket.

We note that our analysis of the Medicare cost report data over time shows the general trends in these cost weights (particularly for the Total Compensation and Pharmaceuticals cost weights) began after 2017 with about half of the cost weight changes

[311] *http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.*

occurring between 2017 and 2019. Consistent with our historical frequency of rebasing the other CMS market baskets, we believe it is important to rebase the FQHC market basket every four to five years to reflect the more recent data and changing cost structure. We are soliciting comments on our proposal to rebase and revise the market basket to reflect a 2022 base year.

TABLE 27: Proposed 2022-Based FQHC Market Basket Cost Weights Compared to 2017-Based FQHC Market Basket Cost Weights

Cost Category	Proposed 2022-based FQHC Market Basket Cost Weight	2017-based FQHC Market Basket Cost Weight
Total	**100.0**	**100.0**
Compensation	**68.5**	**72.6**
FQHC Practitioner Compensation	**24.8**	**28.5**
FQHC Practitioner Wages and Salaries	20.5	23.1
FQHC Practitioner Employee Benefits	4.3	5.4
Clinical Staff Compensation	**15.3**	**16.9**
Clinical Staff Wages and Salaries	12.4	13.6
Clinical Staff Employee Benefits	2.9	3.3
Non-Health Staff Compensation	**28.4**	**27.2**
All Other Products	**9.8**	**8.5**
Pharmaceuticals	3.2	2.4
Utilities	0.5	0.6
Medical Equipment	1.5	1.2
Medical Supplies	2.4	2.2
Miscellaneous Products	2.3	2.2
All Other Services	**14.5**	**12.6**
Professional, Scientific, and Technical Services	8.6	6.4
Administrative and Facilities Support Services	1.5	1.7
All Other Services	4.4	4.5
Capital-Related Costs	**7.2**	**6.4**
Fixed Assets	5.0	4.4
Movable Equipment	2.2	2.0

Note: Totals may not sum due to rounding.

d. Selection of Price Proxies

After developing the cost weights for the proposed 2022-based FQHC market basket, we selected the most appropriate wage and price proxies currently available to represent the rate of price change for each expenditure category. For most of the cost categories, we rely on using the price proxies based on U.S. Bureau of Labor Statistics (BLS) data, as they produce indexes that best meet the criteria of reliability, timeliness, availability, and relevance, and group them into one of the following BLS categories:

- *Employment Cost Indexes.* Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the North American Industry Classification System (NAICS) and the occupational ECIs are based on the Standard Occupational Classification System (SOC).
- *Producer Price Indexes.* Producer Price Indexes (PPIs) measure the average change over time in the selling prices received by domestic producers for their output. The prices included in the PPI are from the first commercial transaction for many products and some services (*https://www.bls.gov/ppi/*).
- *Consumer Price Indexes.* Consumer Price Indexes (CPIs) measure the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services (*https://www.bls.gov/cpi/*). CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the producer level, or if no appropriate PPIs are available.

We evaluate the price proxies using the criteria of reliability, timeliness, availability, and relevance:

- *Reliability.* Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)
- *Timeliness.* Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The

market baskets are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.

- *Availability.* Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.
- *Relevance.* Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied.

The CPIs, PPIs, and ECIs that we have selected to use in the proposed 2022-based FQHC market basket meet these criteria. Therefore, we believe that they continue to be the best measures of price changes for the cost categories to which they would be applied.

Table 28 lists all price proxies we propose to use in the proposed 2022-based FQHC market basket. Below is a detailed explanation of the price proxies we propose for each cost category.

(1) Price Proxies for the Proposed 2022-Based FQHC Market Basket

(a) FQHC Practitioner Wages and Salaries

We propose to use the ECI for Wages and Salaries for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure price growth of this category. There is no specific ECI for physicians or FQHC Practitioners, and therefore, we propose to use an index that is based on professionals that receive advanced training similar to those performing at the FQHC Practitioner level of care. This index is consistent with the price proxy used to measure wages and salaries inflation pressure for physicians own time in the Medicare Economic Index (MEI) and is based on the MEI technical panel recommendation from 2012 for more details see the CY 2014 PFS final rule (78 FR 74266 through 74271). Additionally, this is the same price proxy used for the FQHC Practitioner Wages and Salaries cost category in the 2017-based FQHC market basket (85 FR 84708).

(b) FQHC Practitioner Employee Benefits

We propose to use the ECI for Total Benefits for Private Industry Workers in Professional and Related to measure price growth of this category. This ECI is calculated using the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU10162200000000I) and the relative importance of wages and salaries within total compensation. This is the same price proxy used for the FQHC Practitioner Employee Benefits cost category in the 2017-based FQHC market basket (85 FR 84708).

(c) Clinical Staff Wages and Salaries

We propose to use the ECI for Wages and Salaries for all Civilian Workers in Health Care and Social Assistance (BLS series code CIU10262000000000I) to measure the price growth of this cost category. This cost category consists of wage and salary costs for Nurses, Laboratory Technicians, and all other healthcare staff not included in the FQHC Practitioner compensation categories. Based on the clinical staff composition of these workers, we believe that the ECI for health-related workers is an appropriate proxy to measure wage and salary price pressures for these workers. This is the same price proxy used for the Clinical Staff Wages and Salaries cost category in the 2017-based FQHC market basket (85 FR 84708).

(d) Clinical Staff Employee Benefits

We propose to use the ECI for Total Benefits for all Civilian Workers in Health Care and Social Assistance to measure price growth of this category. This ECI is calculated using the ECI for Total Compensation for all Civilian Workers in Health Care and Social Assistance (BLS series code CIU10162200000000I) and the relative importance of wages and salaries within total compensation. This is the same price proxy used for the Clinical Staff Employee Benefits cost category in the 2017-based FQHC market basket (85 FR 84708).

(e) Non-Health Staff Compensation

We propose to use the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this cost category. The Non-health Staff Compensation cost weight is predominately attributable to administrative and facility type occupations, as reported in the data from the Medicare cost reports. This is the same price proxy used for the Non-Health Staff Compensation cost category in the 2017-based FQHC market basket (85 FR 84708).

(f) Pharmaceuticals

We propose to use the PPI Commodities for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. This price proxy is used to measure prices of Pharmaceuticals in other CMS market baskets, such as the 2018-based Inpatient Prospective Payment System market basket and is the same price proxy used for the Pharmaceuticals cost category in the 2017-based FQHC market basket (85 FR 84708).

(g) Utilities

We propose to use the CPI for Fuel and Utilities (BLS series code CUUR0000SAH2) to measure the price growth of this cost category. This is the same price proxy used for the Utilities cost category in the 2017-based FQHC market basket (85 FR 84708).

(h) Medical Equipment

We propose to use the PPI Commodities for Surgical and Medical Instruments (BLS series code WPU1562) as the price proxy for this category. This is the same price proxy used for the Medical Equipment cost category in the 2017-based FQHC market basket (85 FR 84708).

(i) Medical Supplies

We propose to use a 50/50 blended index that comprises the PPI Commodities for Medical and Surgical Appliances and Supplies (BLS series code WPU156301) and the CPI–U for Medical Equipment and Supplies (BLS series code CUUR0000SEMG). The 50/50 blend is used in all market baskets where we do not have an accurate split available. We note that we believe FQHCs purchase the types of supplies contained within these proxies, including such items as bandages, dressings, catheters, intravenous equipment, syringes, and other general disposable medical supplies, via wholesale purchase, as well as at the retail level. Consequently, we propose to combine the two aforementioned indexes to reflect those modes of purchase. This is the same price proxy used for the Medical Supplies cost category in the 2017-based FQHC market basket (85 FR 84708 through 84709).

(j) Miscellaneous Products

We propose to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the

price growth of this cost category. We believe that using the CPI for All Items Less Food and Energy is appropriate as it reflects a general level of inflation. This is the same price proxy used for the Miscellaneous cost category in the 2017-based FQHC market basket (85 FR 84709).

(k) Professional, Scientific, and Technical Services

We propose to use the ECI for Total Compensation for Private Industry Workers in Professional, Scientific, and Technical Services (BLS series code CIU2015400000000I) to measure the price growth of this cost category. This is the same price proxy used for the Professional, Scientific, and Technical Services cost category in the 2017-based FQHC market basket (85 FR 84709).

(l) Administrative and Facilities Support Services

We propose to use the ECI Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this cost category. This is the same price proxy used for the Administrative and Facilities Support Services cost category in the 2017-based FQHC market basket (85 FR 84709).

(m) All Other Services

We propose to use the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This is the same price proxy used for the All Other Services cost category in the 2017-based FQHC market basket (85 FR 84709).

(n) Fixed Assets

We propose to use the PPI Industry for Lessors of Nonresidential Buildings (BLS series code PCU531120531120) to measure the price growth of this cost category (81 FR 80398). We believe this continues to be the most appropriate price proxy since fixed asset costs in FQHCs should reflect inflation for the rental and purchase of business office space. This is the same price proxy used for the Fixed Assets cost category in the 2017-based FQHC market basket (85 FR 84709).

(o) Movable Equipment

We propose to continue to use the PPI Commodities for Machinery and Equipment (BLS series code WPU11) to measure the price growth of this cost category as this cost category represents nonmedical movable equipment. This is the same price proxy used for the Movable Equipment cost category in the 2017-based FQHC market basket (85 FR 84709).

(2) Summary of Price Proxies of the Proposed 2022-Based FQHC Market Basket

Table 28 shows the cost categories and associated price proxies for the proposed 2022-based FQHC market basket.

TABLE 28: Cost Categories and Price Proxies for the Proposed 2022-based FQHC Market Basket

Cost Description	Price Proxies
FQHC Practitioner Wages and Salaries	ECI for Wages and Salaries for Private Industry Workers in Professional and Related
FQHC Practitioner Employee Benefits	ECI for Total Benefits for Private Industry Workers in Professional and Related
Clinical Staff Wages and Salaries	ECI for Wages and Salaries for All Civilian Workers in Health Care and Social Assistance
Clinical Staff Employee Benefits	ECI for Total Benefits for All Civilian Workers in Health Care and Social Assistance
Non-Health Staff Compensation	ECI for Total Compensation for Private Industry Workers in Office and Administrative Support
Pharmaceuticals	PPI Special Index for Pharmaceuticals for Human Use, Prescription
Utilities	CPI-U for Fuels and Utilities
Medical Equipment	PPI Commodity Index for Surgical and Medical Instruments
Medical Supplies	Composite: PPI Commodity Index for Medical and Surgical Appliances and Supplies (50%) and CPI for Medical Equipment and Supplies (50%)
Miscellaneous Products	CPI-U for All Items Less Food and Energy
Professional, Scientific, and Technical Services	ECI for Total compensation for Private industry workers in Professional, Scientific, and Technical Services
Administrative and Facilities Support Services	ECI for Total Compensation for Private Industry Workers in Office and Administrative Support
All Other Services	ECI for Total Compensation for Private Industry Workers in Service Occupations
Fixed Assets	PPI Industry Index for Lessors of Nonresidential Buildings
Movable Equipment	PPI Commodity Index for Machinery and Equipment

We are soliciting comments on our proposal to rebase and revise the FQHC market basket to reflect a 2022 base year.

e. Proposed CY 2025 Productivity-Adjusted Market Basket Update for FQHCs

For CY 2025 (that is, January 1, 2025, through December 31, 2025), we propose to use an estimate of the proposed 2022-based FQHC market basket to update payments to FQHCs based on the best available data. We propose to use the update based on the most recent historical data available at the time of publication of the final rule. For example, the final CY 2025 FQHC update would be based on the four-quarter moving-average percent change of the proposed 2022-based FQHC market basket through the second quarter of 2024 (based on the final rule's statutory publication schedule). At the time of this proposed rule, we do not have the second quarter of 2024 historical data, and therefore, we propose to use the most recent projection available at the time. Consistent with CMS practice, we estimate the market basket update for the FQHC PPS based on the most recent forecast from IHS Global, Inc. (IGI). IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets and total factor productivity (TFP).

Based on IGI's first quarter 2024 forecast with historical data through the fourth quarter of 2023, the proposed 2022-based FQHC market basket increase factor for CY 2025 is 4.0 percent. For comparison, the 2017-based FQHC market basket percentage increase is also projected to be 4.0 percent in CY 2025; this estimate is based on IGI's first quarter 2024 forecast (with historical data through the fourth quarter of 2023). Table 29 compares the proposed 2022-based FQHC market basket and the 2017-based FQHC market basket annual percent changes from 2021 through 2028.

TABLE 29: Proposed 2022-Based FQHC Market Basket and 2017-Based FQHC Market Basket Percent Changes, CYs 2021 through 2028

	Calendar Year (CY)[1]	Proposed 2022-Based FQHC Market Basket Index Percent Change	2017-Based FQHC Market Basket Index Percent Change
Historical Data	CY 2021	2.4	2.4
	CY 2022	2.2	2.3
	CY 2023	4.3	4.3
	CY 2024	5.0	5.1
	Average 2021-2024	**3.5**	**3.5**
Forecast	CY 2025	4.0	4.0
	CY 2026	3.3	3.3
	CY 2027	2.9	2.9
	CY 2028	2.8	2.9
	Average 2025-2028	**3.3**	**3.3**

1/ CY index percent changes are based on data through the 2nd quarter of the year prior to the update year.
Note that these market basket percent changes do not include any further adjustments as may be statutorily required.
Source: IHS Global Inc. 1st quarter 2024 forecast

Over the historical update time period covering CY 2021 through CY 2024, the average growth rate of the proposed 2022-based FQHC market basket is the same as the average growth rate of the 2017-based FQHC market basket. Over the forecasted time period covering CY 2025 through CY 2028, the average growth rate of the proposed 2022-based FQHC market basket is also the same as the average growth rate of the 2017-based FQHC market basket. So, although the compensation cost weights in the proposed 2022-based FQHC market basket is lower than in the 2017-based FQHC market basket, and the weights for other products and services is higher, there is little impact on the historical or projected FQHC market basket percentage increase.

Section 1834(o)(2)(B)(ii) of the Act describes the methods for determining updates to FQHC PPS payment. We have included a productivity adjustment to the FQHC PPS annual payment update since implementation of the FQHC PPS (81 FR 80393) and we propose to continue to include a productivity adjustment to the proposed 2022-based FQHC market basket. We propose to use the most recent estimate of the 10-year moving average of changes in annual private nonfarm business (economy-wide) total factor productivity (TFP), which is the same measure of TFP applied to other CMS market basket updates including the MEI. The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the U.S. economy. We note that previously the productivity published by BLS was referred to as multifactor productivity. Beginning with the November 18, 2021, release of productivity data, BLS replaced the term ''multifactor productivity'' (MFP) with ''TFP.'' Please see *https://www.bls.gov/productivity/data.htm* for the BLS historical published TFP data. For the final FQHC market basket update, we propose to use the most recent historical estimate of annual TFP as published by the BLS. Generally, the most recent historical TFP estimate is lagged two years from the payment year.

Therefore, we propose to use the 10-year moving average percent change in annual private nonfarm business TFP through 2023 as published by BLS in the CY 2025 FQHC market basket update. We note that TFP is derived by subtracting the contribution of labor and capital input growth from output growth. Since at the time of development of this proposed rule the

measure of TFP for 2023 had not yet been published by BLS, we propose to use IGI's first quarter 2024 forecast of TFP. A complete description of IGI's TFP projection methodology is available on the CMS website at *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information*.

Using IGI's first quarter 2024 forecast, the productivity adjustment for CY 2025 (the 10-year moving average of TFP for the period ending CY 2023) is projected to be 0.5 percent. Therefore, the proposed CY 2025 productivity-adjusted proposed 2022-based FQHC market basket update is 3.5 percent, based on IGI's first quarter 2024 forecast with historical data through the fourth quarter of 2023. This reflects a 4.0 percent increase in the proposed 2022-based FQHC market basket reduced by a 0.5 percentage point productivity adjustment. Finally, we propose that the CY 2025 market basket update and the productivity adjustment will be updated to reflect the most recent historical data available for the final rule.

8. Clarification for Dental Services Furnished in FQHCs

a. Payment for Dental Services Furnished in FQHCs

Section 1862(a)(12) of the Act generally precludes payment under Medicare Parts A or B for any expenses incurred for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. (Collectively here, we will refer to ''the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth'' as ''dental services.'') That section of the statute also includes an exception to allow payment to be made for inpatient hospital services in connection with the provision of such dental services if the individual, because of their underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services. Our regulation at 42 CFR 411.15(i) similarly excludes payment for dental services except for inpatient hospital services in connection with dental services when hospitalization is required because of: (1) the individual's underlying medical condition and clinical status; or (2) the severity of the dental procedure.

Fee for service (FFS) Medicare Parts A and B also make payment for certain dental services in circumstances where the services are not considered to be in connection with dental services within the meaning of section 1862(a)(12) of the Act. In the CY 2023 PFS final rule (87 FR 69663 through 69688), we clarified and codified at § 411.15(i)(3) that Medicare payment under Parts A and B could be made when dental services are furnished in either the inpatient or outpatient setting when the dental services are inextricably linked to, and substantially related and integral to the clinical success of, other covered services. We also added several examples of clinical scenarios that are considered to meet that standard under § 411.15(i)(3) and amended that regulation to add more examples in the CY 2024 PFS final rule (88 FR 79022 through 79029).

In the CY 2024 PFS final rule (88 FR 79038), we received comments requesting we provide payment for inextricably linked dental services in the FQHC setting. Commenters stated that it is critical that CMS consider FQHCs' unique Medicare payment structure and that CMS ensure that policy changes for FQHCs are analogous to any changes made under the PFS. Commenters noted that many FQHCs provide dental services on-site, and health center patients could benefit from the payment policies for dental services inextricably linked to other covered services and suggested that the FQHC billing codes should be edited in tandem. Commenters further noted that ''physicians' services'' component of the Medicare FQHC benefit includes services furnished by dentists. Several commenters urged that the list of billable dental visit codes modified in the proposed rule be added to the list of codes that may be billed in the FQHC setting and requested that any expansion in codes recognized under the PFS for dental-related services also be applied to FQHCs. We acknowledged the commenters concerns and noted our intention to modify operational procedures in the FQHC setting to reflect the expansion of this PFS policy, including updates to billable code lists.

We agree that RHC and FQHC Medicare beneficiaries could benefit from the payment policies established under the PFS for dental services that are inextricably linked to specific medical services. Dentists are defined as physicians in Medicare statute (42 CFR 491.2). Services furnished by physicians are billable visits in RHCs and FQHCs and they could bill for a face-to-face, medically necessary visit furnished by a dentist within their scope of practice. Therefore, we are clarifying in this proposed rule that dental services exactly as described in section II.J and furnished in an RHC or FQHC are RHC and FQHC visits and as such can be paid under the RHC AIR methodology or FQHC PPS.

We would apply and operationalize the dental policies finalized in the CY 2023 and 2024 PFS final rules as applicable also to RHCs and FQHCs and update the FQHC qualifying visit list as appropriate. Consistent with the discussion in section II.J of this proposed rule, if an RHC or FQHC practitioner believes the dental services for which they submit Medicare claims are inextricably linked to a covered service, a modifier may be reported on an RHC or FQHC claim for payment purposes. The KX modifier is reported on an RHC or FQHC claim to indicate that the service is medically necessary, and that the provider has included appropriate documentation in the medical record to support or justify the medical necessity of the service or item. We believe that usage of the KX modifier in the context of claims for dental services inextricably linked to covered services to indicate that the clinician attests that the service is medically necessary, and that the provider has included appropriate documentation is appropriate and will support claims processing and program integrity efforts.

We are clarifying that when RHCs and FQHCs furnish dental services that align with the policies and operational requirements in the physician setting, we would consider those services to be a qualifying visit and the RHC would be paid at the RHC AIR methodology and the FQHC would be paid under the FQHC PPS.

b. Medical and Dental Visits Furnished on the Same Day

If an RHC or FQHC patient has a medically-necessary face-to-face visit with an RHC or FQHC practitioner, and is then seen by another RHC or FQHC practitioner, including a specialist, for further evaluation of the same condition on the same day, or is then seen by another RHC or FQHC practitioner, including a specialist, for evaluation of a different condition on the same day, the multiple encounters would constitute a single RHC or FQHC visit and be payable as one visit regardless of the length or complexity of the visit, whether the second visit is a scheduled or unscheduled appointment, or whether the first visit is related or unrelated to the subsequent visit.

If the RHC or FQHC patient suffers an illness or injury that requires additional diagnosis or treatment on the same day subsequent to the first visit, or has a medical and a mental health visit on the same day, or an RHC patient has an

initial preventive physical exam (IPPE) and a separate medical and/or mental health visit on the same day, then the RHC or FQHC would be paid separately for each visit.

We are seeking comment on whether the multiple visits policy should apply to patients who have an encounter with an RHC or FQHC practitioner and a dentist on the same day or should a subsequent encounter with a dentist be considered an exception to this policy and be paid as a separate billable visit. We are interested in understanding when these situations could occur.

9. ''Grandfathered'' Technical Refinement

a. Background

We have conducted a review of our regulations and guidance to determine where preferred terms may be used. We found several sections in part 405, subpart X, that use the term ''grandfathered.'' For example, in § 405.2462(f)(1) a ''grandfathered tribal FQHC'' is a FQHC that is operated by a tribe or tribal organization under the Indian Self-Determination and Education Assistance Act (ISDEAA); was billing as if it were provider-based to an IHS hospital on or before April 7, 2000, and is not currently operating as a provider-based department of an IHS hospital.

b. Technical Refinement

We believe language in communication products should reflect and speak to the needs of people in the audience of focus. In an effort to represent an ongoing shift to non-stigmatizing language, we are proposing to make a technical change to remove the term ''grandfathered'' from the regulation text in §§ 405.2462, 405.2463, 405.2464, and 405.2469 and replace it with ''historically excepted'' to describe a level of protection provided to certain tribal FQHCs that predates applicable restrictions.

C. Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Conditions for Certification and Conditions for Coverage (CfCs)

1. Background and Statutory Authority

The Rural Health Clinic Services Act of 1977 (Pub. L. 95–210 enacted December 13, 1977) amended the Social Security Act (the Act) by enacting section 1861(aa) to extend Medicare and Medicaid entitlement and payment for outpatient services and emergency care services furnished at a rural health clinic (RHC) by physicians and certain other practitioners, and for services and supplies incidental to their services. Other practitioners include nurse practitioners and physician assistants, and subsequent legislation extended the definition of covered RHC services to include the services of clinical psychologists, clinical social workers, certified nurse midwives, marriage and family therapists, and mental health counselors.

We have broad statutory authority to establish health and safety standards for most Medicare and Medicaid participating provider and supplier types. Section 1861(aa) of the Act authorizes the Secretary to establish the requirements that an RHC and Federally Qualified Health Center (FQHC) must meet to participate in the Medicare Program. As required by subparagraph (iv) of the flush material set out after section 1861(aa)(2)(K) of the Act, Medicare certified RHCs must not be a rehabilitation agency or a facility which is primarily for the care or treatment of mental diseases. These statutory CfC requirements are codified in regulations at 42 CFR part 491. RHCs and FQHCs must meet these requirements to receive Medicare payment for services. These regulations are intended to protect the health and safety of patients receiving care from these facilities. We note that there are approximately 5,462 Medicare-certified RHCs and 11,853 Medicare-certified FQHCs.

In this proposed rule, we also aim to ensure RHCs are provided flexibility in the services they offer, including specialty and laboratory services.

2. Proposed Changes to the RHC and FQHC Conditions for Certification and Conditions for Coverage (CfCs)

a. Provision of Services (42 CFR 491.9)

In accordance with section 1861(aa) of the Act, § 491.9, *Provision of services,* establishes the basic requirements for services RHCs and FQHCs must provide in accordance with applicable Federal, State, and local laws. This CfC also outlines patient care policies, including the development of written policies and the establishment of guidelines for medical management, record-keeping, and drug administration. Additionally, this section specifies the diagnostic, therapeutic, laboratory, and emergency services that RHCs and FQHCs must offer, as well as the necessary agreements or arrangements with other healthcare providers to furnish additional services not available onsite.

RHCs and FQHCs play a crucial role in providing accessible and comprehensive healthcare services in underserved areas, often serving as the primary point of contact for healthcare services for residents living in these communities. Approximately 20 percent of the U.S. population lives in rural areas.[312] When compared to their urban counterparts, rural residents are more likely to be living in poverty, unhealthy, older adults, uninsured or underinsured, and medically underserved.[313] Accounting for the unique circumstances of individuals living in rural areas and the broad array of services RHCs and FQHCs provide to their communities, it is imperative to support rural facilities so they may continue to provide healthcare services to medically underserved populations.

Research shows that accessing primary care is associated with positive health outcomes.[314] Individuals who receive primary care services are more likely to receive preventive care, which results in lower rates of illness and premature death.[315] Furthermore, without access to primary care services, an individual may delay seeking treatment until their illness has worsened. In such cases, they may end up receiving care in the emergency department, which costs more and leads to poorer health outcomes.[316] [317] [318] Rural residents also report difficulty accessing specialty care due to having to travel considerable distances, exacerbated by rural hospitals closing

[312] U.S. Census Bureau. (2023, March 10). *Nation's Urban and Rural Populations Shift Following 2020 Census. U.S. Department of Commerce.* Retrieved April 12, 2024, from *https://www.census.gov/newsroom/press-releases/2022/urban-rural-populations.html.*

[313] Report to the Congress: Medicare and the Health Care Delivery System (June 2012) (*medpac.gov*). Medicare Payment Advisory Commission. (2012, June). *Medicare and the Health Care Delivery System. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun12_entirereport.pdf.*

[314] Shi L. (2012). The impact of primary care: a focused review. *Scientifica, 2012,* 432892. *https://doi.org/10.6064/2012/432892.*

[315] Hostetter, J., Schwarz, N., Klug, M., Wynne, J., & Basson, M. D. (2020). Primary care visits increase utilization of evidence-based preventative health measures. BMC family practice, 21(1), 151. *https://doi.org/10.1186/s12875-020-01216-8.*

[316] Tang, N., Stein, J., Hsia, R. Y., Maselli, J. H., & Gonzales, R. (2010). Trends and characteristics of US emergency department visits, 1997–2007. *JAMA, 304*(6), 664–670. *https://doi.org/10.1001/jama.2010.1112.*

[317] Gallagher, A., Liu, J., Probst, J. C., Martin, A. B., & Hall, J. W. (2013). Maternal obesity and gestational weight gain in rural versus urban dwelling women in South Carolina. The Journal of rural health: official journal of the American Rural Health Association and the National Rural Health Care Association, 29(1), 1–11. *https://doi.org/10.1111/j.1748-0361.2012.00421.x.*

[318] Bailey, B. A., & Cole, L. K. (2009). Rurality and birth outcomes: findings from southern appalachia and the potential role of pregnancy smoking. *The Journal of rural health: official journal of the American Rural Health Association and the National Rural Health Care Association, 25*(2), 141–149. *https://doi.org/10.1111/j.1748-0361.2009.00210.x*

and provider shortages.[319] [320] RHC practitioners have also reported additional barriers to receiving specialized care, which include a shortage of specialty providers, limited availability of the specialty providers, lack of transportation, and not accepting patients who are uninsured or specialists not accepting insurance coverage (Medicare, Medicaid, or private insurance).[321]

Based on feedback from interested parties, including RHC providers and rural health associations, we identified a discrepancy in the guidance, statute, and regulations. Specifically, interested parties questioned the language in the CMS State Operations Manual RHC interpretative guidance as it relates to § 491.9(a)(2), which states that ''RHCs may not be primarily engaged in specialized services.'' [322] The guidance goes on to state that, in this context, ''primarily engaged'' is determined by considering the total hours of an RHC's operation and whether a majority, *i.e.,* more than 50 percent, of those hours involve the provision of RHC services, whereas section 1861(aa)(2)(A) of the Act only reference being primarily engaged in ''furnishing to outpatients'' physician services and services furnished by a physician assistant or a nurse practitioner, clinical psychologist or by a clinical social worker, as cross-referenced by sections 1861(aa)(1)(A) and (B) of the Act. This is codified in the CfCs at § 491.9(a)(2), requiring RHCs and FQHCs to be primarily engaged in ''providing outpatient health services.'' We have enforced a standard requiring that RHCs be primarily engaged in providing primary care services based on the interpretive guidance.

To clarify the requirements and intent of the program regarding the services provided by RHCs and FQHCs, we are proposing changes to the *Provision of services* CfCs. We also aim to ensure RHCs are provided flexibility in the services they offer, including specialty services. To align the requirements and preserve access to primary care services in rural areas, we are proposing to add standards to § 491.9(a)(2) explicitly requiring RHCs and FQHCs to provide primary care services (at § 491.9(a)(2)(i)) and explicitly noting that RHCs cannot be a rehabilitation agency or a facility which is primarily for the care and treatment of mental diseases (at § 491.9(a)(2)(ii)). Under our proposal, RHCs and FQHCs would continue to be required to provide primary care services to their patient populations, but CMS would no longer determine or enforce the standard of RHCs ''being primarily engaged in furnishing primary care services'' and would no longer consider the total hours of an RHC's operation and whether a majority, that is, more than 50 percent, of those hours involve primary care services through the survey process. These proposed requirements, as well as the subsequent proposal discussed in section III.C.2.b. of this proposed rule, will be enforced in accordance with section 1864 of the Act, which requires that CMS use state surveyors to determine whether a provider or supplier subject to certification qualifies for an agreement to participate in Medicare. However, under section 1865 of the Act, providers and suppliers subject to certification may instead elect to be accredited by private accrediting organizations whose Medicare accreditation programs have been approved by CMS as having standards and survey procedures that meet or exceed all applicable Medicare requirements.

This proposal would allow RHCs to provide more outpatient-specialty services within the practitioner's scope of practice to meet the needs of the patient population—for example, internal medicine, pediatrics, geriatrics, obstetrics and gynecology, dermatology, cardiology, neurology, endocrinology, and ear, nose and throat. Section 1861(aa) of the Act does not explicitly state that RHCs must provide primary care services, though we believe this is the intended purpose of the statute. Clause (i) of the second sentence of the flush material after section 1861(aa)(2)(K) of the Act, requires RHCs to be located in an area designated as either an area with a shortage of personal health services under section 330(b)(3) or 1302(7) of the Public Health Service Act or as a health professional shortage area described in section 332(a)(1)(A) of that Act because of its shortage of primary medical care manpower. Additionally, we use the phrase ''the entry point into the health care system'' in the RHC and FQHC CfCs at § 491.9(c)(1). We note that this language is consistent with language used in the Rural Emergency Hospital Conditions of Participation (CoPs) under the requirement for *Additional outpatient medical and health services* (§ 485.524(a)), and the Critical Access Hospital CoPs under the requirement for *Provision of services* (§ 485.635(b)(1)(i)). The American Academy of Family Physicians (AAFP) defines primary care practice as ''A primary care practice serves as the patient's entry point into the health care system and as the continuing focal point for all needed health care services.'' Therefore, we expect RHCs and FQHCs to offer a range of primary health care services to ensure that patients receive the necessary care at the earliest possible point of contact. Primary care services are critical in promoting health, preventing illness, and managing chronic conditions.[323]

This proposal also provides clarification regarding the requirement that RHCs cannot be a rehabilitation agency or a facility which is primarily for the care and treatment of mental diseases. While this requirement is included under § 491.2, *Definitions—Rural health clinic or clinic,* including this requirement under the *Provision of services* CfC at § 491.9(a)(2)(ii) as a separate standard more clearly cites the requirement and allows for a clearer evaluation of compliance with the specific requirement. CMS defines a rehabilitation agency as ''[a]n agency that provides an integrated, multidisciplinary program designed to upgrade the physical functions of handicapped, disabled individuals by bringing together, as a team, specialized rehabilitation personnel.''[324] Rehabilitation services may include physical therapy, occupational therapy, and speech-language pathology services.

CMS acknowledges that the term ''mental diseases'' is outdated and not often used in the field of mental health today. This term can cause stigma against people with mental health conditions and can be a major barrier to seeking help or treatment and can be a cause of reduced likelihood of engaging

[319] Akinlotan, M., Primm, K., Khodakarami, N., Bolin, J., Ferdinand, A. (2021). *Rural-Urban Variations in Travel Burdens for Care: Findings from the 2017 National Household Travel Survey* [Policy brief]. Southwest Rural Health Research Center. *https://srhrc.tamu.edu/publications/travel-burdens-07.2021.pdf.*

[320] Douthit, N., Kiv, S., Dwolatzky, T., & Biswas, S. (2015). Exposing some important barriers to health care access in the Rural USA. *Public Health, 129*(6), 611–620. *https://doi.org/10.1016/j.puhe.2015.04.001.*

[321] Lahr, M., Neprash, H., Henning-Smith, C., Tuttle, M., Hernandez, A. (2019). *Access to Specialty Care for Medicare Beneficiaries in Rural Communities* [Policy brief]. University of Minnesota Rural Health Research Center. *https://rhrc.umn.edu/wp-content/uploads/2019/12/UMN-Access-to-Specialty-Care_12.4.pdf.*

[322] Centers for Medicare & Medicaid Services. (2020, February 21). State Operations Manual Appendix G—Guidance for Surveyors: Rural Health Clinics (RHCs) (pp. 63–64). *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_g_rhc.pdf.*

[323] *Primary Care.* (n.d.). *https://www.cms.gov/priorities/innovation/key-concepts/primary-care.*

[324] Centers for Medicare & Medicaid Services. (2023, September 6). *Outpatient Rehabilitation Providers. CMS.gov. https://www.cms.gov/medicare/health-safety-standards/certification-compliance/outpatient-rehabilitation-providers#:~:text=Rehabilitation%20Agency%20%2D%20An%20agency%20that,a%20team%2C%20specialized%20rehabilitation%20personnel.*

in ongoing treatment. As discussed in section III.C.1 of this proposed rule, the U.S. Congress passed Public Law 95–210 (enacted December 13, 1977) that established criteria for the establishment of Medicare-certified RHCs and has included the term ''mental diseases'' since that time. As we are bound by the current statutory requirements, we have included the term in the RHC CfCs as it appears in the statute. We note that the statute is enacted by Congress and it would take an Act of Congress to make statutory changes.

For the purpose of this proposed rule, the term ''mental diseases'' refers to behavioral health conditions (that is, mental and substance use disorders). As part of the Coverage to Care (C2C) initiative, CMS published the *Roadmap to Behavioral Health,* which defines behavioral health conditions to include mental and substance use disorders.[325] The guide defines mental disorders as changes in a person's thinking, mood, and/or behavior and can only be diagnosed based on the person's ability to function as a result of their symptoms. The guide defines ''substance use disorder'' as when a person's repeated use of alcohol and/or drugs causes clinically significant impairment.[326] This may include health problems, disability, and failure to meet major responsibilities at home, school, or work.

These proposed changes to the RHC CfCs should not be construed as CMS prohibiting or discouraging the provision of RHC specialty services or behavioral health services. An RHC or FQHC may offer such specialty services and behavioral health services to its patients in addition to the primary care services it already provides. However, RHCs cannot be a rehabilitation agency or a facility, which is primarily for the care and treatment of mental diseases. As noted, the term ''mental diseases'' is outdated; therefore, this proposed rule aims to define ''mental diseases'' for the purpose of the RHC and FQHC health and safety standards and future guidance will clarify how CMS will determine whether an RHC is primarily providing care and treatment of mental diseases. CMS would assess a facility's compliance with this proposed requirement based on policies published in subsequent interpretative guidance, which we would publish if this revision is adopted in a final rule.

As we continue to focus on improved access to care for the rural communities served by RHCs, and to ensure that the proposed provisions do not have unintended consequences, we are soliciting public comment on the following questions to gain insight on the anticipated impact of this proposed policy on access to primary care services, behavioral health services, and specialty care services:

- What types of behavioral health services are currently offered by RHCs (that is, therapy, counseling, medication management, substance use disorder treatment, etc.), and how often are these services provided?
- For those RHCs that are currently providing behavioral health services, who provides those services (that is, physician, psychologist, social worker, marriage and family therapist, or mental health counselor)? What is the clinic's capacity to accept new behavioral health patients? What potential impacts do you anticipate for RHCs and the community if they were able to provide more behavioral health services? How would these impacts be addressed?
- Are there specific behavioral health conditions that your clinic is better equipped to treat than others, and if so, what are those behavioral health conditions?
- For those RHCs that are not currently providing behavioral health services, what barriers or challenges does the RHC face that limit the ability to furnish behavioral health services (that is, geographic location, transportation issues, service area size, staffing issues, stigma, regulatory or survey concerns)?
- What standards or criteria should surveyors use to evaluate whether a RHC is operating as a ''facility which is primarily for the care and treatment of mental diseases''?

b. Laboratory Requirements (42 CFR 491.9)

Section 1861(aa)(2)(G) of the Act requires RHCs to provide routine diagnostic services directly (that is, they must be furnished at the RHC, by RHC personnel), including clinical laboratory services. We have implemented this statutory provision through regulations at § 491.9(c)(2), which require RHCs to provide six specific diagnostic laboratory tests directly; chemical examinations of urine by stick or tablet method or both (including urine ketones); hemoglobin or hematocrit; blood glucose; examination of stool specimens for occult blood; pregnancy tests; and primary culturing for transmittal to a certified laboratory. This list reflects the same tests that have been required since RHCs were established in 1978 (43 FR 30529) and were chosen because they were commonly performed in physicians' offices at that time.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578), revised section 353 of the Public Health Service Act to require all clinical laboratories that test human specimens for health purposes to meet certain requirements. CLIA requires that the complexity of tests and the skill in interpreting results determine the extent of supervision and review. Tests are categorized from ''waived'' (those needing minimal supervision) to ''high complexity'' (those requiring the highest level of supervision and review). Regulations implementing CLIA are contained in 42 CFR part 493. Under these regulations, laboratories performing specified tests categorized as waived, physician-performed microscopy moderate or high complexity must obtain a certificate that shows they meet specific standards. All tests RHCs are required to perform are classified as waived under CLIA, as published in the 1992 **Federal Register** and listed at 42 CFR 493.15(c).

We are proposing to remove hemoglobin and hematocrit (H&H) from the listed laboratory services in § 491.9(c)(2) that RHCs must perform directly. In addition, we are proposing to revise paragraph (c)(2)(vi) to reflect current practice for microbiology specimens. Interested parties have expressed concerns with the existing laboratory requirements, citing the financial and physical burdens associated with maintaining the lab equipment that is used for laboratory tests that are ordered infrequently for patients receiving services at the RHC. RHC providers have reported that the H&H laboratory test in particular is overly burdensome. We are therefore proposing to remove the H&H laboratory test from the list of required laboratory tests to increase flexibility in the services offered by RHCs.

A hemoglobin test evaluates the amount of hemoglobin in the blood, which is responsible for carrying oxygen to a person's organs and tissues and transporting carbon dioxide back to the lungs.[327] Hematocrit is the percentage of red blood cells in a person's blood and is tested to evaluate red blood cells.[328]

[325] Centers for Medicare & Medicaid Services, and the Substance Abuse and Mental Health Services Administration. (2023, October). *Roadmap to Behavioral Health: Guide to Mental Health and Substance Use Disorder Services. https://www.cms.gov/files/document/roadmap-behavioral-health-english.pdf.*

[326] SAMHSA. (2023, June 09). *Mental Health and Substance Use Disorders.* Retrieved June 17, 2024, from *https://www.samhsa.gov/find-help/disorders.*

[327] *Hemoglobin test: What it is, procedure & results.* Hemoglobin Test. (n.d.). Retrieved May 7, 2024, from *https://my.clevelandclinic.org/health/diagnostics/17790-hemoglobin-test.*

[328] *Hematocrit test: What it is, levels, high & low range.* Hematocrit Test. (n.d.). Retrieved May 7,

Doctors test hemoglobin and hematocrit levels to evaluate overall health, diagnose a medical condition, or monitor an existing medical condition. While RHCs are currently required to have and maintain the equipment and supplies for these tests onsite, H&H blood tests are typically performed as part of a comprehensive blood count (CBC) and are not ordered separately in accordance with current clinical standards of practice. RHCs report that when laboratory tests are ordered that are not provided by the RHC, such as a CBC, their patients are often sent to the nearest hospital that would have a full-service laboratory available to perform the test. As a result, some RHCs located near hospitals may not be utilizing their laboratory equipment and supplies, or they may be utilizing them on a limited basis. This is because when laboratory tests are ordered by the RHC, and the order includes hemoglobin and hematocrit, and other tests that are not provided by the RHC, the patient will receive all of their ordered laboratory tests at the nearby hospital. Additionally, removing the requirement for these tests to be performed at the RHC limits the number of venipunctures the patient must experience.

In 2021, 66 percent of all RHCs were designated as provider-based RHCs, meaning they are owned and operated as an integral part of a hospital, nursing home, or home health agency.[329] Provider-based RHCs are governed, supervised, and licensed by the parent organization, and most provider-based RHCs are hospital-owned. The remaining 34 percent of RHCs are independent clinics owned by a healthcare provider or entity and though not as common, may be owned and/or operated by a healthcare system. Therefore, we believe a large majority of provider-based—and some independent—RHCs have access to a full-service laboratory, thereby maintaining access to the H&H laboratory test, even if it is no longer required to be provided directly by RHCs.

We have also received feedback that the current requirement at § 491.9(c)(2)(vi) does not reflect current clinical laboratory standards of practice and laboratory techniques. This standard currently lists the laboratory services that must be provided by RHCs, with the list specifically including ''primary culturing for transmittal to a certified laboratory.'' Primary culturing is an outdated microbiology practice that is no longer performed due to modern lab techniques. Instead, RHCs collect specimens using appropriate collection and storage techniques and send them to a certified laboratory without initial culturing. Therefore, we are proposing to update the language in this standard such that the laboratory services RHCs would be required to provide include the ''collection of patient specimens for transmittal to a certified laboratory for culturing.'' This proposal, along with the proposal removing the H&H from the list of required labs, would require that an RHC provide the remaining following laboratory services at § 491.9(c)(2): (1) chemical examinations of urine by stick or tablet methods or both (including urine ketones); (2) blood glucose; (3) examination of stool specimens for occult blood; (4) pregnancy tests; and (5) collection of patient specimens for transmittal to a certified laboratory for culturing. RHCs would still be required under § 491.9(d)(1)(iii) to provide prompt access to a Medicare or Medicaid participating provider or supplier that can furnish an H&H laboratory test and any additional and specialized diagnostic and laboratory services the RHC is not equipped to perform.

This proposal does not prevent RHCs from providing tests not listed in § 491.9. An RHC is free to provide tests consistent with its CLIA certification and can choose a higher level CLIA certification than the certificate of waiver if it wishes to provide tests of higher complexity and comply with all CLIA requirements.

Little information on RHC laboratory utilization is available, so while we are proposing to remove the H&H laboratory test from the list of diagnostic services RHCs are required to provide, we solicit public comment on how this may impact access to H&H laboratory tests in rural areas. We also are soliciting comments on data, evidence, and experience related to laboratory services in RHCs and alternative basic lab services that would be appropriate for RHCs to provide to meet the needs of underserved rural communities.

2024, from *https://my.clevelandclinic.org/health/diagnostics/17683-hematocrit.*

[329] Gale, J. A., Croll, Z., Croom, J., Munk, L., & Jonk, Y. (2022). Community Characteristics and Financial and Operational Performance of Rural Health Clinics in the United States: A Chartbook. University of Southern Maine, Muskie School of Public Service, Maine Rural Health Research Center. *https://digitalcommons.usm.maine.edu/cgi/viewcontent.cgi?article=1016&context=clinics.*

D. Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions

1. Background on the Clinical Laboratory Fee Schedule

Prior to January 1, 2018, Medicare paid for clinical diagnostic laboratory tests (CDLTs) on the Clinical Laboratory Fee Schedule (CLFS) under section 1833(a), (b), and (h) of the Act. Under the previous payment system, CDLTs were paid based on the lesser of: (1) the amount billed; (2) the local fee schedule amount established by the Medicare Administrative Contractor (MAC); or (3) a national limitation amount (NLA), which is a percentage of the median of all the local fee schedule amounts (or 100 percent of the median for new tests furnished on or after January 1, 2001). In practice, most tests were paid at the NLA. Under the previous payment system, the CLFS amounts were updated for inflation based on the percentage change in the Consumer Price Index for All Urban Consumers (CPI–U) and reduced by a productivity adjustment and other statutory adjustments but were not otherwise updated or changed. Coinsurance and deductibles generally do not apply to CDLTs paid under the CLFS.

Section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for CDLTs under the CLFS. A final rule entitled ''Medicare Clinical Diagnostic Laboratory Tests Payment System'' (CLFS final rule), which appeared in the **Federal Register** on June 23, 2016 (81 FR 41036), implemented section 1834A of the Act at 42 CFR part 414, subpart G.

Under the CLFS final rule, ''reporting entities'' must report to CMS during a ''data reporting period'' ''applicable information'' collected during a ''data collection period'' for their component ''applicable laboratories.'' The first data collection period occurred from January 1, 2016, through June 30, 2016. The first data reporting period occurred from January 1, 2017, through March 31, 2017. On March 30, 2017, we announced a 60-day period of enforcement discretion for the application of the Secretary's potential assessment of civil monetary penalties for failure to report applicable information with respect to the initial data reporting period.[330]

[330] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/2017-March-Announcement.pdf.*

In the CY 2018 PFS proposed rule (82 FR 34089 through 34090), we solicited public comments from applicable laboratories and reporting entities to better understand the applicable laboratories' experiences with data reporting, data collection, and other compliance requirements for the first data collection and reporting periods. We discussed these comments in the CY 2018 PFS final rule (82 FR 53181 through 53182) and stated that we would consider the comments for potential future rulemaking or guidance.

As part of the CY 2019 Medicare PFS rulemaking, we finalized two changes to the definition of ''applicable laboratory'' at § 414.502 (see 83 FR 59667 through 59681, 60074; 83 FR 35849 through 35850, 35855 through 35862). First, we excluded Medicare Advantage plan payments under Part C from the denominator of the Medicare revenues threshold calculation to broaden the types of laboratories qualifying as an applicable laboratory. Second, consistent with our goal of obtaining a broader representation of laboratories that could potentially qualify as an applicable laboratory and report data, we also amended the definition of applicable laboratory to include hospital outreach laboratories that bill Medicare Part B using the CMS–1450 14x Type of Bill.

2. Payment Requirements for Clinical Diagnostic Laboratory Tests

In general, under section 1834A of the Act, the payment amount for each CDLT on the CLFS furnished beginning January 1, 2018, is based on the applicable information collected during the data collection period and reported to CMS during the data reporting period and is equal to the weighted median of the private payor rates for the test. The weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory. The payment amounts established under the CLFS are not subject to any other adjustment, such as geographic, budget neutrality, or annual update, as required by section 1834A(b)(4)(B) of the Act. Additionally, section 1834A(b)(3) of the Act, implemented at § 414.507(d), provides for a phase-in of payment reductions, limiting the amounts the CLFS rates for each CDLT (that is not a new advanced diagnostic laboratory test (ADLT) or new CDLT) can be reduced as compared to the payment rates for the preceding year. Under the original provisions enacted by section 216(a) of PAMA, for the first 3 years after implementation (CY 2018 through CY 2020), the reduction could not be more than 10 percent per year. For the next 3 years after implementation (CY 2021 through CY 2023), section 216(a) of PAMA stated that the reduction could not be more than 15 percent per year. Under sections 1834A(a)(1) and (b) of the Act, as enacted by PAMA, for CDLTs that are not ADLTs, the data collection period, data reporting period, and payment rate update were to occur every 3 years. As such, the second data collection period for CDLTs that are not ADLTs occurred from January 1, 2019, through June 30, 2019, and the next data reporting period was originally scheduled to take place from January 1, 2020, through March 31, 2020, with the next update to the Medicare payment rates for those tests based on that reported applicable information scheduled to take effect on January 1, 2021.

Section 216(a) of PAMA established a new subcategory of CDLTs known as ADLTs, with separate reporting and payment requirements under section 1834A of the Act. The definition of an ADLT is set forth in section 1834A(d)(5) of the Act and implemented at § 414.502. Generally, under section 1834A(d) of the Act, the Medicare payment rate for a new ADLT is equal to its actual list charge during an initial period of 3 calendar quarters. After the new ADLT initial period, ADLTs are paid using the same methodology based on the weighted median of private payor rates as other CDLTs. However, under section 1834A(d)(3) of the Act, updates to the Medicare payment rates for ADLTs occur annually instead of every 3 years.

Additional information on the private payor rate-based CLFS is detailed in the CLFS final rule, which implemented section 1834A of the Act as required by PAMA (81 FR 41036 through 41101), and this information is also available on the CMS website.[331]

3. Previous Statutory Revisions to the Data Reporting Period and Phase-In of Payment Reductions

Beginning in 2019, Congress passed a series of legislation to modify the statutory requirements for the data reporting period and phase-in of payment reductions under the CLFS. First, section 105(a)(1) of the Further Consolidated Appropriations Act, 2020 (FCAA) (Pub. L. 116–94, December 20, 2019) amended the data reporting requirements in section 1834A(a) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by 1 year so that data reporting would be required during the period of January 1, 2021, through March 31, 2021, instead of January 1, 2020, through March 30, 2020. The 3-year data reporting cycle for CDLTs that are not ADLTs would resume after that data reporting period. Section 105(a)(1) of the FCAA also specified that the data collection period that applied to the data reporting period of January 1, 2021, through March 30, 2021, would be the period of January 1, 2019, through June 30, 2019, which was the same data collection period that would have applied absent the amendments. In addition, section 105(a)(2) of the FCAA amended section 1834A(b)(3) of the Act regarding the phase-in of payment reductions to provide that payments may not be reduced by more than 10 percent as compared to the amount established for the preceding year through CY 2020, and for CYs 2021 through 2023, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year. These statutory changes were consistent with our regulations implementing the private payor rate-based CLFS at § 414.507(d) (81 FR 41036).

Subsequently, section 3718 of the Coronavirus Aid, Relief, and Economic Security Act, 2020 (CARES Act) (Pub. L. 116–136, March 27, 2020) further amended the data reporting requirements for CDLTs that are not ADLTs and the phase-in of payment reductions under the CLFS. Specifically, section 3718(a) of the CARES Act amended section 1834A(a)(1)(B) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by one additional year, to require data reporting during the period of January 1, 2022, through March 31, 2022. The CARES Act did not modify the data collection period that applied to the next data reporting period for these tests. Thus, under section 1834A(a)(4)(B) of the Act, as amended by section 105(a)(1) of the FCAA, the next data reporting period for CDLTs that are not ADLTs would have been based on the data collection period of January 1, 2019, through June 30, 2019.

Section 3718(b) of the CARES Act further amended the provisions in section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extended the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2024 instead of CY 2023. It further amended section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for CY 2021

[331] *https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/pama-educational-resources.*

is 0 percent, meaning that the payment amount determined for a CDLT for CY 2021 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2020. Section 3718(b) of the CARES Act further amended section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent would apply for CYs 2022 through 2024, instead of CYs 2021 through 2023. In the CY 2021 PFS rulemaking (85 FR 50210 through 50211; 85 FR 84693 through 84694), in accordance with section 105(a) of the FCAA and section 3718 of the CARES Act, we proposed and finalized conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G.

Section 4 of the Protecting Medicare and American Farmers from Sequester Cuts Act (PMAFSCA) (Pub. L. 117–71, December 10, 2021) made additional revisions to the CLFS requirements for the next data reporting period for CDLTs that are not ADLTs and to the phase-in of payment reductions under section 1834A of the Act. Specifically, section 4(b) of PMAFSCA amended the data reporting requirements in section 1834A(a) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by 1 year, so that data reporting would be required during the period of January 1, 2023, through March 31, 2023. The 3-year data reporting cycle for CDLTs that are not ADLTs would resume after that data reporting period. As amended by section 4 of PMAFSCA, section 1834A(a)(1)(B) of the Act provided that in the case of reporting with respect to CDLTs that are not ADLTs, the Secretary shall revise the reporting period under subparagraph (A) such that—(i) no reporting is required during the period beginning January 1, 2020, and ending December 31, 2022; (ii) reporting is required during the period beginning January 1, 2023, and ending March 31, 2023; and (iii) reporting is required every 3 years after the period described in clause (ii).

Section 4 of PMAFSCA did not modify the data collection period that applies to the next data reporting period for these tests. Thus, under section 1834A(a)(4)(B) of the Act, as amended by section 105(a)(1) of the FCAA, the next data reporting period for CDLTs that are not ADLTs (January 1, 2023, through March 31, 2023) would continue to be based on the data collection period of January 1, 2019, through June 30, 2019, as defined in § 414.502.

Section 4 of PMAFSCA further amended the provisions in section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extended the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2025. It further amended section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for each of CY 2021 and 2022 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2021 and 2022 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2020. Section 4(a) of PMAFSCA further amended section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent would apply for CYs 2023 through 2025, instead of CYs 2022 through 2024. In the CY 2023 PFS rulemaking (87 FR 46068 through 46070; 87 FR 69741 through 69744, 70225), in accordance with section 4 of PMAFSCA, we proposed and finalized conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G.

Section 4114 of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328, December 29, 2022) made further revisions to the CLFS requirements for the next data reporting period for CDLTs that are not ADLTs and to the phase-in of payment reductions under section 1834A of the Act. Specifically, section 4114(b) of the CAA, 2023 amended the data reporting requirements in section 1834A(a)(1)(B) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by 1 year, so that data reporting would be required during the period of January 1, 2024, through March 31, 2024, instead of the data reporting period of January 1, 2023, through March 31, 2023. The 3-year data reporting cycle for CDLTs that are not ADLTs would resume after that data reporting period. As amended by section 4114(b) of the CAA, 2023, section 1834A(a)(1)(B) of the Act now provides that in the case of reporting with respect to CDLTs that are not ADLTs, the Secretary shall revise the reporting period under subparagraph (A) such that—(i) no reporting is required during the period beginning January 1, 2020, and ending December 31, 2023; (ii) reporting is required during the period beginning January 1, 2024, and ending March 31, 2024; and (iii) reporting is required every 3 years after the period described in clause (ii).

Section 4114 of the CAA, 2023 did not modify the data collection period that applies to the next data reporting period for CDLTs. Thus, under section 1834A(a)(4)(B) of the Act, the next data reporting period for CDLTs that are not ADLTs (January 1, 2024, through March 31, 2024) would continue to be based on the data collection period of January 1, 2019, through June 30, 2019, as reflected in the definitions of data collection period and data reporting period at § 414.502.

Section 4114(a) of the CAA, 2023 further amended the provisions in section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extended the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2026. It further amended section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for CY 2023 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2023 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2022. Section 4114(a) of the CAA, 2023 further amended section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent will apply for CYs 2024 through 2026, instead of CYs 2023 through 2025. In the CY 2024 PFS rulemaking (88 FR 79083 through 79087; 88 FR 79531), in accordance with section 4114 of the CAA, 2023, we proposed and finalized conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G.

4. Additional Statutory Revisions to the Data Reporting Period and Phase-In of Payment Reductions

On November 17, 2023, section 502 of the Further Continuing Appropriations and Other Extensions Act, 2024 (Pub. L. 118–22) (FCAOEA, 2024) was passed and delayed data reporting requirements for CDLTs that are not ADLTs, and it also delayed the phase-in of payment reductions under the CLFS from private payor rate implementation under section 1834A of the Act. Specifically, section 502(b) of the FCAOEA, 2024 amended the data reporting requirements in section 1834A(a)(1)(B) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by one year, so that data reporting would be required during the period of January 1, 2025, through March 31, 2025, instead of the data reporting period of January 1, 2024, through March 31, 2024. The 3-year data reporting cycle for CDLTs that are not ADLTs would resume after that data reporting period. As amended by section 502(b) of the FCAOEA, 2024, section 1834A(a)(1)(B) of the Act now provides that in the case of reporting

with respect to CDLTs that are not ADLTs, the Secretary shall revise the reporting period under subparagraph (A) such that—(i) no reporting is required during the period beginning January 1, 2020, and ending December 31, 2024; (ii) reporting is required during the period beginning January 1, 2025, and ending March 31, 2025; and (iii) reporting is required every 3 years after the period described in clause (ii).

Section 502 of the FCAOEA, 2024 does not modify the data collection period that applies to the next data reporting period for these tests. Thus, under section 1834A(a)(4)(B) of the Act, the next data reporting period for CDLTs that are not ADLTs (January 1, 2025, through March 31, 2025) will continue to be based on the data collection period of January 1, 2019, through June 30, 2019, as reflected in the definitions of data collection period and data reporting period at § 414.502.

Section 502(a) of the FCAOEA, 2024 further amends the provisions in section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extends the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2027. It further amends section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for CY 2024 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2024 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2023. Section 502(a) of the FCAOEA, 2024 further amends section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent will apply for CYs 2025 through 2027.

As a result of the statutory revisions under the FCAA, CARES Act, PMAFSCA, the CAA, 2023, and the FCAOEA, 2024, there have only been two data collection periods for CDLTs that are not ADLTs to date. The first data collection period for these tests occurred from January 1, 2016, through June 30, 2016, and the second occurred from January 1, 2019, through June 30, 2019. Thus far, there has been only one data reporting period for these tests, which took place from January 1, 2017, through March 31, 2017. We have established CLFS payment rates for these tests using the methodology established in PAMA only one time, effective January 1, 2018, based on the applicable information collected by applicable laboratories during the 2016 data collection period and reported to CMS during the 2017 data reporting period.

Additionally, we have applied the phase-in of payment reductions for the first 3 years of PAMA implementation, CY 2018 through CY 2020, whereby reduction of payment rates could not be more than 10 percent per year as compared to the amount established the prior year. However, the phase-in of payment reductions set forth in PAMA for years 4 through 6 after PAMA implementation, whereby payment cannot exceed 15 percent per year as compared to the amount established the prior year, has not yet occurred.

5. Proposed Conforming Regulatory Changes

In accordance with section 502 of the FCAOEA, 2024, we are proposing to make conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G. Specifically, we are proposing to revise the definitions of both the ''data collection period'' and ''data reporting period'' at § 414.502 to specify that for the data reporting period of January 1, 2025, through March 31, 2025, the data collection period is January 1, 2019, through June 30, 2019. We are also proposing to revise § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017, and is required every 3 years beginning January 2025. In addition, we are proposing to make conforming changes to our requirements for the phase-in of payment reductions to reflect the amendments in section 502(a) of the FCAOEA, 2024. Specifically, we are proposing to revise § 414.507(d) to indicate that for CY 2024, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2023, and for CYs 2025 through 2027, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

We note that the CYs 2024 and 2025 CLFS payment rates for CDLTs that are not ADLTs are based on applicable information collected in the data collection period of January 1, 2016, through June 30, 2016. Under current law, the CLFS payment rates for CY 2026 through CY 2028 will be based on applicable information collected during the data collection period of January 1, 2019, through June 30, 2019, and reported to CMS during the data reporting period of January 1, 2025, through March 31, 2025.

E. Medicare Diabetes Prevention Program (MDPP)

The Centers for Medicare & Medicaid Services' (CMS) Medicare Diabetes Prevention Program Expanded Model (hereafter, ''MDPP'' or ''MDPP expanded model'') is an evidence-based behavioral intervention that aims to prevent or delay the onset of type 2 diabetes for eligible Medicare beneficiaries diagnosed with prediabetes. MDPP is an expansion in duration and scope of the Diabetes Prevention Program (DPP) model test, which was initially tested by CMS through a Round One Health Care Innovation Award (2012–2016).[332] MDPP was established in 2017 as an ''additional preventive service,'' [333] covered by Medicare and not subject to beneficiary cost-sharing, in addition to being available once per lifetime to eligible beneficiaries. To facilitate delivery of MDPP in a non-clinical community setting (to align with the certified DPP model tested by The CMS Innovation Center), CMS created a new MDPP supplier type through rulemaking in the CY 2017 PFS final rule (81 FR 80471), in addition to requiring organizations that wish to participate in MDPP to enroll in Medicare separately, even if they are already enrolled in Medicare for other purposes.

MDPP is a non-pharmacological behavioral intervention consisting of up to 22 intensive sessions furnished over 12 months by a trained Coach who provides training on topics that include long-term dietary change, increased physical activity, and behavior change strategies for weight control and diabetes risk reduction. MDPP sessions must be one hour in length and adhere to a Centers for Disease Control and Prevention (CDC) approved National Diabetes Prevention Recognition Program (National DPP) curriculum.[334] The primary goal of the MDPP expanded model is to help Medicare beneficiaries reduce their risk for developing type 2 diabetes by achieving at least 5 percent weight loss from the first core session (81 FR 80465).

Eligible organizations seeking to furnish MDPP began enrolling in Medicare as MDPP suppliers on January 1, 2018, and began furnishing MDPP on April 1, 2018. As of May 13, 2024, there

[332] The Health Care Innovation Awards funds awards to organizations that implemented the most compelling new ideas to deliver better health, improved care, and lower costs to people enrolled in Medicare, Medicaid and Children's Health Insurance Program (CHIP), particularly those with the highest health care needs. The CMS Innovation Center announced the first batch of awardees for the Health Care Innovation Awards on May 8, 2012, and the second (final) batch on June 15, 2012. For more, see *https://www.cms.gov/priorities/innovation/innovation-models/health-care-innovation-awards.*

[333] 42 CFR 410.64—*Additional preventive services.*

[334] *https://www.cdc.gov/diabetes/prevention/resources/curriculum.html.*

were 301 approved MDPP suppliers.[335] The most recent MDPP evaluation report, reflected that between April 2018 and December 31, 2021, 4,848 Medicare beneficiaries participated in MDPP, including 2,325 FFS beneficiaries and 2,523 MA beneficiaries.[336] Through the Diabetes Prevention Recognition Program (DPRP), CDC administers a national quality assurance program recognizing eligible organizations that furnish the National DPP through its evidence based DPRP Standards,[337] which are updated every 3 years. The CDC established the DPRP in 2012 and possesses significant experience assessing the quality of program delivery by organizations throughout the United States, applying a comprehensive set of national quality standards. For further information on the DPP model test,[338] the CDC's National DPP,[339] and DPRP Standards,[340] please refer to the CY 2017 (81 FR 80471) and CY 2018 PFS (82 FR 52976) final rules and related websites.

The Public Health Emergency (PHE) for COVID–19 prompted changes to allow virtual delivery of the MDPP, among other changes (85 FR 84830 through 84841). Changes to MDPP in the CY 2024 PFS final rule (88 FR 78818) included a simplified payment structure to allow for fee-for-service (FFS) payments for beneficiary attendance while retaining the performance-based payments for diabetes risk reduction (that is, weight loss). Beginning January 1, 2024, payments are made to an MDPP supplier if an MDPP beneficiary attends any core session in the first 6 months or core maintenance session in the second 6 months, allowing payment for up to 22 sessions in a 12-month timeframe. The CY 2024 PFS final rule also extended certain PHE flexibilities, including the option to deliver some or all MDPP sessions via distance learning and for beneficiaries to virtually self-report weight for MDPP distance learning sessions, until December 31, 2027 (88 FR 79241).

CDC released the 2024 DPRP Standards [341] to replace the 2021 DPRP Standards in June 2024. To align MDPP with the 2024 CDC DPRP Standards, we are proposing conforming changes to align with CDC delivery modes. These changes are expected to reduce administrative burden, ensure compliance with existing MDPP regulations, and streamline data reporting for MDPP suppliers. In this year's rule, we are also proposing an additional option for self-reporting weight in an MDPP distance learning session, removing the MDPP bridge payment, and making minor edits to align current rule language pertaining to MDPP with previous rulemaking.

1. Proposed Changes to § 410.79 by Amending Paragraphs (b) and (d)(1)

We established MDPP as an expanded model in 2018 based on a Health Care Innovation Award (HCIA) to the National Young Men's Christian Association (YMCA) of the USA (Y–USA), who tested the CDC's National DPP in the Medicare population through their network of YMCAs in multiple U.S. markets (DPP model test).[342] The DPP model test successfully met statutory criteria for model expansion,[343] demonstrating 5 percent weight loss from their starting weight by participants (a key metric of the program's success) along with statistically significant reductions in Medicare spending, emergency department (ED) visits, and inpatient stays.[344] The MDPP expanded model was implemented through the rulemaking process in two phases, in the CY 2017 PFS (81 FR 80459 through 80483) and CY 2018 PFS final rules (82 FR 53234 through 53339).

MDPP went into effect in 2018, with supplier enrollment starting January 1, 2018, and beneficiary enrollment starting April 1, 2018 (82 FR 53237). After nearly 6 years of implementation, through the CY 2024 PFS final rule, we finalized updates to MDPP based on lessons learned since the expanded model's launch, including updates to definitions and the core services period and extended the flexibilities allowed under the PHE for COVID–19 for a period of 4 years (88 FR 79241).

This year we propose to make conforming changes to § 410.79(b), *Conditions of Coverage,* to align with the 2024 CDC DPRP Standards.[345] In the CY 2018 PFS final rule, we stated our intention to align MDPP with CDC DPRP Standards whenever possible (82 FR 53245). Several commenters encouraged CMS to consider adopting the same definitions for MDPP as CDC uses for the National DPP, including distance learning, online, and combination modalities to better align MDPP and the National DPP. Commenters indicated that the addition of definitions that are consistent with the CDC's definitions will reduce confusion about MDPP (88 FR 79247). To increase this alignment, we worked closely with CDC to update the National DPP and MDPP for CY 2024 final rule (88 FR 79240 through 79256), as well as the 2024 DPRP Standards.[346] We agree in aligning terminology where applicable.

The CY 2024 PFS final rule introduced and defined ''distance learning'' and ''combination delivery'' for MDPP and provided a definition for ''online delivery'' (88 FR 79243). The 2024 CDC DPRP Standards include the following delivery modes with definitions: ''in-person,'' ''distance learning (live),'' ''in-person with a distance learning component,'' ''online (non-live),'' and ''combination with an online component.'' [347] These delivery

[335] Medicare Provider Enrollment, Chain, and Ownership System (PECOS). Unpublished data.

[336] RTI International. Evaluation of the Medicare Diabetes Prevention Program. November 2022. *https://www.cms.gov/priorities/innovation/data-and-reports/2022/mdpp-2ndannevalrpt.*

[337] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

[338] Health Care Innovation Awards. *https://www.cms.gov/priorities/innovation/innovation-models/health-care-innovation-awards.*

[339] *https://www.cdc.gov/diabetes/prevention/index.html.*

[340] *https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf.*

[341] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

[342] L Hinnant, S Razi, R Lewis, A Sun, M Alva, T Hoerger et al. Evaluation of the Health Care Innovation Awards: Community Resource Planning, Prevention, and Monitoring, Annual Report 2015. RTI International. March 2016; *https://www.cms.gov/priorities/innovation/files/reports/hcia-ymcadpp-evalrpt.pdf.*

[343] Paul Spitalnic. Certification of Medicare Diabetes Prevention Program. Mar. 14, 2016. *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Diabetes-Prevention-Certification-2016-03-14.pdf.*

[344] Rojas Smith. L., Amico, P., Hoerger, T. J., Jacobs, S., Payne. J., & Renaud, J.: Evaluation of the Health Care Innovation Awards: Community Resource Planning, Prevention, and Monitoring Third Annual Report Addendum—August 2017 *https://downloads.cms.gov/files/cmmi/hcia-crppm-thirdannrptaddendum.pdf* (pp. 858–914).

[345] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

[346] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

[347] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

modes also serve as organization codes for CDC DPRP recognition. Through this proposed rule, we are proposing to amend § 410.79(b) to add a new term for MDPP, ''in-person with a distance learning component,'' defined as ''MDPP sessions that are delivered in person by trained Coaches where participants have the option of attending sessions via MDPP distance learning. These sessions must be furnished in a manner consistent with DPRP Standards for in-person and distance learning sessions.'' The following examples of an acceptable delivery model for the ''in-person with a distance learning component'' delivery mode are provided in the 2024 CDC DPRP Standards: a combination of in-person and distance learning during the core (first 6 months) and core maintenance (second 6 months) phases; some participants within a cohort using the in-person delivery mode and some participants using the distance learning delivery mode; or participants choosing from session to session which mode (in-person or distance learning) they wish to use.[348]

To further align with 2024 CDC DPRP Standards, we also propose to add a new term at § 410.79(b), ''combination with an online component,'' defined as ''sessions that are delivered as a combination of online (non-live) with in-person or distance learning. These sessions must be furnished in a manner consistent with the DPRP Standards for the modality being used.'' Furthermore, we propose to remove the ''combination delivery'' term from § 410.79(b), which was added in the CY 2024 PFS final rule (88 FR 79241) and is defined as ''MDPP sessions that are delivered by trained Coaches and are furnished in a manner consistent with the DPRP Standards for distance learning and in-person sessions for each individual participant.'' We believe that the MDPP ''combination delivery'' term and definition are no longer needed with the addition of ''in-person with a distance learning component,'' which includes any combination of in-person and distance learning sessions.

Lastly, we are proposing to modify the current term and definition for ''online delivery'' at § 410.79(b), also added by the CY 2024 PFS final rule (88 FR 79241), to align with the 2024 CDC DPRP Standards.[349] First, we are proposing to update the term from ''online delivery'' to ''online'' to align with both the MDPP ''distance learning'' term and CDC DPRP ''online (non-live)'' term. We propose to revise the definition for the MDPP ''online'' delivery mode to provide that sessions that are delivered one hundred percent (100%) through the internet via phone, tablet, or laptop in an asynchronous (non-live) classroom where participants are experiencing the content on their own time without a live (including non-artificial intelligence (AI)) Coach teaching the content. These sessions must be furnished in a manner consistent with the DPRP Standards for online sessions. Live Coach interaction must be offered to each participant during weeks when the participant has engaged with content. Emails and text messages can count toward the requirement for live Coach interaction if there is bi-directional communication between the Coach and participant. Chat bots and AI forums do not count as live Coach interaction. This modified definition adds the term ''non-live'' and further clarifies that Chat bots and AI forums do not constitute live interaction.

In summary, we are revising the ''online'' definition and adding the ''combination with an online component'' term and definition to help align terminology between MDPP and DPRP and prevent confusion about acceptable CDC delivery modes for MDPP. We are confirming that only MDPP ''in-person,'' ''distance learning,'' and ''in-person with a distance learning component'' delivery modes, can be used during the extension of the flexibilities allowed under the COVID–19 PHE, as finalized in the CY 2024 PFS final rule (88 FR 79241), not ''online'' nor ''combination with an online component'' delivery modes.

Furthermore, in the CY 2021 PFS final rule, we established that virtual sessions performed under flexibilities finalized in that rule could only be performed by MDPP suppliers who offered in-person services (85 FR 84830). For the MDPP Extended flexibilities period, we finalized in the CY 2024 PFS final rule to limit virtual delivery to the CDC DPRP definition of ''distance learning'' (88 FR 79243). We stated that the MDPP Extended flexibilities do not include online delivery (or asynchronous virtual), as defined in the CDC DPRP Standards through the ''online'' modality, including virtual make-up sessions (88 FR 79244). A make-up session in MDPP was described in CY 2018 PFS final rule (82 FR 53241) and at § 410.79(a) as ''a core session or a core maintenance session furnished to an MDPP beneficiary when the MDPP beneficiary misses a regularly scheduled core session or core maintenance session.'' The 2024 CDC DPRP Standards allow for National DPP make-up sessions to be furnished using any delivery mode, including online.[350] In alignment with the CY 2024 final rule, we are proposing to amend § 410.79(d)(1) to clarify that MDPP make-up sessions can only be furnished using the modalities permitted by the CY 2024 final rule for MDPP sessions: distance learning and in-person delivery (88 FR 79243 through 79246). Specifically, we propose to add the following: ''MDPP make-up sessions may only use in-person or distance learning delivery.''

We are proposing to amend § 410.79(b) and (d)(1) and seek comment on these proposals.

2. Proposed Changes to § 410.79(e)(3)(iii)

As part of MDPP's Emergency Policy finalized in the CY 2021 PFS final rule, we allowed for virtual weight collection (88 FR 79249). We summarized our policies for alternatives to the requirement for in-person weight collection at *Alternatives to the requirement for in-person weight measurement* (§ 410.79(e)(3)(iii)), which permit an MDPP supplier to obtain weight measurements for MDPP beneficiaries for the baseline weight and any weight loss-based performance achievement goals in the following manner: (1) via digital technology, such as scales that transmit weights securely via wireless or cellular transmission; or (2) via self-reported weight measurements from the at-home digital scale of the MDPP beneficiary (88 FR 79243). We stated that self-reported weights must be obtained during live, synchronous online video technology, such as video chatting or video conferencing, wherein the MDPP Coach observes the beneficiary weighing themselves and views the weight indicated on the at-home digital scale. Alternatively, the MDPP beneficiary may self-report their weight by submitting to the MDPP supplier a date-stamped photo or video recording of the beneficiary's weight, with the

[348] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

[349] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

[350] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

beneficiary visible in their home. The photo or video must clearly document the weight of the MDPP beneficiary as it appears on the digital scale on the date associated with the billable MDPP session. This flexibility has allowed suppliers to bill for MDPP beneficiaries achieving weight loss performance goals.

Overall, commenters on the proposed MDPP Extended flexibilities in the CY 2024 PFS rule were very supportive of CMS continuing to allow virtual weight collection (88 FR 79240 through 79256). However, we received several comments regarding barriers suppliers experienced relating to virtual weight collection during the PHE for COVID–19. For example, several commenters recommended that CMS no longer require date-stamped photos to document the self-reported beneficiary weights (88 FR 79249). The commenters also reported that many of their beneficiaries are unable to take a picture while standing on their home scales due to risk of injury and physical health limitations. Commenters stated that this risk has prevented organizations from submitting claims accurately, since they have several participants who live alone and attend sessions via distance learning (88 FR 79249). We acknowledged in our responses to these comments that some MDPP beneficiaries may lack the technology or capacity to provide a date-stamped photograph to document their body weight measurements. We stated that in situations in which beneficiaries may be unable to self-report their weight according to the MDPP conditions of coverage, suppliers may want to consider collecting weight measurements from the MDPP beneficiary in person.

We have continued to hear from MDPP suppliers and interested parties that the requirement to submit a photo with both the beneficiary's weight on the scale and the beneficiary visible is not physically possible. This problem has become even more relevant in CY 2024 as suppliers continue to expand distance learning to help reach beneficiaries in rural and underserved areas, sometimes across state lines. We previously responded that for situations in which beneficiaries may be unable to self-report their weight according to the MDPP conditions of coverage, suppliers may want to consider collecting weight measurements from the MDPP beneficiary in person (88 FR 79249). However, this may not be a practical option for beneficiaries who have chosen distance learning based on not living within driving distance from an MDPP supplier location. Therefore, we propose revising § 410.79(e)(3)(iii)(C) to provide that self-reported weights must be obtained during live, synchronous online video technology, such as video chatting or video conferencing, wherein the MDPP Coach observes the beneficiary weighing themselves and views the weight indicated on the at-home digital scale, or the MDPP supplier receives 2 (two) date-stamped photos or a video recording of the beneficiary's weight, with the beneficiary visible on the scale, submitted by the MDPP beneficiary to the MDPP supplier. Photo or video must clearly document the weight of the MDPP beneficiary as it appears on their digital scale on the date associated with the billable MDPP session. If choosing to submit 2 photos, one photo must show the beneficiary's weight on the digital scale, the second photo must show the beneficiary visible in their home, and both photos must be date-stamped. Similar to options in paragraphs (e)(3)(iii)(A) and (B) in § 410.79, this revised option in paragraph (e)(30(iii)(C) is only available for MDPP beneficiaries reporting their weight for an MDPP distance learning session. We are continuing to require the date-stamp on both photos to ensure program integrity in the virtual setting. We are proposing to amend § 410.79(e)(3)(iii). We seek comment on these proposals.

Lastly, we finalized in the CY 2021 PFS final rule that the flexibilities under § 410.79(e)(3)(iii) and (iv) would only apply only to MDPP suppliers that have and maintain CDC DPRP ''in-person'' recognition (85 FR 84831). In the CY 2024 PFS final rule, we extended flexibilities allowed during the PHE for COVID–19 or 4 years, or through December 31, 2027 (88 FR 79241). We also confirmed that that the Extended flexibilities would continue to only apply to MDPP suppliers that have and maintain CDC DPRP ''in-person'' recognition, and that virtual only suppliers were not permitted to furnish the Set of MDPP services because MDPP beneficiaries may elect to return to in-person services, and MDPP suppliers need to be able to accommodate their request (88 FR 79248).

To reduce confusion as MDPP suppliers transition to the new CDC DPRP recognition for ''in-person with a distance learning component,'' we are clarifying that MDPP suppliers can have and maintain either CDC's ''in-person'' or the new ''in-person with a distance learning component'' CDC DPRP code. The 2024 CDC DPRP Standards, implemented in June 2024, introduced and defined the new ''in-person with a distance learning component'' modality and associated code.[351] This new modality and code for recognition include a combination of in-person and distance learning delivery, which are both modalities currently permitted until December 31, 2027 (88 FR 79241). The new MDPP term and definition for ''in person with a distance learning component'' that we are proposing to align with the 2024 CDC DPRP Standards will replace the current MDPP ''combination delivery'' term, which we are proposing to remove in this rulemaking. Aligning terminology for delivery of MDPP that involves a combination of in-person and distance learning delivery with the 2024 CDC DPRP Standards would reduce administrative burden to MDPP suppliers and allow them to streamline CDC DPRP data submission (that is, they will not have to submit data for two CDC organization codes). MDPP suppliers will not be required to switch to this new code if they already have an in-person code; it is only being made available for their convenience.

3. Proposed Changes to § 414.84(a), (c), (d), and (e)

We further propose to amend § 414.84(a), (d), and (e) to remove the MDPP bridge payment. This payment is no longer necessary in MDPP's CY 2024 FFS payment structure for attendance and could introduce the potential for fraud, waste, or abuse.

The CY 2017 PFS final rule confirmed that a beneficiary may change MDPP suppliers at any time (81 FR 80470). The MDPP bridge payment was introduced in the CY 2018 PFS final rule at § 414.84(a) and is defined as follows: ''Bridge payment means a one-time payment to an MDPP supplier for furnishing its first MDPP session to an MDPP beneficiary who has previously received one or more MDPP services from a different MDPP supplier'' (81 FR 80470). The CY 2018 PFS final rule specified that an MDPP supplier that had previously been paid either a bridge payment or a performance payment for an MDPP beneficiary was not eligible to be paid a bridge payment for that beneficiary, along with other conditions. An MDPP supplier may only receive one bridge payment per MDPP beneficiary, however, there is no limit on how many MDPP suppliers can receive a bridge payment for the same beneficiary (82 FR 53361).

[351] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

The CY 2018 PFS final rule also noted that the MDPP bridge payment was intended to be similar (that is, the same amount) to the payment for the first core session furnished by the previous supplier and would be received only if the subsequent supplier did not furnish the first core session to the MDPP beneficiary (82 FR 53361). In the performance-based payment structure, the bridge payment was intended to prevent scenarios where subsequent MDPP suppliers would receive no payment for sessions furnished to MDPP beneficiaries who changed suppliers during the MDPP services period in the absence of the bridge payment. We stated that the bridge payment was not intended to be a performance payment; rather, it would account for the financial risk a subsequent MDPP supplier took on by furnishing services to a beneficiary changing MDPP suppliers during the MDPP services period (82 FR 53293). However, such risk is not applicable in an FFS payment structure.

Along with the performance payments for weight loss, the MDPP bridge payment was retained in the CY 2024 Fee Schedule for MDPP (88 FR 79252). Currently, a subsequent MDPP supplier can receive both an attendance payment and a bridge payment for the first session attended by an MDPP beneficiary who switches suppliers. For example, in CY 2024, if a beneficiary changed suppliers on MDPP session 8, the subsequent supplier could receive both the attendance payment for session 8 ($25) and the bridge payment ($25). The bridge payment for this beneficiary could only be received by this supplier once, but if the beneficiary changed suppliers again (for example, on session 17), the new (second) subsequent supplier could also receive the bridge payment in addition to the payment for session 17 ($25). This could continue as many times as the beneficiary changed suppliers until they have the maximum of 22 sessions paid, across all suppliers, with no maximum on the total number of bridge payments. In the CY 2018 PFS final rule, we noted some program integrity risk that organizations could coordinate to bill multiple bridge payments that would ultimately increase total MDPP payments to separately enrolled MDPP suppliers to serve the financial interests of the umbrella organization. This scenario could occur if MDPP suppliers systematically encouraged beneficiaries to change suppliers for the purpose of being paid the bridge payment (82 FR 53294). Due to these reasons, we propose to amend § 414.84(a), (d), and (e) to remove reference to, and requirements of the MDPP bridge payment. Per our Regulatory Impact Analysis, we expect removal of the MDPP bridge payment to be budget neutral for the Medicare program. We seek comment on these proposals.

Additionally, at § 414.84(c), facilitate Medicare Administrative Contractors (MACs) in processing claims for same day make-up sessions in MDPP, we are proposing to require MDPP suppliers to append an existing claim modifier to any claim for G9886 or G9887 that indicates a make-up session that was held on the same day as a regularly scheduled MDPP session. The CY 2018 PFS final rule permits an MDPP beneficiary to have one make-up session on the same day as a regularly scheduled session and for a beneficiary to have one make-up session per week (82 FR 53360), consistent with CDC DPRP Standards.[352] In the CY 2024 PFS final rule, we stated that we wanted to encourage suppliers to schedule make-up sessions on days other than the same day of a regularly scheduled session to avoid claims being rejected or denied under the new CY 2024 FFS payment schedule and to allow beneficiaries to receive the benefit as intended by having access to the full 12 months MDPP service period to build the skills needed to reduce their risk for diabetes (88 FR 79250).

However, since then, we have heard from MDPP suppliers that same day make-up sessions are an essential flexibility that assist an MDPP beneficiary in staying on track with the curriculum and their cohort after an MDPP beneficiary needs to miss a regularly scheduled session. To help prevent potential claim rejections for duplicate services, we are proposing to require MDPP suppliers to append a modifier to the applicable G-code for the second session held on the same day as a regularly scheduled MDPP session. Specifically, we are proposing to add § 414.84(c)(4), which states that ''Current Procedural Terminology (CPT) Modifier 79 (repeat services by same physician) must be appended to any claim for G9886 or G9887 to identify a MDPP make-up session that was held on the same day as a regularly scheduled MDPP session.'' We believe this new requirement would contribute minimal additional complexity to the payment structure while creating a flexibility that would have value for the program, particularly for beneficiaries in the core phase of MDPP who may not have transportation to 2 in-person sessions in one week or have the flexibility to make time on more than one day per week for a distance learning session. Additionally, we believe the existing limitation on one make-up session per week would be sufficient to ensure program benefit because whether the make-up session is held on the same day, or the next day would likely have minimal impact on program duration and intensity. To clarify, we are proposing that the CPT Modifier 79 would only need to be appended to the HCPCS code (G9886 or G9887) that identifies the session that included content from a previously held session that serves as a makeup session for the session the MDPP beneficiary missed, which was held on the same day as a regularly scheduled MDPP session. This modifier would not need to be included on claims for make-up sessions held on different days than regularly scheduled MDPP sessions.

Lastly, with the removal of § 414.84(d), we are proposing to amend the current § 414.84(e) to be the new § 414.84(d). We are also removing from the new § 414.84(d) the reference to updating the MDPP bridge payment, as the bridge payment has been proposed to be removed from this CY 2025 Physician Fee Schedule rulemaking.

We also seek comment on these proposals.

4. Aligning language with previous rulemaking in §§ 410.79, 424.205, and 414.84

We are proposing minor edits throughout §§ 410.79, 424.205, and 414.84 to update outdated references and align with previous rulemaking pertaining to MDPP terminology, payment structure, and requirements. This includes updating references to the performance-based payments for attendance and ongoing maintenance sessions, which were both removed from the 2024 MDPP Fee Schedule by the CY 2024 PFS final rule (88 FR 79252), as well as including the clarification that suppliers can offer MDPP sessions via distance learning, a flexibility extended by the CY 2024 PFS final rule (88 FR 79241), where applicable.

At § 410.79(b), we propose to update the definition for the ''Set of MDPP services'' to remove the reference to ''ongoing maintenance'' sessions. All references to and requirements for the MDPP ''ongoing maintenance'' phase were removed by the CY 2024 PFS finale rule (88 FR 79256). We are revising this definition to read: ''Set of MDPP services means the series of

[352] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

MDPP sessions, composed of core sessions and core maintenance sessions, and subject to paragraph (c)(3) of this section offered over the course of the MDPP services period.''

We also propose § 410.79(e)(3)(iv)(F)(*3*) to state that no more than 12 virtual sessions offered monthly during the ongoing maintenance session intervals, months 13 through 24 for beneficiaries enrolled before January 1, 2022.

This proposed revision adds the date that the CY 2022 PFS final rule was effective, which is the date when no more MDPP beneficiaries could enroll in ongoing maintenance sessions (86 FR 65317).

At § 410.79(e)(3)(v)(F)(*2*), we propose to remove the reference to weight measurement at an ongoing maintenance session, so the paragraph provides that for an MDPP beneficiary who began receiving the Set of MDPP services on or after January 1, 2021, has suspended services during an applicable 1135 waiver event, the MDPP supplier must use the baseline weight recorded at the beneficiary's first core session.

At § 424.205(c)(10), we propose revision to specify in-person and distance learning delivery for MDPP core and core maintenance sessions, to provide that, except as allowed under § 424.205(d)(8), the MDPP supplier must offer an MDPP beneficiary no fewer than all of the following:

- 16 in-person or distance learning core sessions no more frequently than weekly for the first 6 months of the MDPP services period, which begins on the date of attendance at the first such core session.
- 1 in-person or distance learning core maintenance session each month during months 7 through 12 (6 months total) of the MDPP services period.

At § 424.205(f)(1)(ii), we propose to remove reference to the HICN, as Medicare is now using Medicare Beneficiary Identifiers (MBIs),[353] to state: Basic beneficiary information for each MDPP beneficiary in attendance, including but not limited to beneficiary name, MBI, and age.

At § 424.205(f)(2)(i), we propose to replace ''whether a core session, a core maintenance session, an in-person make-up session, or a virtual make-up session'' with the two currently permitted types of sessions (that is, in-person and distance learning), to state: Documentation of the type of session (in-person or distance learning).

At § 424.205(f)(5), we propose to remove the references to the MDPP performance-based payments for attendance in paragraphs (f)(5)(i) and (ii) because these payments were removed in the CY 2024 Fee Schedule for MDPP (88 FR 79252). In their place, we are adding references to the performance payment for the required minimum 5 percent weight loss (82 FR 53289). We also propose to correct the references to § 414.84(b), and also to remove the reference to the ongoing maintenance sessions from 424.205(f)(5)(iv).

At § 414.84(b)(1), we propose to clarify that the performance payment for the required minimum weight loss is made for 5 percent weight loss, as reflected in the CY 2024 Fee Schedule (88 FR 79252), and can be made for a distance learning, as well as an in-person MDPP session, as allowed by the COVID–19 PHE flexibilities (85 FR 84830 through 84841) and their extension (88 FR 79241). Performance Goal 1 provides that it achieves the required minimum 5-percent weight loss. CMS makes a performance payment to an MDPP supplier for an MDPP beneficiary who achieves the required minimum weight loss as measured in-person or during a distance learning session during a core session or core maintenance session furnished by that supplier.

Similarly, we propose to revise § 414.84(b)(2) for 9 percent weight loss. Performance Goal 2 provides that it achieves 9-percent weight loss. CMS makes a performance payment to an MDPP supplier for an MDPP beneficiary who achieves at least a 9-percent weight loss as measured in-person or in a distance learning session during a core session or core maintenance session furnished by that supplier.

We seek comment on these proposals.

F. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished By Opioid Treatment Programs (OTPs)

1. Background

Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271, October 24, 2018) established a new Medicare Part B benefit for OUD treatment services furnished by OTPs during an episode of care beginning on or after January 1, 2020. In the CY 2020 PFS final rule (84 FR 62630 through 62677 and 84 FR 62919 through 62926), we implemented Medicare coverage and provider enrollment requirements and established a methodology for determining the bundled payments for episodes of care for the treatment of OUD furnished by OTPs. We also established in the CY 2020 PFS final rule new codes and finalized bundled payments for weekly episodes of care that include methadone, oral buprenorphine, implantable buprenorphine, injectable buprenorphine or naltrexone, and non-drug episodes of care, as well as add-on codes for intake and periodic assessments, take-home dosages for methadone and oral buprenorphine, and additional counseling.

Since the CY 2020 PFS final rule, we have made several refinements and expansions to services covered under the Medicare OTP benefit. Specifically, we adopted new add-on codes for take home supplies of nasal naloxone and injectable naloxone (85 FR 84683 through 84692) in the CY 2021 PFS final rule, and a new add-on code and payment for a higher dose of nasal naloxone (86 FR 65340 and 65341) in the CY 2022 PFS final rule. We have also finalized various telecommunications flexibilities, including: to allow OTPs to furnish individual and group therapy and substance use counseling via two-way interactive audio-video telecommunications (84 FR 62630 through 62677 and 84 FR 62919 through 62926) in the CY 2020 PFS final rule, and via audio-only telephone calls when audio-video telecommunications are not available to the beneficiary (86 FR 65342) in the CY 2022 PFS final rule; to allow the OTP intake add-on code to be furnished via two-way interactive audio-video telecommunications when billed for the initiation of treatment with buprenorphine, and via audio-only telecommunications when audio-video telecommunications are not available to the beneficiary, to the extent that these technologies are authorized by the Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) at the time the service is furnished (87 FR 69775 through 69777) in the CY 2024 final rule; and to allow periodic assessments to be furnished via two-way interactive audio-video telecommunications as clinically appropriate (85 FR 84690) in the CY 2021 final rule. OTPs may furnish these aforementioned services via telecommunications systems provided all other applicable requirements are met. Additionally, for the purposes of the geographic adjustment, we have clarified, in the CY 2023 final rule, that services furnished via OTP mobile units will be treated as if the services were furnished in the physical location of the

[353] *https://www.cms.gov/training-education/partner-outreach-resources/new-medicare-card/medical-beneficiary-identifiers-mbis.*

OTP for purposes of determining payments to OTPs under the Medicare OTP bundled payment codes and/or add-on codes, as long as services are medically reasonable and necessary and comply with SAMHSA and DEA guidance (87 FR 69768 through 69777). Lastly, we have made a few changes to various pricing methodologies under the OTP benefit in the 2023 PFS final rule, including: revising our methodology for pricing the drug component of the methadone weekly bundle and the add-on code for take-home supplies of methadone by using the Producer Price Index (PPI) for Pharmaceuticals for Human Use (Prescription) to better reflect the changes in methadone costs for OTPs over time (87 FR 69768 through 69777); and modifying the payment rate for individual therapy in the non-drug component of the bundled payment to base the payment rate on the rate for longer therapy sessions that better account for the greater severity of needs for patients with an OUD (87 FR 69768 through 69777).

More recently, for CY 2024, CMS made further modifications and expansions to covered services for the treatment of OUD by OTPs. In the CY 2024 PFS final rule (88 FR 79089 through 79093), CMS finalized an extension to allow periodic assessments to be furnished audio-only through the end of CY 2024 when video is not available to the extent that use of audio-only communications technology is permitted under the applicable SAMHSA and DEA requirements at the time the service is furnished, and all other applicable requirements are met. In the final rule, we noted that extending these flexibilities another year would allow CMS time to further consider this issue, including whether periodic assessments should continue to be furnished using audio-only communication technology following the end of CY 2024. Lastly, in the CY 2024 Outpatient Prospective Payment System (OPPS) final rule (88 FR 81845 through 81858), CMS finalized an add-on code for intensive outpatient program (IOP) services furnished by OTPs for the treatment of OUD and added a new paragraph (ix) in the definition of ''Opioid disorder treatment service'' at § 410.67(b) to describe such services. We stated that Medicare would pay for IOP services provided by OTPs if each service is medically reasonable and necessary and not duplicative of any service paid for under any bundled payments billed for an episode of care in a given week, and other applicable requirements are met. We believe that payment for IOP services will improve continuity of care between different treatment settings and levels of care, and further promote health equity for Medicare beneficiaries that may face barriers to accessing treatment, such as racial/ethnic minorities and/or beneficiaries aged 65 or older. We continue to monitor utilization of OUD treatment services furnished by OTPs to ensure that Medicare beneficiaries have appropriate access to care. For CY 2025, we are proposing several modifications to the policies governing Medicare coverage and payment for OUD treatment services furnished by OTPs.

2. Telecommunication Flexibilities for Periodic Assessments and Initiation of Treatment With Methadone

We have finalized several flexibilities for OTPs regarding the use of telecommunications, both during the Public Health Emergency (PHE) for the Coronavirus Disease 2019 (COVID–19) and outside of the PHE. In the CY 2020 PFS final rule, we finalized a policy allowing OTPs to furnish substance use counseling and individual and group therapy via two-way interactive audio-video communication technology. In the interim final rule with comment period (IFC) entitled ''Medicare and Medicaid Programs: Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,'' which appeared in the April 6, 2020 **Federal Register** (85 FR 19258), we revised paragraphs (iii) and (iv) in the definition of *opioid use disorder treatment service* at § 410.67(b) on an interim final basis to allow the therapy and counseling portions of the weekly bundles, as well as the add-on code for additional counseling or therapy, to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology during the PHE for the COVID–19 if beneficiaries do not have access to two-way audio-video communications technology, provided all other applicable requirements are met. In the CY 2022 PFS final rule (86 FR 65341 through 65343), we finalized that after the conclusion of the PHE for COVID–19, OTPs are permitted to furnish substance use counseling and individual and group therapy via audio-only telephone calls when audio and video communication technology is not available to the beneficiary. As we explained in the CY 2022 PFS final rule (86 FR 65342), we interpret the requirement that audio/video technology is ''not available to the beneficiary'' to include circumstances in which the beneficiary is not capable of or has not consented to the use of devices that permit a two-way, audio/video interaction because in each of these instances audio/video communication technology is not able to be used in furnishing services to the beneficiary. In the CY 2023 PFS final rule (87 FR 69775 through 69777), we further extended telecommunication flexibilities for the initiation of treatment with buprenorphine outside of the PHE for COVID–19 in paragraph (vi) in the definition of *opioid use disorder treatment service* at § 410.67(b). Specifically, we allowed the OTP intake add-on code to be furnished via two-way, audio-video communications technology when billed for the initiation of treatment with buprenorphine, to the extent that the use of audio-video telecommunications technology to initiate treatment with buprenorphine is authorized by DEA and SAMHSA at the time the service is furnished. We also permitted the use of audio-only communication technology to initiate treatment with buprenorphine in cases where audio-video technology is not available to the beneficiary, provided all other applicable requirements are met.

a. Proposal To Allow Periodic Assessments To Be Furnished Via Audio-Only Telecommunications on a Permanent Basis

In recent years, we have finalized several telecommunication flexibilities for periodic assessments furnished by OTPs. In the IFC entitled ''Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program,'' which appeared in the May 8, 2020 **Federal Register** (85 FR 27558), we revised paragraph (vii) in the definition of ''Opioid use disorder treatment service'' at § 410.67(b) on an interim final basis to allow periodic assessments to be furnished during the PHE for COVID–19 via two-way interactive audio-video telecommunication technology and, in cases where beneficiaries do not have access to two-way audio-video communication technology, to permit the periodic assessments to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology, provided all other applicable requirements are met. In the CY 2021 PFS final rule (85 FR 84690), we finalized our proposal to revise paragraph (vii) in the definition of ''Opioid use disorder treatment service'' at § 410.67(b) to provide that periodic assessments (HCPCS code G2077) must be furnished during a face-

to-face encounter, which includes services furnished via two-way interactive audio-video communication technology, as clinically appropriate, provided all other applicable requirements are met, on a permanent basis.

Furthermore, in the CY 2023 PFS proposed rule (87 FR 46093), we sought comment on whether we should allow periodic assessments to continue to be furnished using audio-only communication technology following the end of the PHE for COVID–19 for patients who are receiving treatment via buprenorphine, and if this flexibility should also continue to apply to patients receiving methadone or naltrexone. In response, several commenters advocated for CMS to continue to allow periodic assessments to be furnished audio-only when video is not available after the end of the PHE. Commenters highlighted that allowing audio-only flexibilities would further promote health equity for individuals who are economically disadvantaged, live in rural areas, are members of racial and ethnic minorities, lack access to reliable broadband or internet access, or do not possess devices with video capability. Commenters also indicated that periodic assessments are no less complex than intake/initial assessments, and thus are equally appropriate for audio-video and audio-only care, and that permitting audio-only flexibilities would allow an opportunity for both the provider and patient to jointly determine that the patient would individually benefit from telehealth services. After considering these comments, we determined that it would be appropriate to allow periodic assessments to be furnished audio-only when video is not available through the end of CY 2023, to the extent that it is authorized by SAMHSA and DEA at the time the service is furnished and, in a manner consistent with all applicable requirements. We stated our belief that this modification would allow continued beneficiary access to these services for the duration of CY 2023 in the event the PHE terminated before the end of 2023 and that it would also grant additional time for CMS to further consider telecommunication flexibilities associated with periodic assessments.

Moreover, section 4113 of Division FF, Title IV, Subtitle A of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328, December 29, 2022) extended the telehealth flexibilities enacted in the Consolidated Appropriations Act, 2022 (CAA, 2022) (Pub. L. 117–103, March 15, 2022). Specifically, it amended sections 1834(m), 1834(o), and 1834(y) of the Act to delay the requirement for an in-person visit prior to furnishing certain mental health services via telecommunications technology by physicians and other practitioners, Rural Health Clinics (RHCs), and Federally Qualified Health Centers (FQHCs) until dates of service on or after January 1, 2025, if the PHE for COVID–19 had ended prior to that date. Additionally, it extended the flexibilities that were available during the PHE that allowed for certain Medicare telehealth services defined in section 1834(m)(4)(F)(i) of the Act to be furnished via an audio-only telecommunications system through December 31, 2024, if the PHE for COVID–19 had ended prior to that date. The PHE for COVID–19, which was declared under section 319 of the Public Health Service Act, expired at the end of the day on May 11, 2023, so the aforementioned flexibilities were extended through the end of CY 2024.

To better align coverage for periodic assessments furnished by OTPs with the telehealth flexibilities described in section 4113 of the CAA, 2023 for other settings under Medicare, in the CY 2024 PFS final rule (88 FR 79089 through 79093; 79528), we finalized extending the audio-only flexibilities for periodic assessments furnished by OTPs through the end of CY 2024 in paragraph (vii) in the definition of ''Opioid use disorder treatment service'' at § 410.67(b). We finalized to allow periodic assessments to be furnished audio-only when video is not available to the extent that use of audio-only communications technology is permitted under the applicable SAMHSA and DEA requirements at the time the service is furnished, and all other applicable requirements are met. In submitted comments supporting the proposal, commenters reiterated evidence showing that audio-only telehealth encounters are more prominent among individuals who are older, Black, Hispanic, American Indian/Alaska Native, Spanish-speaking, living in areas with low broadband access, low-income, and with public insurance, suggesting that the proposal would have positive health equity implications for these populations.[354] Several other commenters raised that audio-only flexibilities are important since many underserved populations may experience challenges in partaking in video-based telehealth services, due to not possessing the needed technological proficiencies to operate video-based services, not having a caregiver able to assist them with appointments, feeling discomfort with the use of video, and because of the cost of high-speed internet and data required for video technologies. Several other commenters shared evidence that audio-only visits produce many of the same benefits as video-based visits,[355] and that patients often report that audio-only visits left them feeling supported and with greater privacy, provided increased access to behavioral health professionals, and helped reduce transportation barriers.[356] Lastly, a large number of commenters requested that CMS make the extension for audio-only periodic assessments permanent beyond CY 2024. Commenters stated that extending this policy permanently would retain a beneficiary's right to decide with their provider how best to receive their care and would curtail existing barriers that Medicare beneficiaries with an OUD may face in accessing care. In response to these comments that requested indefinitely extending these audio-only flexibilities for periodic assessments, CMS stated that extending these flexibilities for one additional year at the time would allow the agency time to further examine the issue, including to understand if a permanent extension would be appropriate for patients who are receiving treatment via buprenorphine, methadone, and/or naltrexone at OTPs, and whether proper safeguards are in place so these services can be delivered in a way that would not diminish safety or quality of care for Medicare beneficiaries with an OUD.

We continue to monitor the services provided under the OTP benefit to

[354] J.A. Rodriguez et al., ''Differences in the Use of Telephone and Video Telemedicine Visits During the COVID–19 Pandemic,'' The American Journal of Managed Care 27, no. 1 (2021), *https://www.ajmc.com/view/differences-in-the-use-of-telephone-and-video-telemedicine-visits-during-the-covid-19-pandemic*; R.P. Pierce and J.J. Stevermer, ''Disparities in Use of Telehealth at the Onset of the COVID–19 Public Health Emergency,'' Journal of Telemedicine and Telecare (2020): 1–7, *https://doi.org/10.1177/1357633X20963893*; J.E. Chang et al., ''Patient Characteristics Associated with Phone Versus Video Telemedicine Visits for Substance Use Treatment During COVID–19,'' J Addict Med 16, no. 6 (2022): 659–65; C. Shoff, T–C Yang, B.A. Shaw, ''Trends in Opioid Use Disorder Among Older Adults: Analyzing Medicare Data, 2013–2018,'' American Journal of Preventive Medicine 60, no.6 (2021): 850–855, *https://doi.org/10.1016/j.amepre.2021.01.010.*

[355] Danila, M.I., Sun, D., Jackson, L.E., Cutter, G., Jackson, E.A., Ford, E.W., DeLaney, E., Mudano, A., Foster, P.J., Rosas, G., Melnick, J.A, Curtis, J.R., & Saag, K.G. (2022, November). ''Satisfaction with modes of telemedicine delivery during COVID–19: A randomized, single-blind, parallel group, noninferiority trial.'' The American Journal of the Medical Sciences, 364 (5).

[356] Kang AW, Walton M, Hoadley A, DelaCuesta C, Hurley L, Martin R. ''Patient Experiences with the Transition to Telephone Counseling during the COVID–19 Pandemic.'' Healthcare (Basel). 2021;9(6):663. Published 2021 Jun 2. *doi:10.3390/healthcare9060663.*

ensure flexibilities for OUD treatment services are consistent with flexibilities authorized in other settings under Medicare, as medically reasonable and necessary for the diagnosis and treatment of OUD. In the CY 2022 PFS final rule, we revised the regulatory definition of ''interactive telecommunications system'' at § 410.78(a)(3) for Medicare Telehealth services paid under the PFS beyond the termination of the PHE for COVID–19 to allow for inclusion of audio-only services under certain circumstances. Specifically, we redefined ''interactive telecommunications system'' to include audio-only communications technology when used for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders furnished to a patient in their home. We also finalized to limit payment for audio-only services to services furnished by a physician or practitioner that has the technical capability at the time of the service to use two-way audio-video telecommunications, but where the patient is not capable of, or does not consent to, the use video technology for the service, and the patient is located at their home at the time of service. Lastly, we clarified that SUD services are considered mental health services for purposes of the expanded definition of ''interactive telecommunications system'' to include audio-only services under § 410.78(a)(3). In short, these flexibilities and policy clarifications that permit audio-only telecommunication flexibilities for the treatment of a SUD, which can include an OUD, already exist under other payment systems in Medicare.

Therefore, to better align coverage for periodic assessments furnished by OTPs with other telehealth services furnished under the PFS for the diagnosis, evaluation, or treatment of a mental health disorder including SUDs, and in response to many supportive comments received in response to the CY 2024 PFS proposed rule that advocated for allowing OTPs to furnish periodic assessments via audio-only telecommunications on a permanent basis, we are proposing to allow OTPs to furnish periodic assessments using audio-only communications technology when video is not available on a permanent basis beginning January 1, 2025. Under this proposal, we would allow periodic assessments to be furnished via audio-only when video is not available to the extent that use of audio-only communications technology is permitted under the applicable SAMHSA and DEA requirements at the time the service is furnished, and all other applicable requirements are met.

We believe permanently extending this flexibility would meaningfully promote access to care for the Medicare population, as supported by our analysis of claims data showing the proportion of telephonic audio-only visits increases with the age of the patient, with 17-percent of visits delivered via audio-only interaction for patients 41–60 years of age, 30-percent for patients 61 to 80 years of age, and 47 percent of visits for patients over 81 years of age.[357] Evidence further reveals that Medicare beneficiaries who are older than 65 years old, racial/ethnic minorities, dual-enrollees in Medicare and Medicaid, or living in rural areas, or who experience low broadband access, low-income, and/or for whom English in not their primary language, are more likely to be offered and use audio-only telemedicine services than audio-video services.[358] Other evidence also suggests that while Tribal populations, including American Indian and Alaska Natives, have the highest rates of OUD prevalence among Medicare beneficiaries, one-third of these populations do not have adequate access to high-speed broadband and continue to rely on audio-only visits.[359] Telemedicine flexibilities have been shown to be feasible and effective for rural patients with an OUD with data supporting that telemedicine flexibilities have helped improve treatment retention in OUD treatment, especially for rural patients who are older and covered by Medicare.[360] Lastly, these audio-only flexibilities would be meaningful for OTPs and their patients because telehealth services have become widely used among SUD treatment facilities as regular service offerings. During the COVID–19 pandemic, SUD treatment facilities increased telemedicine offerings by 143 percent, and as of 2021, almost 60 percent of SUD treatment facilities offer telehealth.[361] Now, telephone-based (that is, audio-only) therapy provided by SUD programs has been found to be one of the most common modes of telehealth for treatment of OUD.[362] Given the prevalence of audio-only modalities of care for the treatment of OUD, permanently extending this flexibility could help prevent disruptions to care in OTP settings that may regularly provide periodic assessments via audio-only telehealth to Medicare beneficiaries. For these reasons, we believe a permanent extension would be appropriate for patients who are receiving buprenorphine, methadone, and/or naltrexone at OTPs, and that proper safeguards are in place so these services can be delivered in a way that would not diminish safety or quality of care for Medicare beneficiaries with an OUD.

Accordingly, we are proposing to revise paragraph (vii) of the definition of ''Opioid treatment services'' at § 410.67(b) of the regulations to remove the references to the ''Public Health Emergency, as defined in § 400.200 of this chapter'' and ''through the end of CY 2024,'' in order to reflect that this flexibility would be implemented on a permanent basis. We would continue to state that ''in cases where a beneficiary does not have access to two-way audio-video communications technology, periodic assessments can be furnished using audio-only telephone calls if all other applicable requirements are met.'' We welcome comments on this proposal to permanently extend this audio-only flexibility for periodic assessments.

[357] Lee, G., & Stewart, K. (n.d.). ''2021 Medicare coverage and payment for audio only services (Telephone e/m).'' AAMC. *https://www.aamc.org/media/55296/download.*

[358] *Rodriguez, J.A., Betancourt, J.R., Sequist, T.D., & Ganguli, I. (2021).* ''Differences in the use of telephone and video telemedicine visits during the COVID–19 pandemic.'' *The American Journal of Managed Care, 27(1), 21–26. https://doi.org/10.37765/ajmc.2021.88573*; Koma, W., Cubanski, J., & Published, T.N. (2021, May 19). ''Medicare and telehealth: Coverage and use during the covid-19 pandemic and options for the future.'' KFF. *https://www.kff.org/medicare/issue-brief/medicare-and-telehealth-coverage-and-use-during-the-covid-19-pandemic-and-options-for-the-future/; ;Benjenk, I., Franzini, L., Roby, D., & Chen, J. (2021).* ''Disparities in Audio-Only Telemedicine use among Medicare beneficiaries during the coronavirus disease 2019 pandemic.'' *Medical Care, 59(11), 1014. https://doi.org/10.1097/MLR.0000000000001631.*

[359] Federal Communications Commission. (2020). ''2020 Broadband Deployment Report'' (FCC 20–50). *https://docs.fcc.gov/public/attachments/FCC-20-50A1.pdf*; Centers for Medicare and Medicaid Services, Division of Tribal Affairs. (n.d.). Telehealth and COVID–19. *https://www.cms.gov/files/document/aian-telehealthwebinar.pdf*; Shoff, C., Yang, T.-C., & Shaw, B.A. (2021). ''Trends in opioid use disorder among older adults: Analyzing Medicare data, 2013–2018.'' American Journal of Preventive Medicine, 60(6), 850–855. *https://doi.org/10.1016/j.amepre.2021.01.010.*

[360] *Lira, M.C., Jimes, C., & Coffey, M.J. (2023).* ''Retention in telehealth treatment for opioid use disorder among rural populations: A retrospective cohort study.'' *Telemedicine Journal and E-Health, 29(12), 1890–1896. https://doi.org/10.1089/tmj.2023.0044.*

[361] Cantor, J., McBain, R.K., Kofner, A., Hanson, R., Stein, B.D., & Yu, H. (2022). ''Telehealth adoption by mental health and substance use disorder treatment facilities in the covid-19 pandemic.'' Psychiatric Services (Washington, DC), 73(4), 411–417. *https://doi.org/10.1176/appi.ps.202100191;*

[362] *Hughes, P.M., Verrastro, G., Fusco, C.W., Wilson, C.G., & Ostrach, B. (2021).* ''An examination of telehealth policy impacts on initial rural opioid use disorder treatment patterns during the COVID–19 pandemic.'' *The Journal of Rural Health, 37(3), 467–472. https://doi.org/10.1111/jrh.12570.*

b. Proposal To Allow OTPs To Use Audio-Visual Telecommunications for Initiation of Treatment With Methadone

Prior to the PHE for COVID–19, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Pub. L. 110–425) amended the Controlled Substances Act and instructed the DEA to promulgate regulations that required healthcare providers to conduct an in-person examination in the presence of a practitioner prior to prescribing controlled substances (for example, methadone, buprenorphine, etc.) to patients, with certain exceptions. These statutory provisions prevented the distribution and dispensing of controlled substances by means of the internet without at least one in-person medical evaluation before writing a prescription. Similarly, SAMHSA regulations under 42 CFR 8.12(f)(2) have historically required a complete physical evaluation before a patient begins treatment at an OTP. However, after the declaration of the PHE for COVID–19, the DEA and SAMHSA jointly issued flexibilities for prescribing of controlled substances via telehealth to ensure patient therapies would remain accessible. Consequently, OTPs were exempted from the requirement to perform an in-person physical evaluation for any patient who would be treated by the OTP with buprenorphine if a program physician, primary care physician, or an authorized healthcare professional under the supervision of a program physician, determines that an adequate evaluation of the patient can be accomplished via telehealth through an audio-video or audio-only evaluation.[363] At the time, this exemption applied exclusively to patients with an OUD being treated at an OTP with buprenorphine, and it did not apply to new patients initiating treatment with methadone. This meant that new OTP patients starting treatment with methadone would need to still receive an in-person physical evaluation prior to the OTP prescribing methadone. Accordingly, in the CY 2023 PFS final rule (87 FR 69775 through 69777), we revised the regulation in paragraph (vi) of the definition of ''Opioid treatment services'' at § 410.67(b) to allow the OTP intake add-on code to be furnished via two-way audio-video communications technology when billed for the initiation of treatment with buprenorphine, to the extent that the use of audio-video telecommunications technology to initiate treatment with buprenorphine is authorized by DEA and SAMHSA at the time the service is furnished. We also permitted the use of audio-only communication technology to initiate treatment with buprenorphine in cases where audio-video technology is not available to the beneficiary. We stated that section 1834(m)(7) of the Act allows telehealth services for the treatment of a diagnosed SUD or co-occurring mental health disorder to be furnished to individuals at any telehealth originating site, including in a patient's home, and that some codes describing new patient office/outpatient visits are already under the Medicare Telehealth list (CPT codes 99202 through 99205). Therefore, we believed that these changes for the initiation of treatment with buprenorphine via audio-only or audio-video telecommunications would also be consistent with existing flexibilities under the PFS. Consistent with SAMHSA and DEA requirements at the time of CY 2023 PFS rulemaking, we also noted that this exemption applied exclusively to OTP patients treated with buprenorphine and did not apply to new patients treated with methadone. Notably, SAMHSA recently finalized and codified this flexibility at 42 CFR 8.12(f)(2)(v)(B),[364] so that OTPs may use audio-visual or audio-only platforms when evaluating patients who are being admitted for treatment at the OTP with schedule III medications (such as buprenorphine) on a permanent basis.

Furthermore, in their recent final rule published in the **Federal Register** in February of 2024 (89 FR 7528), SAMHSA made reforms to full examination requirements for initiation of treatment with methadone at § 8.12(f)(2)(v)(A). Specifically, SAMHSA now allows for audio-visual telehealth initiation for any new patient who will be treated by the OTP with methadone if a practitioner or primary care provider determines that an adequate evaluation of the patient can be accomplished via an audio-visual telehealth platform. When audio-visual technologies are not available or their use is not feasible for a patient, it is acceptable to use audio-only devices, but only when the patient is in the presence of a licensed practitioner who is registered to prescribe (including dispense) controlled medications. In finalizing this new flexibility, SAMHSA reasoned that ''evidence underlying the initiation of buprenorphine using telehealth also is applicable to the treatment of OUD with methadone, and warrants expanding access to methadone therapy by applying some of the buprenorphine in-person examination flexibilities to treatment with methadone in OTPs (89 FR 7533).'' [365] They also noted that video-based telehealth was overwhelmingly supported by commenters for medical intake, periodic medical assessments, and methadone or buprenorphine initiation by OTP practitioners. SAMHSA did not extend the flexibility to allow the use of audio-only telehealth platforms in assessing new patients who will be treated by the OTP with methadone due to safety concerns, as they stated ''methadone, in comparison to buprenorphine, holds a higher risk profile for sedation in patients presenting with mild somnolence which may be easier to identify through an audio-visual telehealth platform (89 FR 7533).'' [366]

These new flexibilities to allow new patients to initiate treatment with methadone via audio-visual telehealth is significant, as the majority of patients who are being treated at an OTP receive methadone.[367] Methadone is used to treat those with a confirmed diagnosis of OUD, and is a synthetic opioid agonist that eliminates withdrawal symptoms and relieves drug cravings by acting on opioid receptors in the brain.[368] Methadone has been associated with reducing the risk of drug overdose, opioid-related acute care, all-cause mortality, and opioid-related mortality.[369] It has also been shown to

[363] *https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)DEASAMHSA buprenorphinetelemedicine(Final)+Esign.pdf; https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/buprenorphine-at-opioid-treatment-programs.*

[364] 89 FR 7528, February 2, 2024 (*https://www.federalregister.gov/documents/2024/02/02/2024-01693/medications-for-the-treatment-of-opioid-use-disorder*).

[365] *Chan, B., Bougatsos, C., Priest, K.C., McCarty, D., Grusing, S., & Chou, R. (2022).* ''Opioid treatment programs, telemedicine and COVID–19: A scoping review.'' *Substance Abuse, 43(1), 539–546. https://doi.org/10.1080/08897077.2021.1967836.*

[366] *https://www.govinfo.gov/content/pkg/FR-2024-02-02/pdf/2024-01693.pdf.*

[367] American Association for the Treatment of Opioid Dependence, National Association of State Alcohol and Drug Abuse Directors, & Opioid Response Network. (2022). ''Technical Brief: Census of Opioid Treatment Programs.'' *https://nasadad.org/wp-content/uploads/2022/12/OTP-Patient-Census-Technical-Brief-Final-for-Release.pdf.*

[368] National Institute on Drug Abuse. (2021, December). ''How do medications to treat opioid use disorder work?'' *https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/how-do-medications-to-treat-opioid-addiction-work.*

[369] Wakeman, S.E., Larochelle, M.R., Ameli, O., Chaisson, C.E., McPheeters, J.T., Crown, W.H., Azocar, F., & Sanghavi, D.M. (2020). ''Comparative effectiveness of different treatment pathways for opioid use disorder.'' JAMA Network Open, 3(2), e1920622. *https://doi.org/10.1001/jamanetworkopen.2019.20622*; Sordo, L., Barrio, G., Bravo, M.J., Indave, B.I., Degenhardt, L., Wiessing, L., Ferri, M., & Pastor-Barriuso, R. (2017). ''Mortality risk during and after opioid substitution treatment: Systematic review and meta-analysis of

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retain patients in treatment, reduce consequences of injection drug use such as HIV/Hepatitis C transmission, and contribute to quality of life improvements for patients.[370] However, many barriers currently exist for patients seeking to receive methadone treatment. Currently, only SAMHSA-certified OTPs can dispense and administer methadone for the treatment of OUD as provided under section 303(g)(1) of the Controlled Substances Act (21 U.S.C. 823(g)(1)) and 42 CFR part 8. This often means that daily travel might be necessary if it is determined that the risks of giving take-home doses outweigh the benefits, unless patients are eligible to receive take-home doses after meeting certain conditions. Most adults in methadone treatment report at least one barrier to accessing treatment, including lack of reliable transportation, distance from home to treatment, and work schedule conflicts.[371] Frequent travel to an OTP also disproportionately impacts rural residents who already face lower odds of finding an OTP in their area, and therefore, must spend nearly 2–5 times the amount of average drive time to access the closest OTP compared to their urban counterparts.[372] Research has also shown that the number of missed doses of methadone increases for residents living longer distances from an OTP. Additionally, people living with disabilities are less likely to receive Medications for Opioid Use Disorder (MOUDs), and some data also shows that many SUD treatment programs are not physically accessible for these populations.[373] The existence of these physical barriers to accessing methadone and treatment at OTP facilities, especially among historically underserved populations, warrants additional considerations to the extent that telehealth flexibilities can mitigate these barriers to accessing care, as long as these flexibilities are medically appropriate and reasonable for the diagnosis and treatment of OUD.

To be consistent with SAMHSA's reforms to telehealth flexibilities for initiation of treatment with methadone at § 8.12(f)(2)(B)(v), past conforming regulations under the Medicare OTP benefit to allow telecommunication flexibilities for initiation of treatment with buprenorphine, and to contribute towards efforts to reduce barriers in accessing care for Medicare beneficiaries seeking treatment with methadone, we are proposing to make similar telecommunication flexibilities under the Medicare OTP benefit. Specifically, we are proposing to allow the OTP intake add-on code (HCPCS code G2076) to be furnished via two-way audio-video communications technology when billed for the initiation of treatment with methadone, to the extent that the use of audio-video telecommunications technology to initiate treatment with methadone is authorized by DEA and SAMHSA at the time the service is furnished. We note that under this proposal, the initiation of treatment with methadone using telecommunications technology would be considered an intake activity for purposes of paragraph (vi) of the definition of ''Opioid treatment services'' at § 410.67(b) only to the extent that the use of such telecommunications technology is permitted under the applicable DEA and SAMHSA regulations and guidance at the time the services are furnished. However, at this time, we are not proposing to extend the flexibility to allow the use of audio-only telecommunications for intake activities described in paragraph (vi) of the definition of ''Opioid treatment services'' at § 410.67(b) for initiation of treatment with methadone, as these flexibilities are not currently permitted by SAMHSA and the DEA. We recognize that methadone is characterized as a schedule II controlled substance, which means that it still has higher potential for misuse with potential physical dependence.[374] Unlike buprenorphine that is a schedule III controlled substance, methadone is a full agonist and does not have a ''ceiling effect,'' which provides more protective overdose factors when taking additional doses of the drug.[375] Thus, use of audio-visual telecommunications for initiation of treatment with methadone would balance potential safety concerns associated with methadone, such as its higher potential for misuse and risk for sedation in patients presenting with mild somnolence which may be easier to identify via a audio-visual telehealth platform, while still allowing patients the flexibility of initiating treatment via (audio-visual) telehealth at an OTP.

We believe that this proposal may meaningfully improve access to care, promote positive health outcomes, and advance health equity among Medicare beneficiaries. Data indicate that expanded use of telehealth and flexibilities for the provision of MOUD during the COVID–19 pandemic was associated with improved care retention and a reduction in medically treated overdoses among Medicare beneficiaries.[376] Similarly, telehealth initiation for buprenorphine to treat OUD was associated with improved treatment retention in a subset of U.S states.[377] Other research has not found

cohort studies.'' The BMJ, 357, j1550. *https://doi.org/10.1136/bmj.j1550*; Larochelle, M.R., Bernson, D., Land, T., Stopka, T.J., Wang, N., Xuan, Z., Bagley, S.M., Liebschutz, J.M., & Walley, A.Y. (2018). ''Medication for opioid use disorder after nonfatal opioid overdose and association with mortality: A cohort study.'' Annals of Internal Medicine, 169(3), 137. *https://doi.org/10.7326/M17-3107.*

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[371] Pasman, E., Kollin, R., Broman, M., Lee, G., Agius, E., Lister, J.J., Brown, S., & Resko, S. M. (2022). ''Cumulative barriers to retention in methadone treatment among adults from rural and small urban communities.'' Addiction Science & Clinical Practice, 17(1), 1–10. *https://doi.org/10.1186/s13722-022-00316-3.*

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[374] *https://www.dea.gov/drug-information/drug-scheduling.*

[375] Whelan, P.J., & Remski, K. (2012). ''Buprenorphine vs methadone treatment: A review of evidence in both developed and developing worlds.'' Journal of Neurosciences in Rural Practice, 3(1), 45–50. *https://doi.org/10.4103/0976-3147.91934.*

[376] Jones, C.M., Shoff, C., Hodges, K., Blanco, C., Losby, J.L., Ling, S.M., & Compton, W.M. (2022). ''Receipt of telehealth services, receipt and retention of medications for opioid use disorder, and medically treated overdose among Medicare beneficiaries before and during the covid–19 pandemic.'' JAMA Psychiatry, 79(10), 981–992. *https://doi.org/10.1001/jamapsychiatry.2022.2284.*

[377] Hammerslag, L.R., Mack, A., Chandler, R.K., Fanucchi, L.C., Feaster, D.J., LaRochelle, M.R., Lofwall, M.R., Nau, M., Villani, J., Walsh, S.L., Westgate, P.M., Slavova, S., & Talbert, J.C. (2023).

significant differences in clinical severity and complexity markers (for example, OUD-related emergency department visits) between patients receiving telemedicine inductions into treatment versus in-person examinations,[378] suggesting that quality of care can be maintained through initiation of treatments via telehealth. Thus, many of these benefits associated with telehealth flexibilities for initiating treatment with other MOUDs can be potentially replicated by allowing initiation of treatment with methadone via audio-visual telecommunications. Additionally, we believe this proposal would meaningfully impact health equity. Individuals from Black, American Indian and Alaska Native, and Hispanic populations are significantly less likely to initiate treatment for a SUD, as well as individuals from economically disadvantaged communities.[379] Despite these disparities, during the COVID–19 pandemic, the odds of initiating treatment for a SUD increased for most age, race, ethnicity, and socioeconomic status subgroups, which may have been explained by increases in treatment initiation occurring through telehealth.[380] Thus, promoting flexibilities for telecommunication modalities of treatment initiation in regards to methadone may provide additional options for accessing treatment, especially for populations who often experience barriers in beginning treatment. Lastly, we believe this proposal is in alignment with the HHS Overdose Prevention Strategy, which aims to broaden access to evidence-based care that increases willingness to engage and remain in treatment.[381] Similarly, this proposal would further the goals of the National Drug Control Strategy, which strives to expand policies that improve SUD treatment engagement by lowering various barriers to enter and participate in treatment, such as through telemedicine treatment initiation.[382]

Accordingly, we are proposing to revise the regulations for intake activities at paragraph (vi) within the definition of ''opioid use disorder treatment service'' at § 410.67(b). We are proposing to add a new paragraph (vi)(A) within the description of intake activities to separately list flexibilities for intake activities furnished via communications technology, and we are proposing to add and reserve a new paragraph (vi)(B). We are proposing to move the language related to the existing flexibilities for the initiation of treatment with buprenorphine to paragraph (vi)(A)(*1*). Additionally, in the definition of ''opioid use disorder treatment service'' at § 410.67(b), we are proposing to codify telecommunications flexibilities for initiation of treatment with methadone at paragraph (vi)(A)(*2*). Specifically, we propose that services to initiate treatment with methadone may be furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements, if an OTP determines that an adequate evaluation of the patient can be accomplished through audio-video communication technology. We look forward to comments related to this proposal.

3. Proposals Related to Reforms to 42 CFR Part 8

In the CY 2020 PFS final rule, we implemented payment and coverage for opioid use disorder treatment services, including services such as substance use counseling by a professional to the extent authorized under State law to furnish such services, individual and group therapy with a physician, psychologist (or other mental health professional to the extent authorized under State law), and other items and services that the Secretary determines are appropriate (but in no event to include meals or transportation), as authorized by section 1861 of the Act (84 FR 62630 through 62677 and 84 FR 62919 through 62926). Consequently, we included these services within the definition of OUD treatment services at § 410.67(b) and incorporated payment for these services as part of the non-drug component at § 410.67(d)(2)(ii). We also created an add-on code described by HCPCS code G2080 to reflect an additional 30 minutes of counseling or individual or group therapy provided in a week. We further finalized additional adjustments to the bundled payment for an episode of care, such as intake activities and periodic assessments. At the time, we noted that both initial and periodic assessments are required under SAMHSA regulations, and that they were integral services for the establishment and maintenance of OUD treatment for a beneficiary at an OTP (84 FR 62634). We codified definitions of these services within the definition of *OUD treatment services* at § 410.67(b); at paragraph (vi), we stated that intake activities include initial medical examination services required under 42 CFR 8.12(f)(2) and initial assessment services required under § 8.12(f)(4); at paragraph (vii) we stated that periodic assessment services include those required under § 8.12(f)(4). Services under § 8.12(f) are required services as part of Federal opioid treatment standards for OTPs, as regulated by SAMHSA. Accordingly, we created HCPCS code G2076 [*Intake activities, including initial medical examination that is a complete, fully documented physical evaluation and initial assessment conducted by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician or qualified personnel that includes preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psycho-social, economic, legal, or other supportive services that a patient needs, conducted by qualified personnel (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure*], and code G2077 [*Periodic assessment; assessing periodically by qualified personnel to determine the most appropriate combination of services and treatment (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure*] in order to have a mechanism to make payment under Medicare to OTPs for these required services. In the CY 2021 and CY 2022 PFS final rules (85 FR 84682 through 84690; 86 FR 65338 through 65341), we also established payment for take-home supplies of naloxone and overdose education furnished in conjunction with

''Telemedicine buprenorphine initiation and retention in opioid use disorder treatment for Medicaid enrollees.'' JAMA Network Open, 6(10), e2336914. *https://doi.org/10.1001/jamanetworkopen.2023.36914.*

[378] Barsky, B.A., Busch, A.B., Patel, S.Y., Mehrotra, A., & Huskamp, H.A. (2022). ''Use of telemedicine for buprenorphine inductions in patients with commercial insurance or Medicare advantage.'' JAMA Network Open, 5(1), e2142531. *https://doi.org/10.1001/jamanetworkopen.2021.42531.*

[379] Acevedo, A., Panas, L., Garnick, D., Acevedo-Garcia, D., Miles, J., Ritter, G., & Campbell, K. (2018). ''Disparities in the treatment of substance use disorders: Does where you live matter?''. The Journal of Behavioral Health Services & Research, 45(4), 533–549. *https://doi.org/10.1007/s11414-018-9586-y.*

[380] Palzes, V.A., Chi, F.W., Metz, V.E., Sterling, S., Asyyed, A., Ridout, K.K., & Campbell, C.I. (2023). ''Overall and telehealth addiction treatment utilization by age, race, ethnicity, and socioeconomic status in California after covid–19 policy changes.'' JAMA Health Forum, 4(5), e231018. *https://doi.org/10.1001/jamahealthforum.2023.1018.*

[381] *https://www.hhs.gov/overdose-prevention/.*

[382] *https://www.whitehouse.gov/wp-content/uploads/2022/04/National-Drug-Control-2022Strategy.pdf.*

providing an opioid antagonist medication.

Additionally, in the CY 2020 PFS final rule, we codified requirements specified in the section 1861(jjj)(2) of the Act for OTPs. Specifically, we defined an ''opioid treatment program'' at § 410.67(b) as an entity that is an OTP as defined in § 8.2 (or any successor regulation) that meets the applicable requirements for an OTP. For an OTP to participate and receive payment under the Medicare program, the OTP must be enrolled in Medicare under section 1866(j) of the Act, have in effect a certification by SAMHSA for such a program, and be accredited by an accrediting body approved by SAMHSA. Lastly, an OTP must meet additional conditions as the Secretary may find necessary to ensure the health and safety of individuals being furnished services under such program and the effective and efficient furnishing of such services.

Recently, SAMHSA issued a new final rule (89 FR 7528), which made major reforms to 42 CFR part 8, governing requirements for OTPs in providing medications for the treatment of OUD and many other services. The rule provides significant refinements, as 42 CFR part 8 was published over 21 years ago, by reflecting new paradigms of care for OUD that have become increasingly patient-centered and evidence-based. The regulatory reforms for opioid treatment standards reflect an understanding that OUD is a chronic condition, and to be successful, treatment interventions should be individualized and include harm reduction and recovery support services, among other services.[383] Consequently, SAMHSA redefined comprehensive treatment at § 8.2 to specify that treatment at OTPs includes ''the continued use of MOUD provided in conjunction with an individualized range of appropriate harm reduction, medical, behavioral health, and recovery support services.'' At the same time, SAMHSA constructed a new definition of harm reduction services at § 8.2. In particular, harm reduction ''refers to practical, evidence-based strategies, including: overdose education; testing and intervention for infectious diseases including counseling and risk mitigation activities forming part of a comprehensive, integrated approach to address human immunodeficiency virus (HIV), viral hepatitis, sexually transmitted infections, and bacterial and fungal infections; distribution of opioid overdose reversal medications; linkage to other public health services; and connecting those who have expressed interest in additional support to peer services.'' Harm reduction approaches are especially important to reduce certain health and safety issues associated with drug use through care that is intended to be free of stigma and centered on the needs of people who use drugs. Decades of research have shown that harm reduction strategies provide significant benefits in preventing drug overdose deaths and transmission of infectious diseases among those who use drugs, educate individuals and community members about reducing the negative consequences associated with drug use, and link individuals to SUD treatment and other recovery resources.[384] Harm reduction is also a crucial component of the HHS Overdose Prevention Strategy, which aims to promote evidence-based harm reduction services, including those that are integrated within healthcare delivery, and to expand sustainable funding strategies for harm reduction services.[385] Besides defining harm reduction, SAMHSA also finalized a new definition for ''recovery support services'' at § 8.2. Specifically, recovery is the process of change through which people improve their health and wellness, live self-directed lives, and strive to reach their full potential. Recovery support services can include, but are not limited to, community-based recovery housing, peer recovery support services, social support, linkage to and coordination among allied service providers and a full range of human services that facilitate recovery and wellness contributing to an improved quality of life. The services extend the continuum of care by strengthening and complementing substance use disorder (SUD) treatment interventions in different settings and stages. Recovery support services are a vital part SUD treatment, as they take into account the relapsing and chronic nature of a SUD, and emphasize the need for continuous care to keep individuals engaged in treatment, especially along different stages of recovery.[386] Recovery support services are also a component of the HHS Overdose Prevention Strategy, which recognizes that treatment alone may not be enough to support long-term recovery, and that enabling access to quality integrated and coordinated recovery support services is important to prevent drug overdoses.[387]

Furthermore, SAMHSA made updates to existing definitions that include some of the services currently covered under the Medicare OTP benefit. For example, a psychoeducational service element was added to the definition of counseling services at § 8.12(f)(5), so that both counseling and psychoeducational services would also include harm reduction education and recovery-oriented counseling. New guidelines on counseling related to preventing exposure to and transmission of various infectious diseases were also added. As part of these services, at § 8.12(f)(5)(iii), OTPs also must continue to provide directly, or through referral to adequate and reasonably accessible community resources, vocational training, education, and employment services for patients who request such services or for whom these needs have been identified and mutually agreed-upon as beneficial by the patient and program staff. Notably, SAMHSA also made updates to their descriptions of initial and periodic assessment activities at § 8.12(f)(4), which initially informed the definitions of intake activities and periodic assessments in the definition of ''OUD treatment services'' at § 410.67(b) and the creation of codes describing these services (HCPCS codes G2076 and G2077) when CMS first implemented the Medicare OTP benefit in the CY 2020 PFS final rule. When introducing these changes in their proposed rule in December 2022 (87 FR 77330), SAMHSA noted that ''changes to the initial and periodic medical services sections are intended to promote key issues for OTP medical practitioners and the OTP multi-disciplinary team to address with a patient as part of treatment. This includes areas that may increase the risk of a patient leaving care prematurely, such as unmet mental health or other disability, medical and oral health needs, the need for culturally supportive care that addresses race, ethnicity, sexual orientation, religion or gender identity, and social determinants of health, such as housing and transportation, that may pose barriers to treatment engagement, or harm reduction and recovery support service needs.'' New changes to the

[383] 89 FR 7528, February 2, 2024 (*https://www.federalregister.gov/documents/2024/02/02/2024–01693/medications-for-the-treatment-of-opioid-use-disorder*).

[384] *https://www.cdc.gov/overdose-prevention/php/od2a/harm-reduction.html. https://nida.nih.gov/research-topics/harm-reduction.*

[385] *https://www.hhs.gov/overdose-prevention/harm-reduction.*

[386] Stanojlović, M., & Davidson, L. (2021). ''Targeting the barriers in the substance use disorder continuum of care with peer recovery support.'' Substance Abuse: Research and Treatment, 15, 117822182097698. *https://doi.org/10.1177/1178221820976988*; *https://www.samhsa.gov/find-help/recovery.*

[387] *https://www.hhs.gov/overdose-prevention/recovery-support.*

definition of initial assessments now include patient-centered language regarding the need for care plans to include the patient's goals and mutually agreed-upon actions for the patient to meet those goals, and new references are added for harm reduction interventions and recovery support services to be included as components of care plans if a patient needs and wishes to pursue these services. For example, patient-centered care plans developed during initial assessments may reflect a ''patient's goals and mutually agreed-upon actions for the patient to meet those goals, including harm reduction interventions; the patient's needs and goals in the areas of education, vocational training, and employment; and the medical and psychiatric, psychosocial, economic, legal, housing, and other recovery support services that a patient needs and wishes to pursue (89 FR 73558).'' Lastly, regarding periodic assessment services at § 8.12(f)(4)(ii), SAMHSA requires that these examinations should occur not less than one time each year and be conducted by an OTP practitioner. The periodic physical examination should include review of MOUD dosing, treatment response, other SUD treatment needs, responses and patient-identified goals, and other relevant physical and psychiatric treatment needs and goals. The periodic physical examination should be documented in the patient's clinical record. In whole, these regulatory changes largely reflect significant changes in evidence-based practice and towards patient-centered care in the treatment of OUD that have occurred in the past couple of decades, including considerations of the need to address unmet health related social needs (HRSN) that impose barriers on a patient's ability to initiate, engage, and remain in treatment, including in areas of education, employment, and housing as well as in harm reduction strategies that decrease the negative consequences associated with a patient's use or abuse of opioids, and recovery support services that address the chronic nature of OUD and the need for supports across the full continuum of care.

In addition to these reforms to opioid treatment standards at 42 CFR part 8, there have been recent activities under the PFS, and through other CMS programs, that have addressed the social determinants of health (SDOH), which often affect the diagnosis and treatment of a patient's medical problem. Healthy People 2030, which is a 10-year HHS initiative to identify public health priorities that help individuals, organizations, and communities across the U.S improve health and well-being,[388] defines the SDOH, as the ''conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.'' [389] SDOH include many domains that largely impact health, including economic stability, education, healthcare, the neighborhood and built environment, and social and community context. Some studies have estimated that SDOH can affect as much as 50 percent of the variation in health outcomes compared to clinical care impacting only 20 percent.[390] For example, individuals with a higher income have been found to exhibit lower mortality, higher life expectancy, and slower declines in physical mobility; individuals who lack insurance are less likely to obtain necessary medical care and prescription medications; and, food insecurity is associated with higher rates of birth defects, cognitive problems, hospitalization rates, asthma, and behavioral health problems.[391] Moreover, SDOH act as structural and contextual factors that shape the conditions impacting health, and their unequal distribution impacts the development of HRSNs at the individual level, which refer to an individual's needs that might include housing, healthy foods, transportation, financial assistance, etc. An inability to address these HRSNs put individuals at a higher risk for exacerbating health conditions, and it is a major driver of health inequities.[392] Health equity is the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes, which is complicated by SDOH such as poverty, unequal access to healthcare, lack of education or employment, stigma, and discrimination.[393] Therefore, in light of decades of research showing that these upstream factors drive health outcomes, and evidence suggesting interventions in healthcare settings that address social needs can improve the treatment of an individual's condition, CMS recently finalized coding and payment for SDOH risk assessments in the CY 2024 PFS final rule (88 FR 78932). HCPCS code G0136 describes SDOH risk assessments (*Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5–15 minutes, not more often than every 6 months*) that may be billed when practitioners spend time and resources assessing HRSNs that interfere with the practitioner's ability to diagnose or treat the patient. These assessments, which may also be provided during a behavioral health visit, are often administered as part of an assessment of patient histories, risk, and in informing medical decision-making around the care and treatment of the disease or illness. They are often accomplished through the use of a standardized evidence-based tool that include the domains of food insecurity, housing insecurity, transportation needs, and utility difficulties. Besides establishing standalone payment for SDOH risk assessments, in the CY 2024 PFS final rule, CMS also created coding and payment for community health integration (CHI) (HCPCS codes G0019 & G0022) and principal illness navigation services (PIN) (HCPCS codes G0023, G0024, G0140, and G0146). Both CHI and PIN services involve a person-centered assessment to better understand the patient's life story, care coordination, contextualizing health education, building patient self-advocacy skills, health system navigation, facilitating behavioral change, providing social and emotional support, and facilitating access to community-based social services (for

[388] *https://health.gov/healthypeople/about#:~:text=What%20is%20Healthy%20People%20202030,over%20the%20first%204%decades.*

[389] *https://health.gov/healthypeople/priority-areas/social-determinants-health.*

[390] Whitman, A., Chapell, A., Aysola, V., Zuckerman, R., & Sommers, B. (2022). ''Addressing Social Determinants of Health: Examples of Successful Evidence-Based Strategies and Current Federal Efforts'' (ASPE, Office of Health Policy HP–2022–12). *https://aspe.hhs.gov/sites/default/files/documents/e2b650cd64cf84aae8ff0fae7474af82/SDOH-Evidence-Review.pdf*; Hood, C. M., Gennuso, K. P., Swain, G. R., & Catlin, B. B. (2016). ''County health rankings: Relationships between determinant factors and health outcomes.'' American Journal of Preventive Medicine, 50(2), 129–135. *https://doi.org/10.1016/j.amepre.2015.08.024.*

[391] National Academies of Sciences, E., Medicine, N. A. of, Nursing 2020–2030, C. on the F. of, Flaubert, J. L., Menestrel, S. L., Williams, D. R., & Wakefield, M. K. (2021). ''Social determinants of health and health equity. In The Future of Nursing 2020–2030: Charting a Path to Achieve Health Equity.'' National Academies Press (U.S.). *https://www.ncbi.nlm.nih.gov/books/NBK573923/.*

[392] Whitman, A., Chapell, A., Aysola, V., Zuckerman, R., & Sommers, B. (2022). ''Addressing Social Determinants of Health: Examples of Successful Evidence-Based Strategies and Current Federal Efforts'' (ASPE, Office of Health Policy HP–2022–12). *https://aspe.hhs.gov/sites/default/files/documents/e2b650cd64cf84aae8ff0fae7474af82/SDOH-Evidence-Review.pdf.*; *https://www.whitehouse.gov/wp-content/uploads/2023/11/SDOH-Playbook-3.pdf.*

[393] *https://www.cms.gov/pillar/health-equity.*

example, housing, utilities, transportation, food assistance) to address unmet SDOH needs. The services described by the CHI codes address unmet SDOH needs that affect the diagnosis and treatment of the patient's medical problems. PIN services focus on Medicare beneficiaries diagnosed with high-risk conditions (for example, dementia, HIV/AIDS, and cancer) in order to identify and connect them with appropriate clinical and support resources.

Moreover, many of these aforementioned services, including harm reduction interventions, recovery support services, addressing HRSN, and facilitating access to community-based social services to address these needs, ordinarily occur in OTP settings. In 2022, approximately 92 percent of OTP facilities offered various recovery support services, including peer support (59.6 percent), assistance locating housing for clients (75.0 percent), employment counseling (49.5 percent), and assistance helping patients obtain social services (81.2 percent). The majority of OTPs also offered various types of harm reduction services, including testing for various types of infectious diseases (>55 percent), health education (>77%), and naloxone and overdose education (92.3 percent). Many OTPs also conduct community outreach services to those in need of OUD treatment (76.1 percent) and case management services (87.8 percent).[394] Additionally, as part of initial and periodic assessment services at § 8.12(f)(4), OTPs must designate in the care plan a patient's needs and goals in the areas of harm reduction interventions, education, vocational training, and employment, along with the medical and psychiatric, psychosocial, economic, legal, housing, and other recovery support services that a patient needs and wishes to pursue, which all reflect consideration to various health-related social needs. The new definitions of harm reduction and recovery support services at § 8.2 are also inclusive of activities that involve linkage to and coordination with providers that address a full range of human and public health services to facilitate recovery and wellness for a SUD. Lastly, in the CY 2020 PFS final rule we responded to public comments pertaining to the above-mentioned activities. Specifically, several commenters stated that OTPs often provide case management and/or care management services and requested that CMS consider reimbursing for these services either as part of the standard bundle or as an adjustment to the bundled payment, as applicable. A few commenters stated that OTPs serve as a fixed point of responsibility in the provision of whole person-centered care and improving health outcomes through collaborative arrangements with health care providers outside of the OTP and that the goal of care management is to reduce health care costs, specifically preventable hospital admissions, readmissions, and avoidable emergency room visits. The commenters also stated in the CY 2020 final rule that OTP staff also help patients with accessing food benefits, housing, and employment searches, which are critical components for sustained recovery, as part of the goal of complete case management (84 FR 62648). At the time, CMS stated that we would consider making payment for these type of care management activities for future rulemaking, including activities whereby OTPs collaborate with providers outside the OTPs to help patients access social services. We believed it was appropriate to work with OTPs to better understand how these services are furnished in an OTP setting, as well as to continue to look at data on specific items and services that may fit within the scope of OUD treatment services.

a. Proposal To Establish Payment for Social Determinants of Health Risk Assessments

The recent refinements to initial assessments under § 8.12(f)(4)(i) likely necessitate additional resource costs for OTPs in order to comply with the opioid treatment standards for assessing various SDOHs (for example, education, vocational training, employment, economic, legal, housing, etc.) that impact a patient's HRSNs, and to identify a patient's goals for harm reduction interventions and needs for recovery support services as they relate to the treatment of an OUD. We recognize that the paradigm for OUD treatment and care has evolved rapidly since the implementation of the Medicare OTP benefit in CY 2020, and that providers have increasingly incorporated interventions to address HRSNs that increase the risk of a patient leaving OUD treatment prematurely or that pose barriers to treatment engagement. We additionally acknowledge that coding already exists under the PFS that accounts for the resources involved in conducting these types of assessments. For these reasons, we are proposing to establish payment for SDOH risk assessments as part of intake activities within OUD treatment services, as long as these assessments are medically reasonable and necessary for the diagnosis or treatment of an OUD, and OTPs have a reason to believe unmet HRSNs or the need for harm reduction intervention or recovery support services identified during such an assessment could interfere with the OTP's ability to diagnose or treat the patient's OUD. As previously stated, the SDOH include broad structural and contextual domains that may impact health (for example, economic stability, education, healthcare, neighborhood and built environment, and social and community context) and the development of HRSNs at the individual-level (for example, housing and utilities assistance, transportation assistance, financial assistance, healthy foods, personal safety, employment, recovery support and harm reduction services). We understand that there are multiple standardized, evidence-based SDOH risk-assessment tools utilized across the healthcare system that are structured to assess a patient across various SDOH domains.[395] If an OTP furnishes SDOH risk assessments as part of initial assessments under § 8.12(f)(4)(i), we would expect that the assessment tools used would allow the OTP to identify more specific individual-level HRSNs as part of the care plan, including giving consideration to potential harm reduction and recovery support services needs.

Specifically, we are proposing to update the payment rate for intake activities described by HCPCS code G2076 by adding in the value of the non-facility rate for SDOH risk assessments described by HCPCS code (G0136). We believe HCPCS code G0136 may serve as a reasonable proxy to reflect the value and resources required for the type of assessment service activities that OTPs are required to provide according to SAMHSA requirements under § 8.12(f)(4)(i), including an assessment to identify a patient's unmet HRSNs or the need for harm reduction intervention and recovery support services that are critical to the treatment of an OUD. We understand that OTPs have been involved in collaborative agreements with organizations who address HRSN sand offer various recovery support services (84 FR 62648), and we believe that for OTPs to appropriately identify

[394] Table SU17b: Substance use treatment facilities, by services provided and facility type: Number and column percent, 2022: *https://www.samhsa.gov/data/sites/default/files/reports/rpt42714/NSUMHSS-Annual-Detailed-Tables-22.pdf.*

[395] *https://prapare.org/wp-content/uploads/2021/10/What-is-PRAPARE_2.1.21-1.pdf; https://www.cms.gov/priorities/innovation/media/document/ahcm-screeningtool-companion.*

these types of organizations that target a specific need, identifying these HRSNs as part of SDOH risk assessments is likely needed prior to engaging in activities to coordinate service delivery. However, we seek comment on whether these types of SDOH assessments ordinarily complement the type of community coordination activities that OTPs perform.

Establishing payment to account for SDOH risk assessments as part of intake activities under the OTP benefit is important, as unmet HRSNs identified as part of such assessments significantly impact outcomes for OUD treatment. Evidence shows that healthcare providers who screen for SDOH in their settings have found that patients who screen positive for a HRSN were significantly more likely to have a history of substance use or mental illness compared to patients who did not have an HRSN.[396] For example, one review found that between 50 to 90 percent of patients in publicly funded OTPs were unemployed, and that older adults identified to have misused opioids were 22-percent less likely to be employed.[397] Patients with an OUD are also more likely to have a lower educational attainment, encounter financial hardship, and housing instability.[398] Even more, food insecurity has been indicated to be a strong predictor of prescription opioid misuse and abuse.[399] The SDOH and their contribution to unmet HRSNs have also heavily impacted the rates of drug overdoses. For example, one study examined 28 different SDOH measures that collectively explained 89-percent of the variance in drug-overdose mortality across states.[400] Housing insecurity, in particular, negatively affects the population with an OUD, as this risk factor has been increasing over time among those seeking treatment with an OUD.[401] One analysis conducted by the State of Massachusetts has revealed alarming evidence that the risk of death from an opioid overdose is 30-times higher for those who have experienced homelessness.[402] Lower median household income and unemployment have also been associated with an increase in opioid death rates.[403] Moreover, unmet HRSNs have also hampered access to treatment among Medicare beneficiaries with a SUD, as evidence has shown that among Medicare beneficiaries with an SUD who were not receiving treatment, one-third reported financial barriers and one-fifth reported logistical barriers such as lack of access to transportation as rationales for not receiving treatment.[404] Lastly, many of these SDOH factors have impaired treatment retention and completion rates. Those with lower levels of educational attainment and who are unemployed are less likely to complete SUD treatment, and individuals who are experiencing homelessness are significantly less likely to remain in treatment.[405] Therefore, screening for the SDOH and identifying these unmet HRSNs as part of intake assessments may help OTPs link patients with an identified social need to appropriate resources that can impact the diagnosis of an OUD or address barriers to treating an OUD.

As previously stated above, we are proposing to update the adjustment to the bundled payment for an episode of care for intake activities (G2076) by adding in the value of the non-facility rate for SDOH risk assessments (G0136: *Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5–15 minutes, not more often than every 6 months*), which is currently assigned a non-facility rate of $18.66 under the PFS. Currently, the CY 2024 payment rate for the intake add-on code (G0276) is $201.73 and adding the value of a crosswalk to the CY 2024 non-facility rate of $18.66 would result in a payment rate of approximately $220.39. We believe that incorporating the value of G0136 into the intake activities adjustment would be the most appropriate, as we believe assessment activities related to SDOH are more likely to occur during intake assessments when a new patient is admitted to an OTP. SAMHSA treatment guidelines recommend that during initial screenings, OTPs should identify barriers and medical and psychosocial risk-factors that may hinder a patient's ability to meet treatment requirements, including co-occurring health conditions, and vocational, legal, financial, transportation, and family concerns.[406] We note that intake activities (G2076) should only be billed for new patients (that is, patients starting treatment at the OTP), and since SDOH risk assessments would be bundled into the code describing intake activities, this billing requirement would similarly apply. However, we seek comment on the frequency with which these SDOH risk assessments occur, and whether it would be more appropriate if these assessments occur when OTPs furnish

[396] Chukmaitov, A., Dahman, B., Garland, S.L., Dow, A., Parsons, P.L., Harris, K.A., & Sheppard, V.B. (2022). ''Addressing social risk factors in the inpatient setting: Initial findings from a screening and referral pilot at an urban safety-net academic medical center in Virginia, USA.'' Preventive Medicine Reports, 29, 101935. *https://doi.org/10.1016/j.pmedr.2022.101935.*

[397] Zanis, D.A., & Coviello, D. (2001). ''A case study of employment case management with chronically unemployed methadone maintained clients.'' Journal of Psychoactive Drugs, 33(1), 67–73. *https://doi.org/10.1080/02791072.2001.10400470*; Albright, D.L., Johnson, K., Laha-Walsh, K., McDaniel, J., & McIntosh, S. (2021). ''Social determinants of opioid use among patients in rural primary care settings.'' Social Work in Public Health, 36(6), 723–731. *https://doi.org/10.1080/19371918.2021.1939831.*

[398] Albright, D.L., Johnson, K., Laha-Walsh, K., McDaniel, J., & McIntosh, S. (2021). ''Social determinants of opioid use among patients in rural primary care settings.'' Social Work in Public Health, 36(6), 723–731. *https://doi.org/10.1080/19371918.2021.1939831*; Arsene, C., Na, L., Patel, P., Vaidya, V., Williamson, A.A., & Singh, S. (2023). ''The importance of social risk factors for patients diagnosed with opioid use disorder.'' Journal of the American Pharmacists Association, 63(3), 925–932. *https://doi.org/10.1016/j.japh.2023.02.016.*

[399] Men, F., Fischer, B., Urquia, M.L., & Tarasuk, V. (2021). ''Food insecurity, chronic pain, and use of prescription opioids.'' SSM—Population Health, 14, 100768. *https://doi.org/10.1016/j.ssmph.2021.100768.*

[400] Cesare, N., Lines, L.M., Chandler, R., Gibson, E.B., Vickers-Smith, R., Jackson, R., Bazzi, A.R., Goddard-Eckrich, D., Sabounchi, N., Chisolm, D.J., Vandergrift, N., & Oga, E. (2024). ''Development and validation of a community-level social determinants of health index for drug overdose deaths in the HEALing Communities Study.'' Journal of Substance Use and Addiction Treatment, 157, 209186. *https://doi.org/10.1016/j.josat.2023.209186.*

[401] Sulley, S., & Ndanga, M. (n.d.). ''Inpatient opioid use disorder and social determinants of health: A nationwide analysis of the national inpatient sample (2012–2014 and 2016–2017).'' Cureus, 12(11), e11311. *https://doi.org/10.7759/cureus.11311.*

[402] *https://www.mass.gov/files/documents/2017/08/31/legislative-report-chapter-55-aug-2017.pdf.*

[403] Rangachari, P., Govindarajan, A., Mehta, R., Seehusen, D., & Rethemeyer, R.K. (2022). ''The relationship between Social Determinants of Health (Sdoh) and death from cardiovascular disease or opioid use in counties across the United States (2009–2018).'' BMC Public Health, 22(1), 236. *https://doi.org/10.1186/s12889–022–12653–8* Hollingsworth, A., Ruhm, C.J., & Simon, K. (2017). Macroeconomic conditions and opioid abuse (Working Paper 23192). National Bureau of Economic Research. *https://doi.org/10.3386/w23192.*

[404] Parish, W. J., Mark, T.L., Weber, E.M., & Steinberg, D.G. (2022). ''Substance use disorders among Medicare beneficiaries: Prevalence, mental and physical comorbidities, and treatment barriers.'' American Journal of Preventive Medicine, 63(2), 225–232. *https://doi.org/10.1016/j.amepre.2022.01.021.*

[405] Mennis, J., & Stahler, G. J. (2016). Racial and ethnic disparities in outpatient substance use disorder treatment episode completion for different substances. Journal of Substance Abuse Treatment, 63, 25–33. *https://doi.org/10.1016/j.jsat.2015.12.007*; Gaeta Gazzola, M., Carmichael, I.D., Christian, N.J., Zheng, X., Madden, L.M., & Barry, D. T. (2023). ''A national study of homelessness, social determinants of health, and treatment engagement among outpatient medication for opioid use disorder-seeking individuals in the United States.'' Substance Abuse, 44(1–2), 62–72. *https://doi.org/10.1177/0889707723116729.*

[406] SAMHSA. (2012). Medication-assisted treatment for opioid addiction in opioid treatment programs. *https://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/Bookshelf_NBK64164.pdf.*

periodic assessments described by HCPCS code G2077.

When OTPs bill the intake add-on code (G2076), we are not proposing to require that OTPs performed SDOH risk assessments in a specific manner, but rather that OTPs continued to perform initial assessment services consistent with SAMHSA certification requirements at § 8.12(f)(4)(i) that already largely reflect these type of SDOH risk assessment activities; and, that OTPs abided by other applicable requirements under the Medicare OTP benefit at § 410.67, including those listed in the definition of intake activities at paragraph (vi) within the definition of ''OUD treatment service'' at § 410.67(b). This also means that for the purposes of Medicare payment, if SDOH risk assessments are furnished, they must be related to the diagnosis or treatment of OUD, and any HRSNs identified through SDOH risk assessments performed should be documented in the patient's medical record to indicate how assessing and addressing the HRSN relates to the treatment and diagnosis of an OUD. We reiterate that our proposal to incorporate the value of HCPCS code G0136 into the OTP intake add-on code (G2076) is meant to serve as a reasonable proxy to reflect the value and resources of the type of initial assessment service activities that OTPs are required to provide under SAMHSA requirements, which now include more specific updates to a patient's care plan with considerations of a patient's goals related to harm reduction interventions, needs for recovery support services, and other HRSNs. However, if OTPs utilize SDOH risk assessments during intake activities, CMS is not proposing to require OTPs to utilize a specific type of SDOH risk assessment tool, consistent with similar existing requirements under the PFS for these services. If OTPs do furnish these assessment services, CMS encourages OTPs to adopt evidence-based, validated tools that are already available (such as the CMS Accountable Health Communities tool, the Protocol for Responding to and Assessing Patients Assets, Risks and Experiences (PRAPARE), and instruments identified for Medicare Advantage Special Needs Population Health Risk Assessment);[407] that include the domains of food insecurity, housing insecurity, transportation needs, and utility difficulties, and that can be furnished in a manner appropriate for the patient's educational, developmental, and health literacy level, and that are culturally and linguistically appropriate. We understand that there is not a national consensus around one specific tool, and OTPs should choose the tool that fits their needs and allows them to appropriately detect unmet HRSNs, as well as other needs for harm reduction interventions and recovery support services that are integral to the treatment of an OUD.

Lastly, in light of these proposed changes, we are proposing to revise the current descriptor for the intake add-on code for consistency with revisions to § 8.12(f)(4)(i) and to reflect furnishing an SDOH risk assessment: G2076 (*Intake activities, including initial medical examination that is a complete, fully documented physical evaluation and initial assessment conducted by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician or qualified personnel that includes preparation of a care plan, which may be informed by administration of a standardized, evidence-based Social Determinants of Health Risk Assessment to identify unmet health-related social needs, and that includes the patient's goals and mutually agreed-upon actions for the patient to meet those goals, including harm reduction interventions; the patient's needs and goals in the areas of education, vocational training, and employment; and the medical and psychiatric, psychosocial, economic, legal, housing, and other recovery support services that a patient needs and wishes to pursue, conducted by qualified personnel (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure*). We welcome public comments related to this proposal.

b. Request for Information on Payment for Coordinated Care and Referrals to Community-Based Organizations That Address Unmet Health-Related Social Needs, Provide Harm Reduction Services, and/or Provide Recovery Support Services

In the discussion above, we noted that SAMHSA's recent reforms to 42 CFR part 8 finalized new definitions for harm reduction and recovery support services, which are included as components of the type of services that OTPs may provide. Some examples of harm reduction strategies include overdose education, distribution of opioid overdose reversal medications, and linkage to other public health services. Recovery support services can include, but are not limited to, community-based recovery housing, social support, and linkage to and coordination among allied service providers and a full range of human services that facilitate recovery and wellness. Under the Medicare OTP benefit, we have already established payment for some of these services, including take-home supplies of opioid antagonist medications for emergency treatment of known or suspected opioid overdose (for example, naloxone), overdose education furnished in conjunction with opioid antagonist medications, and social support via group therapy. However, we do not currently have specific coding for activities that OTPs may conduct to coordinate care and make referrals or ''link'' to community-based organizations (CBOs) that help facilitate a patient's needs and goals related to harm reduction and recovery support services, as well as to address unmet HRSNs. We understand that a referral is an important aspect of following up on unmet HRSNs identified during an initial assessment service and/or SDOH risk assessment so that a patient can be connected to resources or services that may help address their unmet HRSN that interferes with treatment of their OUD. Additionally, we have received previous comments that OTPs often have collaborative agreements with providers outside of the OTP. For these reasons, we are seeking comment to understand how OTPs are currently coordinating care and making referrals to CBOs that address unmet HRSNs, provide harm reduction services, and/or provide recovery support services.

Some evidence has indicated that providers who coordinate care with CBOs to address HRSNs (for example, housing, transportation, care management, etc.) can positively influence health outcomes,[408] and that SUD treatment facilities establishing relationships with community-based peer support services, educational and employment agencies, housing agencies, and other organizations have been able to better support a patient's engagement in SUD treatment.[409] Additionally, harm

[407] *https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.*; *https://www.nachc.org/research-and-data/prapare/*; CMS–10825.

[408] McCarthy, D., Lewis, C., Horstman, C., Bryan, A., & Shah, T. (2022). ''Guide to Evidence for Health-Related Social Needs Interventions: 2022 Update'' [ROI Calculator for Partnerships to Address the Social Determinants of Health]. The Commonwealth Fund. *https://www.commonwealthfund.org/sites/default/files/2022-09/ROI_calculator_evidence_review_2022_update_Sept_2022.pdf.*

[409] O'Brien, P., Crable, E., Fullerton, C., & Hughey, L. (2019). ''Best Practices and Barriers to Engaging People with Substance Use Disorders in Treatment.'' ASPE. *https://aspe.hhs.gov/sites/default/files/private/pdf/260791/BestSUD.pdf.*

reduction organizations, including syringe service programs, function as important facilitators of entry to treatment, as individuals who partake in these programs are five times more likely to enter treatment, more likely to remain engaged in treatment, and more likely to reduce their injection drug use.[410] Additionally, recovery support services, such as those linking individuals in SUD treatment who are also experiencing homelessness with supportive or transitional housing, have resulted in improved uptake of behavioral health visits;[411] and, recovery support services facilitated by peers who have recovered from a SUD have been shown to reduce relapse rates, improve treatment retention, enhance the provider and patient relationship, and boost overall treatment experience.[412] Therefore, there is evidence to suggest that linkage to these types of community-based resources may contribute to improved outcomes related to OUD treatment; however, we seek comment on additional evidence that demonstrates how this type of services would directly help OTPs address the diagnosis or treatment of an OUD. CMS would also be interested in additional evidence describing how these community-based resources and coordination of these services with MOUD provided by OTPs would impact access to treatment for Medicare beneficiaries who may face barriers in accessing treatment, such as those who are residents of rural areas, racial/ethnic minorities, living with a disability, dual-enrollees in Medicare and Medicaid, and low-income, or other populations who may face barriers in accessing treatment. Additionally, we seek to identify the types of entities, service providers, and organizations that OTPs may interact with on a regular basis to address a patient's unmet HRSNs and needs or goals related to harm reduction and recovery support services. For example, we seek to understand if these entities would typically include housing or transportation agencies, local support groups, syringe service programs, non-profits that provide financial assistance, etc. We are also seeking information on the types of collaborative arrangements that OTPs typically have with these CBOs, including how frequently (for example, weekly, monthly, annually, etc.) OTPs coordinate care or make referrals to these CBOs for patients with an OUD, the types of circumstances that warrant an OTP interacting with these CBOs, and the workflows originating from the initial SDOH assessment to identify these HRSNs to a beneficiary successfully receiving referred services. We are also interested in learning to what extent some of these programs are already integrated into OTP settings.

Moreover, we are also interested in learning when these coordinated activities and/or referrals occur in the process of furnishing care to a beneficiary. For example, a component of SAMHSA's new revised standards for MOUD treatment under counseling and psychoeducational services at § 8.12(f)(5)(iii) suggests that OTPs must provide directly, or through referral to adequate and reasonably accessible community resources, vocational training, education, and employment services for patients who request such services or for whom these needs have been identified and mutually agreed upon as beneficial by the patient and program staff. Thus, we are soliciting comment on whether these coordination and referral services typically occur during SUD counseling session services, or if they may occur during initial or periodic assessments, therapy sessions, or as part of other services. We are also interested in understanding if, when billing for intake activities (G2076), periodic assessments (G2077), additional therapy/counseling (G2080), and/or the non-drug component code (G2074) under the Medicare OTP benefit, OTPs are already accounting for these coordinated care and referral services as part of those codes.

We are also interested in additional information related to payment for these types of coordinated care or referral services. Specifically, we seek comment on the resource costs that OTPs must expend to coordinate or make referrals to community-based services that address HRSNs, harm reduction, or recovery support needs. We are also especially interested in whether there is existing coding that properly describes these types of coordinated care or referral services, or whether there are elements to these types of services that are unique to OTPs and require new coding. We seek comment on if any of the following codes below may describe the type of coordinated care or referral activities that OTPs may provide, or if there are other codes that more precisely match the type of coordinated care or referral activities at OTPs: community health integration (G0019& G0022), principal illness navigation (G0023, G0024, G0140, G0146), chronic care management (99437, 99439, 99490, 99491), complex chronic care management (99487, 99489), principal care management (99424, 99425, 99426, 99427), or other codes, including any other relevant codes used by other payers.

Lastly, we are seeking information on whether OTPs already receive funding for these types of coordinated care or referral services from other public or private sources, and if additional payment would be duplicative or unnecessary. We are interested in learning, for example, if OTPs already receive state or Federal grants for these types of activities (for example, the SAMHSA Harm Reduction Grant Program, Rural Communities Opioid Response Program, State Opioid Response Grants, Building Communities of Recovery, Substance Use Prevention, Treatment, and Recovery Services Block Grant, etc.).[413] Additionally, CMS would like to understand if OTPs already receive payment from states who might already cover these services under state Medicaid programs, including through section 1115 waiver demonstrations and delivery system reform incentive payments, state plan amendments, managed care contracts, or other service benefits and payment arrangements,[414] and if new coding under the Medicare OTP benefit may unintentionally supplant coverage for dually eligible beneficiaries. We appreciate any feedback submitted by the public on these questions and issues to better understand activities that OTPs conduct to coordinate care and make referrals to CBOs that address unmet health-related social needs, provide

[410] Hagan, H., McGough, J.P., Thiede, H., Hopkins, S., Duchin, J., & Alexander, E.R. (2000). ''Reduced injection frequency and increased entry and retention in drug treatment associated with needle-exchange participation in Seattle drug injectors.'' Journal of Substance Abuse Treatment, 19(3), 247–252. *https://doi.org/10.1016/s0740-5472(00)00104-5*.

[411] Brennan, K., Buggs, K., Zuckerman, P., Muyeba, S., Henry, A., Gettens, J., & Kunte, P. (2020). ''The Preventive Effect of Housing First on Health Care Utilization and Costs among Chronically Homeless Individuals.'' *https://www.bluecrossmafoundation.org/sites/g/files/csphws2101/files/2020-12/Housing%20First_summary_Final.pdf*.

[412] Reif, S., Braude, L., Lyman, D.R., Dougherty, R.H., Daniels, A.S., Ghose, S.S., Salim, O., & Delphin-Rittmon, M.E. (2014). ''Peer recovery support for individuals with substance use disorders: Assessing the evidence.'' Psychiatric Services, 65(7), 853–861. *https://doi.org/10.1176/appi.ps.201400047*.

[413] *https://www.samhsa.gov/grants/grant-announcements/sp-22-001*; *https://grants.hrsa.gov/2010/Web2External/Interface/FundingCycle/ExternalView.aspx?fCycleID=af0c3bac-6d99-4314-ab7b-c1602e6c471c*; *https://www.samhsa.gov/grants/grants-dashboard*; *https://nashp.org/funding-options-for-states/*.

[414] Artiga, S., & Published, E. H. (2018, May 10). ''Beyond health care: The role of social determinants in promoting health and health equity.'' KFF. *https://www.kff.org/racial-equity-and-health-policy/issue-brief/beyond-health-care-the-role-of-social-determinants-in-promoting-health-and-health-equity/*;*https://www.health.ny.gov/diseases/aids/consumers/prevention/medicaid_harm_reduction.htm*.

harm reduction services, and/or provide recovery support services.

4. Establishing Payment for New FDA-Approved Opioid Agonist and Antagonist Medications

Section 1861(jjj)(1)(A) of the Act establishes Medicare payment for opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) for use in the treatment of OUD and as part of OUD treatment services under the OTP benefit. Additionally, section 1834(w)(2) of the Act granted CMS the authority to establish multiple bundled payments in stating that the ''Secretary may implement this subsection through one or more bundles based on the type of medication provided (such as buprenorphine, methadone, naltrexone, or a new innovative drug), the frequency of services, the scope of services furnished, characteristics of the individuals furnished such services, or other factors as the Secretary determine appropriate.'' In the CY 2020 PFS final rule, we finalized basing the OTP bundled payments, in part, on the type of medication used for treatment that reflect those drugs currently approved by the FDA under section 505 of the FFDCA for use in treatment of OUD. Accordingly, at § 410.67(d)(1) we specified that CMS would establish categories of bundled payments for OTPs for an episode of care, including categories for each type of opioid agonist and antagonist treatment medication, a category for medications not otherwise specified, and a category for episodes of care in which no medication is provided. At § 410.67(d)(2) we finalized that the bundled payment amounts for an episode of care would be based on both a drug and non-drug component, and we codified the payment methodology for determining these components. At § 410.67(d)(4), we described various adjustments that could be made to the bundled payment. Since the implementation of the Medicare OTP benefit on January 1, 2020, we have established bundled payments and/or add-on codes for the following medications: methadone (G2067 & G2078), oral buprenorphine (G2068 & G2079), injectable buprenorphine (G2069), buprenorphine implants (G2070 through G2072), naltrexone (G2073), nasal naloxone (G2215 & G1028), injectable naloxone (G2216), and medication not otherwise specified (G2075) (for new FDA-approved opioid agonist or antagonist medications for OUD treatment that is not specified in one of our existing codes). In this CY 2025 PFS proposed rule, we are proposing new payment for injectable buprenorphine and nalmefene hydrochloride products furnished by OTPs.

a. Coding and Payment for a New Nalmefene Hydrochloride Product, Opvee®

In May of 2023, the FDA approved the first nalmefene hydrochloride (nalmefene) nasal spray (under the brand name Opvee®), which is indicated for the emergency treatment of known or suspected opioid overdose induced by natural or synthetic opioids. This is the first FDA approval of a nasal spray for nalmefene hydrochloride for health care and community use, and it is intended for immediate administration as emergency therapy in settings where opioids may be present. Nalmefene acts as an opioid receptor antagonist and when administered quickly, it can reverse the effects of an opioid overdose including respiratory depression, sedation, and low blood pressure.[415] Newly approved Opvee® delivers 2.7 milligrams (mg) of nalmefene in a single spray into the nasal cavity. After the first dose is administered, if the patient does not respond, or responds and then relapses into respiratory depression, additional doses of the Opvee® nasal spray may be administered with an additional spray every 2 to 5 minutes until emergency medical assistance arrives.[416] Compared to naloxone which has a half-life of approximately 2 hours and also rapidly reverses the effects of an opioid overdose, nalmefene has a half-life of 11 hours which means that it remains in the body much longer than other overdose reversal drugs.[417] The rise of dangerous synthetic opioids, such as fentanyl and its analogs sufentanil and carfentanil, have made it increasingly difficult for first responders to reverse the effects of an overdose. These synthetics have a high potency and longer half-lives than naloxone (7–8 hours for fentanyl; 6–9 hours for sufentanil; 5–6 hours for carfentanil; and 1.3–2.4 hours for naloxone), which means that very high doses of naloxone are often required to treat opioid overdose and prevent recurring overdose symptoms,[418] which further demonstrates the necessity for new overdose reversal products that can counter these highly potent opioid synthetics. In one study, 2.7 mg of Opvee® reversed respiratory depression to baseline levels within 5 minutes, whereas 4 mg of intranasal naloxone did so within 20 minutes,[419] demonstrating the effectiveness of Opvee® in quickly reversing symptoms of opioid overdose.

In the CY 2021 PFS final rule (85 FR 84683 through 84692), we adopted new add-on codes for take-home supplies of nasal naloxone (G2215) and injectable naloxone (G2216). Additionally, we used our discretionary authority in section 1861(jjj)(1)(F) of the Act (which generally authorizes us to include as an OTP treatment service other items and services we determine are appropriate) to extend the definition of OUD treatment services to include short-acting opioid antagonist medications for the emergency treatment of known or suspected opioid overdose, such as naloxone, and overdose education furnished in conjunction with opioid antagonist medication. We also established an adjustment at § 410.67(d)(4)(i)(E) to the weekly bundled payments when the OTP furnishes take-home supplies of these medications. This adjustment includes both a drug component and a non-drug component for overdose education. The payment methodology for the drug component of the adjustment was finalized at § 410.67(d)(2)(i) and is updated annually using the most recent data available at the time of ratesetting. The amount of the non-drug component of the adjustment, which includes overdose education, is based on the CY 2020 Medicare payment rate for CPT code 96161 (*Administration of caregiver focused health risk assessment instrument (e.g., depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument*). We also finalized that any payment to an OTP for naloxone would be duplicative if a claim for the same medication is separately paid under Medicare Part B or Part D for the same beneficiary on the same date of service, and that we would

[415] *https://www.fda.gov/news-events/press-announcements/fda-approves-prescription-nasal-spray-reverse-opioid-overdose.*

[416] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217470Orig1s000.pdf.*

[417] Harris, E. (2023). ''FDA approves nalmefene, a longer-lasting opioid reversal nasal spray.'' JAMA, 329(23), 2012. *https://doi.org/10.1001/jama.2023.9608.*

[418] Krieter, P., Gyaw, S., Crystal, R., & Skolnick, P. (2019). ''Fighting fire with fire: Development of intranasal nalmefene to treat synthetic opioid overdose.'' The Journal of Pharmacology and Experimental Therapeutics, 371(2), 409–415. *https://doi.org/10.1124/jpet.118.256115.*

[419] Ellison, M., Hutton, E., Webster, L., & Skolnick, P. (2024). ''Reversal of opioid-induced respiratory depression in healthy volunteers: Comparison of intranasal nalmefene and intranasal naloxone.'' The Journal of Clinical Pharmacology, jcph.2421. *https://doi.org/10.1002/jcph.2421.*

recoup any duplicative payment made to an OTP for naloxone.

Furthermore, in the CY 2022 PFS final rule (86 FR 65340 and 65341), we established a new add-on code and payment for a higher dose of nasal naloxone (G0128). We also finalized that the adjustment includes take-home supplies of opioid antagonist medications in the list of items for which the non-drug component will be geographically adjusted using the Geographic Adjustment Factor (GAF) and the payment amount will be updated annually by the growth in the Medicare Economic Index (MEI). Lastly, we revised our regulations at § 410.67(d)(5) to state explicitly that payments for medications that are delivered, administered or dispensed to a beneficiary as part of an adjustment to the bundled payment are considered a duplicative payment if a claim for delivery, administration or dispensing of the same medication(s) for the same beneficiary on the same date of service was also separately paid under Medicare Part B or Part D. We clarified that this revision would apply not only to duplicative payments for take-home supplies of naloxone, but also to duplicative payments for additional take-home supplies of other medications that are made under § 410.67(d)(4)(i)(D).

In light of a novel nalmefene product, Opvee®, receiving FDA approval as an opioid antagonist medication for the emergency treatment of known or suspected opioid overdose, we are proposing to make payment for this new drug under the Medicare OTP benefit. Expanding access to overdose reversal medications, such as nalmefene, is a critical component to confronting the opioid crisis. The number of drug overdose deaths involving prescription opioids has grown by nearly five-fold in the past two decades. In 2021, almost 81,000 opioid overdose deaths occurred in the U.S, and nearly 88 percent of opioid-involved deaths involved synthetic opioids like fentanyl and fentanyl analogs (acetylfentanyl, furanylfentanyl, and carfentanil). Due to the high potency of drugs in the nation's drug supply, this has often meant that higher doses, or even multiple doses, of overdose reversal medications are needed per overdose event to revive a patient.[420] These increasing rates of drug overdose deaths has also been seen among the Medicare-eligible population with adults aged 65 and over experiencing the largest percentage increase (28 percent) in drug overdose deaths rates between 2020 and 2021,[421] and the rate of drug overdose deaths involving synthetic opioids among this age group increased by over 53 percent in only one year (between 2019 and 2020).[422] Over 50,000 Medicare Part D beneficiaries were estimated to have experienced an opioid overdose in 2021, and the number of these beneficiaries receiving naloxone has grown.[423] Not only has the opioid crisis impacted the Medicare-eligible population, but health disparities in drug overdose deaths have persisted. Non-Hispanic Black men aged 65 and over have experienced drug overdose death rates that are more than four times higher than Hispanics and non-Hispanic whites.[424] In addition, death rates from drug overdoses among people aged 65 and over have increased at faster rates for men than women.[425] Expanding access to overdose reversal medications is important, including for populations at a greater risk for drug overdose, as overdose reversal medications have been regarded as an evidence-based strategy to help individuals quickly respond to an overdose to reduce drug overdose deaths, increase survival rates, and reduce opioid-related emergency department visits.[426] Lastly, we believe this proposal to pay for Opvee® under the OTP benefit would further the objectives of the HHS Overdose Prevention Strategy and the National Drug Control Strategy, which both aim to widen availability and access to opioid overdose reversal treatments.[427]

Section 1861(jjj)(1)(A) of the Act recognizes opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by the FDA under section 505 of the FFDCA for the use in treatment of OUD, but nalmefene is not on the list of drugs for the treatment of OUD.[428] When CMS first finalized payment for nasal and injectable naloxone under the OTP benefit in the CY 2021 PFS final rule (85 FR 84682 through 84689 and 85026 through 85027), we used our discretionary authority under section 1861(jjj)(1)(F) of the Act to finalize and extend the definition of OUD treatment services to include short acting opioid antagonist medications (e.g naloxone) that are approved by the FDA under section 505 of the FFDCA for the emergency treatment of known or suspected opioid overdose. Since nalmefene was approved by the FDA under section 505(b)(2) authority,[429] and is an opioid antagonist and on the list of overdose reversal drugs approved by the FDA,[430] we believe nalmefene is consistent with our definition of OUD treatment service at § 410.67(d), which describes opioid antagonist medications that are approved by the FDA under section 505 of the FFDCA for the emergency treatment of known or suspected opioid overdose at paragraph (viii). Therefore, we believe it is appropriate to propose new payment for nalmefene as it would align with existing authority under § 410.67(b) that recognizes opioid antagonist medications which treat known or suspected opioid overdose as an OUD treatment service.

We are proposing to create a new adjustment to the bundled payment for nalmefene hydrochloride (Opvee®) described by GOTP1 *[Take-home supply of nasal nalmefene hydrochloride; one carton of two, 2.7 mg per 0.1 mL nasal sprays (provision of the services by a Medicare-enrolled Opioid Treatment Program); (List separately in addition to each primary code)].* We would price this new add-on code based on the established methodology under the OTP benefit for determining the adjustment for take-home supplies of opioid antagonist medications at § 410.67(d)(4)(i)(E). This adjustment would include both a drug component and a non-drug component. The amount of the drug component would be determined using the methodology for pricing the drug component of an episode of care at § 410.67(d)(2)(i), which tends to use ASP data when available (with certain exceptions). Accordingly, consistent with the approach used to price the drug component for nasal naloxone (HCPCS code G2215 & G1028), we would apply the average sales price (ASP) payment methodology set forth in section 1847A of the Act to determine the payment for the new naloxone hydrochloride nasal spray product, except that payment amounts would not include any add-on percentages if either ASP or wholesale acquisition cost (WAC) is used. As stated in the CY 2021 PFS final rule (85

[420] *https://www.cdc.gov/drugoverdose/deaths/index.html.*

[421] *https://www.cdc.gov/nchs/products/databriefs/db457.htm.*

[422] *https://blogs.cdc.gov/nchs/2023/06/30/7408/.*

[423] *https://oig.hhs.gov/oei/reports/OEI-02-22-00390.pdf.*

[424] *https://www.cdc.gov/nchs/products/databriefs/db455.htm.*

[425] *https://blogs.cdc.gov/nchs/2022/11/30/7193/.*

[426] *https://www.cdc.gov/drugoverdose/pdf/pubs/2018-evidence-based-strategies.pdf.*

[427] *https://www.hhs.gov/overdose-prevention/*; *https://www.whitehouse.gov/wp-content/uploads/2022/04/National-Drug-Control-2022Strategy.pdf.*

[428] *https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat.*

[429] *https://www.fda.gov/media/171605/download.*

[430] *https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-naloxone-and-nalmefene.*

FR 84685), we continue to believe that using ASP provides a transparent and public benchmark for manufacturers' actual pricing as it reflects the manufacturers' actual sales prices to all purchasers (with limited exceptions as noted in section 1847A(c)(2) of the Act) and is the only pricing methodology that includes off-invoice rebates and discounts as described in section 1847A(c)(3) of the Act. Therefore, we believe ASP to be the most market-based approach to set drug prices, including for the new nalmefene nasal product. As we stated in the CY 2020 PFS final rule, we also continue to believe that limiting the payment amount to 100-percent of the volume-weighted ASP for a HCPCS code will incentivize the use of the most clinically appropriate drug for a given patient (84 FR 62651 through 62656). We understand that many OTPs purchase medications directly from manufacturers, thereby limiting the markup from distribution channels.

Furthermore, as stated in the CY 2020 PFS final rule (84 FR 62650), we usually use the typical maintenance dose to calculate the drug component for the OTP benefit. As part of determining a payment rate for the proposed bundles for OUD treatment services, a dosage of the applicable medication is often selected to calculate the costs of the drug component of the bundle. According to the product information for Opvee®, each unit-dose nasal spray device delivers 2.7 mg of nalmefene in 0.1 mL.[431] Each unit-dose device contains a single dose of nalmefene, so it delivers its entire contents automatically and cannot be reused. Each carton contains two unit-dose nasal spray devices to allow for an additional repeat dose if needed. Thus, we are proposing to price the drug component of the code for nalmefene based on an assumption of a typical dosage for this new product to be a carton containing two 2.7 mg nasal sprays. We would, therefore, multiply the payment amount of 100-percent of the volume-weighted ASP reported for 2.7 mg of nalmefene by two in order to reflect a carton of two nasal spray devices. We seek comment on whether this amount (a carton of two, 2.7 mg nasal sprays) reflects the typical maintenance dosage for this drug when administered. The payment limit for Opvee® in the April 2024 ASP pricing file is $92.033, which reflects a carton of two, 2.7mg nasal sprays and would be used to price the drug component of GOTP1.

Additionally, consistent with the methodology established in § 410.67(d)(4)(i)(E), we propose to include a non-drug component for GOTP1 that would include payment for overdose education. Overdose education is an important component of overdose prevention and includes educating patients and caregivers on how to recognize respiratory depression, the signs and symptoms of a possible opioid overdose, how to administer overdose reversal medications, and the importance of calling 911 or getting emergency medical help right away, even after the overdose reversal medication is administered.[432] Additionally, overdose education paired with distribution of overdose reversal medications has been found to be effective in improving knowledge about opioid overdose, improving attitudes toward using overdose reversal medications, training individuals to safely and effectively manage overdoses, and reducing opioid-related mortality.[433] For these reasons, we are proposing to include a non-drug component to GOTP1 based on the CY 2020 Medicare payment rate for CPT code 96161 *(Administration of caregiver-focused health risk assessment instrument (e.g., depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument)* and updated to reflect the MEI updates that have been applied since that time. This is consistent with the payment methodology for naloxone and the language in § 410.67(d)(4)(i)(E). In addition, the language at § 410.67(d)(4)(ii) currently states that the non-drug component of the adjustments for take-home supplies of opioid antagonist medications will be geographically adjusted using the geographic adjustment factor described in § 414.26. Separately, § 410.67(d)(4)(iii) states that the non-drug component of the adjustments for take-home supplies of opioid antagonist medications will be updated annually using the Medicare Economic Index described in § 405.504. Since we are proposing to establish payment for Opvee® through an adjustment to the bundled payment, and since Opvee® is also considered an opioid antagonist medication, we are also proposing to update the non-drug component for the adjustment of GOTP1 annually based on the GAF and MEI.

Furthermore, consistent with our established criteria for opioid antagonist medications at § 410.67(d)(4)(i)(E), we are also proposing to limit payment for Opvee® to one add-on code (GOTP1) every 30 days. However, we believe that access to Opvee® should not be limited when it is medically reasonable and necessary as part of the treatment for OUD and known or suspected opioid overdose. Therefore, similar to flexibilities established for frequency limits for naloxone, we are proposing to allow exceptions to this limit in the case where the beneficiary overdoses and uses the initial supply of nalmefene dispensed by the OTP to the extent that it is medically reasonable and necessary to furnish additional nalmefene. We note that section 1862(a)(1)(A) of the Act requires that for payment to be made for most Part A and Part B services furnished to Medicare beneficiaries, those services must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the malfunctioning of a malformed body member. If an additional supply of Opvee® is needed within 30 days of the original supply being provided, we propose that OTPs must document in the medical record the reason for the exception. Moreover, section 1834(w)(1) of the Act, added by section 2005(c) of the SUPPORT Act, requires the Secretary to ensure, as determined appropriate by the Secretary, that no duplicative payments are made under Medicare Part B or Part D for items and services furnished by an OTP. Similar to naloxone, we recognize that nalmefene may also be appropriately available to beneficiaries through other Medicare benefits, including under Medicare Part D. At § 410.67(d)(5), we define duplicative payment to involve circumstances when medications are delivered, administered or dispensed to a beneficiary are paid as part of the OTP bundled payment, and where the delivery, administration or dispensing of the same medication (that is, same drug, dosage and formulation) is also separately paid under Medicare Part B or Part D for the same beneficiary on the same date of service. Consistent with § 410.67(d)(5), we propose that CMS recoup duplicative payments made to an OTP for Opvee®. CMS expects that if the OTP provides reasonable and necessary medications for an OUD as part of an episode of care, the OTP will take measures to ensure that there is no claim for payment for these drugs other

[431] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217470Orig1s000.pdf.*

[432] *https://www.fda.gov/media/140360/download#.*

[433] Razaghizad, A., Windle, S. B., Filion, K. B., Gore, G., Kudrina, I., Paraskevopoulos, E., Kimmelman, J., Martel, M. O., & Eisenberg, M. J. (2021). ''The effect of overdose education and naloxone distribution: An umbrella review of systematic reviews.'' American Journal of Public Health, 111(8), e1–e12. *https://doi.org/10.2105/AJPH.2021.306306.*

than as part of the OTP bundled payments. Thus, Opvee® billed by an OTP as an add-on to the bundled payment should not be reported to or paid under a Medicare Part D plan.

We welcome comments related to this proposal to establish an adjustment to the bundled payment for Opvee® [*(GOTP1: Take-home supply of nasal nalmefene hydrochloride; one carton of two, 2.7 mg per 0.1 mL nasal sprays (provision of the services by a Medicare-enrolled Opioid Treatment Program); (List separately in addition to each primary code)*], as well as comments related to applicable requirements and criteria for billing this code.

b. Coding and Payment for New Injectable Buprenorphine Product Brixadi®

Another medication for the treatment of OUD for which the Secretary may establish payment is buprenorphine, which is a partial opioid agonist that is FDA approved to treat OUD. Buprenorphine is a schedule III substance, meaning it has low to moderate potential for physical dependence.[434] When taken as prescribed, it can diminish the effects of opioid withdrawal symptoms and cravings.[435] In the CY 2020 PFS final rule (84 FR 62630 through 62677 and 84 FR 62919 through 62926), we established a weekly bundled payment under the Medicare OTP benefit for injectable buprenorphine (HCPCS G2069: *Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)*). CMS also established payment for other formulations of buprenorphine, including weekly bundles for oral buprenorphine (G0268), buprenorphine implants (G2070 through G2072), and take-home supplies of oral buprenorphine (G2079), as well as other medications like methadone and naltrexone. At § 410.67(d)(2), we codified that the bundled payment for episodes of care in which a medication is provided will consist of a payment for a drug component, reflecting payment for the applicable FDA-approved opioid agonist or antagonist medication in the patient's treatment plan, and a non-drug component, reflecting payment for all other OUD treatment services reflected in the patient's treatment plan (including dispensing/administration of the medication, if applicable). The payments for the drug component and non-drug component are added together to create the bundled payment amount. In the CY 2020 PFS final rule, CMS finalized a payment methodology for the drug component related to implantable and injectable medications at 42 CFR 410.67(d)(2)(i)(A), which applied to the bundled payment for injectable buprenorphine (G2069).

For implantable and injectable medications paid under the OTP benefit, the payment is determined using the methodology set forth in section 1847A of the Act, except that the payment amount must be 100 percent of the ASP, if ASP is used; and the payment must be 100 percent of the WAC, if WAC is used. We also stated in the CY 2020 PFS final rule that the typical maintenance dose to calculate the drug component for payment under the OTP benefit, as dosing for some, but not all, of the drugs varies considerably (84 FR 62650). As part of determining a payment rate for the proposed bundles for OUD treatment services, a dosage of the applicable medication must be selected to calculate the costs of the drug component of the bundle. In the CY 2020 PFS final rule, we finalized using a 100 mg monthly dose for the extended-release buprenorphine injection to use as the typical or average maintenance dose to calculate the drug component of the bundle for injectable buprenorphine (G2069). At the time of ratesetting for the CY 2020 PFS rule, the only injectable extended-release buprenorphine drug available and approved by the FDA under section 505 of the FFDCA for the treatment of OUD was Sublocade®;[436] and, the drug component for the bundle was based on a crosswalk to its respective HCPCS codes Q9991 (Buprenorphine XR 100 mg or less) and Q9992 (Buprenorphine XR over 100 mg) using the methodology set forth in section 1874A of the Act, except that the payment amount was 100-percent of the ASP. In the CY 2020 PFS final rule, we noted that the HCPCS codes for extended-release buprenorphine injection had the same payment rate, thus we did not believe it was necessary to establish a second typical maintenance dose to calculate the payment rate for the drug. For the non-drug component of the weekly bundle for injectable buprenorphine (G2069), we finalized that in addition to services for substance use counseling, individual and group therapy, and toxicology testing, we would include the Medicare non-facility rate for administration of an injection in our determination of the payment rate based on CPT code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*).

In May of 2023, the FDA approved a new drug application (NDA) under section 505(b)(2) of the FFDCA for another extended-release buprenorphine injection (Brixadi®) for subcutaneous use to treat moderate to severe OUD.[437] Clinical data suggest that Brixadi® likely contributes to high rates of treatment retention, reductions in opioid withdrawal and cravings, and fewer levels of illicit opioid use.[438] Brixadi® is available in two formulations, a weekly injection (containing 50 mg of buprenorphine per mL) that can be used in patients who have started treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine-containing products, and a monthly injection (containing 356 mg of buprenorphine per mL) for patients already being treated with buprenorphine. The weekly and monthly formulations of the drug are available at varying doses, including lower doses that may be appropriate for those who do not tolerate higher doses of extended-release buprenorphine that are currently available.[439] The weekly doses are 8 mg, 16 mg, 24 mg, and 32 mg, and should be administered in 7-day intervals; and the monthly doses are 64 mg, 96 mg, and 128 mg, and should be administered in 28-day intervals.[440]

Buprenorphine is associated with decreasing the risk for overdose, opioid-related mortality, and all-cause mortality.[441] Data also shows that

[434] *https://www.dea.gov/drug-information/drug-scheduling.*

[435] National Academies of Sciences, Engineering, and Medicine. (2019). ''The effectiveness of medication-based treatment for opioid use disorder.'' In M. Mancher & A. I. Leshner (Eds.), Medications for Opioid Use Disorder Save Lives. National Academies Press (U.S.). *https://www.ncbi.nlm.nih.gov/books/NBK541393/.*

[436] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209819s001lbl.pdf.*

[437] *https://www.fda.gov/news-events/press-announcements/fda-approves-new-buprenorphine-treatment-option-opioid-use-disorder.*

[438] Frost, M., Bailey, G. L., Lintzeris, N., Strang, J., Dunlop, A., Nunes, E. V., Jansen, J. B., Frey, L. C., Weber, B., Haber, P., Oosman, S., Kim, S., & Tiberg, F. (2019). ''Long-term safety of a weekly and monthly subcutaneous buprenorphine depot in the treatment of adult out-patients with opioid use disorder.'' Addiction, 114(8), 1416–1426. *https://doi.org/10.1111/add.14636.*

[439] *https://www.fda.gov/news-events/press-announcements/fda-approves-new-buprenorphine-treatment-option-opioid-use-disorder.*

[440] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/210136Orig1s000lbl.pdf.*

[441] Larochelle, M. R., Bernson, D., Land, T., Stopka, T. J., Wang, N., Xuan, Z., Bagley, S. M., Liebschutz, J. M., & Walley, A. Y. (2018). ''Medication for opioid use disorder after nonfatal

Continued

buprenorphine helps retain individuals in treatment, lowers illicit opioid use, and reduces drug-related behaviors that increase the risk for HIV transmission.[442] In particular, long-acting (for example, extended-release) injectable forms of buprenorphine have been shown to promote adherence to treatment while reducing the need for daily dosing, and to enhance patient-reported outcomes through improvements in quality of life, accessibility, social relationships, participation in employment, more flexible personal and professional schedules, and other treatment satisfaction measures.[443] Finally, a large percentage of Medicare beneficiaries with an OUD continue to face challenges in accessing medication, especially enrollees who are older, female, and who identify as racial/ethnic minorities.[444] The most common reasons for not receiving SUD treatment include financial barriers in affordability and coverage.[445] Establishing coverage and payment for a new medication to treat OUD may provide more MOUD treatment options, reduce financial barriers to accessing medication, and aid health equity efforts among Medicare beneficiaries. Accordingly, for these reasons and because sections 1861(s)(2), 1861(jjj)(1)(A), and 1833(a)(1) of the Act provide that the Secretary is to provide coverage and payment for OUD treatment services including opioid agonist and antagonist medications that are FDA approved for use in the treatment of OUD, we are proposing to establish payment for the weekly and monthly formulations for this new FDA-approved injectable buprenorphine product, Brixadi®, which we believe would further efforts to address the opioid crisis and expand access to evidence-based treatment for OUD.

We are proposing to establish two different payments, one for each of the weekly and monthly injectable formulations of Brixadi®. To establish payment for the weekly and monthly formulations of Brixadi®, we are proposing to use the existing payment methodology for implantable and injectable medications codified at § 410.67(d)(2)(i)(A). This regulation specifies that payment is determined using the methodology set forth in section 1847A of the Act, except that the payment amount must be 100 percent of the ASP, if ASP is used; and the payment must be 100 percent of the WAC, if WAC is used.

Payment limits[446] for most drugs and biologicals separately payable under Medicare Part B are determined using the methodology in section 1847A of the Act, and in many cases, payment is based on the ASP plus a statutorily mandated 6 percent add-on. Most drugs payable under Part B are paid under the ''incident to'' benefit under section 1861(s)(2) of the Act, which includes drugs and biologicals not usually self-administered by the patient. The ASP payment limit determined under section 1847A of the Act reflects a volume-weighted ASP for all national drug codes (NDCs) that are assigned to a HCPCS code. The ASP is calculated quarterly using manufacturer-submitted data on sales to all purchasers (with limited exceptions as articulated in section 1847A(c)(2) of the Act, such as for sales at nominal charge and sales exempt from best price) with manufacturers' rebates, discounts, and price concessions reflected in the manufacturer's determination of ASP.

Paragraphs (4)(A) and (6) of sections 1847A(b) of the Act require that the Medicare Part B payment limit for a single-source drug or biological be determined using all of the NDCs assigned to it. Section 1847A(b)(5) of the Act further states that the payment limit shall be determined without regard to any special packaging, labeling, or identifiers on the dosage form or product or package. In 2007, CMS issued a program instruction,[447] as permitted under section 1847A(c)(5)(C) of the Act, stating that the payment limit for a single source drug or biological will be based on the pricing information for products produced or distributed under the applicable FDA approval (such as a New Drug Application (NDA) or Biologics License Application (BLA)). Therefore, all versions of a single source drug or biological product (or NDCs) marketed under the same FDA approval number (for example, NDA or BLA, including supplements) are considered the same drug or biological for purposes of payments made under section 1847A of the Act and are crosswalked to the same billing and payment code.

We continue to believe that use of ASP provides a transparent and public benchmark for manufacturers' pricing as it reflects the manufacturers' actual sales prices to all purchasers (with limited exceptions) and is the only pricing methodology that includes off invoice rebates and discounts as described in section 1847A(c)(3) of the Act. Additionally, since many other injectable drugs are paid for under Medicare part B through the ASP payment methodology in 1847A, we presume that this methodology is appropriate for pricing Brixadi®. We also propose to limit the payment amount to 100-percent of ASP without a 6-percent add-on percentage since, as we have previously noted, it is our

opioid overdose and association with mortality: A cohort study.'' Annals of Internal Medicine, 169(3), 137. *https://doi.org/10.7326/M17-3107;* Wakeman, S. E., Larochelle, M. R., Ameli, O., Chaisson, C. E., McPheeters, J. T., Crown, W. H., Azocar, F., & Sanghavi, D. M. (2020). ''Comparative effectiveness of different treatment pathways for opioid use disorder.'' JAMA Network Open, 3(2), e1920622. *https://doi.org/10.1001/jamanetworkopen.2019.20622.*

[442] Shulman, M., Wai, J. M., & Nunes, E. V. (2019). Buprenorphine treatment for opioid use disorder: An overview. CNS Drugs, 33(6), 567–580. *https://doi.org/10.1007/s40263-019-00637-z;* Thomas, C. P., Fullerton, C. A., Kim, M., Montejano, L., Lyman, D. R., Dougherty, R. H., Daniels, A. S., Ghose, S. S., & Delphin-Rittmon, M. E. (2014). Medication-assisted treatment with buprenorphine: Assessing the evidence. Psychiatric Services (Washington, DC), 65(2), 158–170. *https://doi.org/10.1176/appi.ps.201300256;* Gowing, L., Farrell, M. F., Bornemann, R., Sullivan, L. E., & Ali, R. (2011). Oral substitution treatment of injecting opioid users for prevention of HIV infection. The Cochrane Database of Systematic Reviews, 8, CD004145. *https://doi.org/10.1002/14651858.CD004145.pub4.*

[443] Maremmani, I., Dematteis, M., Gorzelanczyk, E. J., Mugelli, A., Walcher, S., & Torrens, M. (2023). Long-acting buprenorphine formulations as a new strategy for the treatment of opioid use disorder. Journal of Clinical Medicine, 12(17), 5575. *https://doi.org/10.3390/jcm12175575;* Farrell, M., Shahbazi, J., Byrne, M., Grebely, J., Lintzeris, N., Chambers, M., Larance, B., Ali, R., Nielsen, S., Dunlop, A., Dore, G. J., McDonough, M., Montebello, M., Nicholas, T., Weiss, R., Rodgers, C., Cook, J., & Degenhardt, L. (2022). Outcomes of a single-arm implementation trial of extended-release subcutaneous buprenorphine depot injections in people with opioid dependence. International Journal of Drug Policy, 100, 103492. *https://doi.org/10.1016/j.drugpo.2021.103492;* Lintzeris, N., Dunlop, A. J., Haber, P. S., Lubman, D. I., Graham, R., Hutchinson, S., Arunogiri, S., Hayes, V., Hjelmström, P., Svedberg, A., Peterson, S., & Tiberg, F. (2021). Patient-reported outcomes of treatment of opioid dependence with weekly and monthly subcutaneous depot vs daily sublingual buprenorphine: A randomized clinical trial. JAMA Network Open, 4(5), e219041. *https://doi.org/10.1001/jamanetworkopen.2021.9041;* Martin, E., Maher, H., McKeon, G., Patterson, S., Blake, J., & Chen, K. Y. (2022). Long-acting injectable buprenorphine for opioid use disorder: A systematic review of impact of use on social determinants of health. Journal of Substance Abuse Treatment, 139, 108776. *https://doi.org/10.1016/j.jsat.2022.108776.*

[444] *https://oig.hhs.gov/oei/reports/OEI-02-23-00250.pdf.*

[445] Parish, W. J., Mark, T. L., Weber, E. M., & Steinberg, D.G. (2022). Substance use disorders among Medicare beneficiaries: Prevalence, mental and physical comorbidities, and treatment barriers. American Journal of Preventive Medicine, 63(2), 225–232. *https://doi.org/10.1016/j.amepre.2022.01.021.*

[446] In general, CMS establishes a single, national payment limit to Medicare Administrative Contractors (MACs) for payment of some Part B-covered drugs and biologicals whose payment is determined based on the methodology described in section 1847A of the Act. CMS provides an ASP pricing file to MACs, which is updated quarterly. *https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files.*

[447] *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_annoucement.pdf.*

understanding that many OTPs purchase directly from drug manufacturers, thereby limiting the markup from distribution channels.

As we stated in our discussion above, we use the typical or average maintenance dose of a drug to determine the drug costs for each of the bundles. In the CY 2020 PFS final rule, we noted that there are often variations in the dosage and frequency of administration of medications, but that ''payment based on the typical dose means that, across the Medicare beneficiaries served by the OTP, the payment amount should be reasonable and represent the average costs incurred in furnishing the drug component of the OUD treatment services.'' (84 FR 62650). Therefore, in the CY 2020 PFS final rule, we finalized using the typical maintenance dose to establish the drug costs for each of the bundles as our approach to addressing variable dosing of medications. (84 FR 62650).

In the CY 2020 PFS final rule, we finalized a 100 mg monthly dose for the extended-release buprenorphine injection as the typical maintenance dose, which we used to calculate the drug component of the weekly bundle for injectable buprenorphine (G2069). At the time, we did not establish a second typical maintenance dose because both HCPCS codes for the extended release buprenorphine injection, that is, Sublocade® [Q9991 (*Buprenorphine XR 100 mg or less*) and Q9992 (*Buprenorphine XR over 100 mg*)] had the same payment limit because, as explained above in this section, all NDCs marketed under the same FDA approval number are considered the same drug or biological for purposes of payments made under section 1847A of the Act and are crosswalked to the same billing and payment code. The weekly and monthly formulations of Brixadi® are described by HCPCS codes J0577 (*Injection, buprenorphine extended release (brixadi), less than or equal to 7 days of therapy*) and J0578 (*Injection, buprenorphine extended release (brixadi), greater than 7 days and up to 28 days of therapy*). In the same manner as Sublocade®, and as explained in the coding announcement for HCPCS codes J0577 and J0578,[448] because all versions of a single source drug or biological product (or NDCs) marketed under the same FDA approval number are considered the same drug or biological for purposes of payments made under section 1847A of the Act, the payment limits for both J0577 and J0578 are calculated using all the NDCs marketed under the applicable FDA approval. However, since the dose descriptions for these codes are based on days of therapy (and not a measurement of the amount of drug, like per 1 mg, as is the case with Sublocade®), the payment limits for the two codes are different; in the April 2024 ASP pricing file, the payment limit for J0577 is $404.086 and the payment limit for J0578 is $1,616.346. Therefore, we do not believe it is appropriate to bundle the weekly and monthly formulations into a single bundled payment since, unlike the drug Sublocade®, the Brixadi® formulations have different payment limits, and pricing them under the same bundle would not adequately represent the average costs incurred in furnishing these different formulations in an OTP setting. Additionally, creating a single bundled payment rate that does not reflect the type and cost of the drug used could result in access issues for beneficiaries, especially in the event that the bundled payment amount for one drug significantly drops and unintentionally incentivizes treatment towards a drug with a higher bundled payment amount.

In establishing the two different payments for the weekly and monthly injectable buprenorphine formulations of Brixadi®, first, we propose to crosswalk the monthly formulation of Brixadi® (J0578: *Injection, buprenorphine extended release (brixadi), greater than 7 days and up to 28 days of therapy*) to the drug component of our existing bundled payment for injectable buprenorphine described by HCPCS code G2069 (*Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program*). We propose to average the payment limits of Sublocade® and monthly Brixadi® by adding their two payment limits together and dividing the sum by two, in order to update the payment for the drug component of HCPCS code G2069. We believe including the average of the payment limits of Sublocade® and Brixadi® in the drug component of G2069 rather than the sum of their respective individual payment limits is appropriate because we do not expect that a beneficiary would receive two different types of buprenorphine monthly medication injections simultaneously from an OTP (for example, both Sublocade® and Brixadi® during the same episode of care and date of service). We believe that averaging the price of the two types of buprenorphine monthly medication injections would be further be appropriate because the individual payment limits for each of the drug codes (Q9991, Q9992, and J0578) would both be informed by ASP data and comparable as they would be priced by the same ASP payment methodology (ASP+0). We also note that bundling the monthly formulation of Brixadi® into the existing HCPCS code (G2069) for injectable buprenorphine would be appropriate and no more administratively complex for OTPs since G2069 is already billed on a monthly basis; Sublocade®, which is already reflected in the drug component of G2069 is administered on a monthly basis to beneficiaries as would be the monthly formulation of Brixadi®, so OTPs could continue to bill G2069 once each month when either monthly Brixadi® or Sublocade® is administered, as appropriate.[449]

Additionally, the average typical dose of G2069 is 100mg of buprenorphine administered monthly, as finalized in the CY 2020 PFS final rule (84 FR 62651). The monthly formulations of Brixadi® can range from 64 mg, to 96 mg, to 128 mg. The median of these different doses for the monthly formulation of Brixadi® (96 mg) would approximate the average typical dose of the current injectable buprenorphine bundle (100 mg). We note that the different monthly doses of Brixadi® are assigned to the same HCPCS code J0578 (*Injection, buprenorphine extended release (brixadi), greater than 7 days and up to 28 days of therapy*) and have the same payment limit regardless of the monthly dose (64 mg, 96 mg, or 128 mg), so selecting a typical dose of monthly Brixadi® to potentially adjust the drug component of G2069 would not meaningfully change the payment rate. Therefore, we are not proposing to establish an average typical dose different than 100 mg for injectable buprenorphine administered on a monthly basis for purposes of calculating the drug component under the OTP benefit, though we seek comment on whether this average typical dose (100 mg) is close to the dose for the monthly formulation of Brixadi® that patients receive on average.

In all, we believe that bundling the monthly formulation of Brixadi® into

[448] *https://www.cms.gov/files/document/2023-hcpcs-application-summary-quarter-4-2023-drugs-and-biologicals-updated-03/04/2024.pdf.*

[449] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209819s001lbl.pdf.*

our current injectable buprenorphine coding under the OTP benefit would be appropriate for several reasons, including: the costs for furnishing these drugs, as shown by similar ASP payment limits for monthly Brixadi® (J0578) and the two HCPCS codes for Sublocade® (Q9991 and Q9992) ($1,616.346 and $1,874.902, respectively, are comparable as reflected in the April 2024 ASP file); the average maintenance dosage for Sublocade® (100 mg) is comparable to the median monthly dosage for Brixadi® (96 mg) and; both drugs have similar frequencies and costs of administration (on a monthly basis) with a fee paid to the OTP for one administration of an injection once a month. We believe that our proposed payment methodology would be consistent with section 1834(w)(2) of the Act, which allows the Secretary to implement bundled payments for OUD treatment services with considerations to the type of medication provided and the frequency of the services, and thus permit multiple bundles that represent injectable buprenorphine (proposed GOTP2 and G2069) and the frequency with which injectable buprenorphine is administered (weekly versus monthly). We propose to still calculate the non-drug component of HCPCS code G2069 consistent with the methodology we use to calculate the non-drug component, which is specified at § 410.67(d)(2)(ii). We are proposing to change the code descriptor for HCPCS code G2069 to take out references to a ''weekly bundle'' to make it clear that the code is to be billed on a monthly basis. Specifically, we would revise the code descriptor to state the following: HCPCS code G2069 *(Medication assisted treatment, buprenorphine (injectable) administered on a monthly basis; bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)*). Lastly, consistent with current guidance in Chapter 39 of the Medicare Claims Processing Manual, we would still expect that HCPCS code G2069 ''would be billed for the week during which the injection was administered and that HCPCS code G2074, which describes a bundle not including the drug, would be billed during any subsequent weeks that at least one non-drug service is furnished until the injection is administered again, at which time HCPCS code G2069 would be billed again for that week.'' [450]

For the weekly formulation of Brixadi®, we propose to calculate a new bundled payment described by GOTP2 (*Medication assisted treatment, buprenorphine (injectable) administered on a weekly basis; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program*). For the drug component of HCPCS code GOTP2, we propose to base the payment on a crosswalk to the weekly Brixadi® formulation described by HCPCS code J0577 *(Injection, buprenorphine extended release (brixadi), less than or equal to 7 days of therapy),* which would also be based on the payment methodology specified at § 410.67(d)(2)(i)(A) for implantable and injectable medications, consistent with the existing monthly injectable buprenorphine bundle. We believe that establishing a separate weekly bundled payment reflecting the weekly formulation of Brixadi® would more appropriately pay for the subset of beneficiaries who receive less than a monthly dosage of injectable buprenorphine on average, or who choose to discontinue treatment for the drug before the end of the month. Additionally, establishing a separate weekly bundled payment would contribute to stabilizing the payment of the drug component for the monthly bundle of injectable buprenorphine (G2069) since the ASP payment limit for weekly Brixadi® costs less than the payment for the drug component of G2069 ($404.086 April 2024 ASP payment limit versus $1,780.167 for the CY 2024 payment rate of the drug component of G2069) and may decrease payment after the weekly Brixadi payment limit is averaged into the drug component of G2069®. Establishing a separate weekly bundled payment is also more appropriate because weekly Brixadi® requires more frequent administration costs than monthly injectable buprenorphine (weekly Brixadi® must be injected at least once every 7 days compared to once a month for Sublocade® and monthly Brixadi®). Thus, a different bundle for weekly Brixadi® may more closely reflect the costs incurred by OTPs. Furthermore, as noted above in this section, different weekly doses are assigned to the same HCPCS code J0577 *(Injection, buprenorphine extended release (brixadi), less than or equal to 7 days of therapy)* and have the same payment limit regardless of the weekly dose. Therefore, we do not believe it is appropriate to propose an average typical dose for the weekly formulation of Brixadi® for purposes of calculating the drug component of GOTP2 under the OTP benefit.

Second, we propose to also establish payment for the non-drug component of GOTP2 consistent with the methodology utilized for the monthly bundle of injectable buprenorphine (G2069). Specifically, we would continue to pay for substance use counseling, individual and group therapy, and toxicology testing that are included in the non-drug components for each of the bundled payments reflecting an episode of care, but we would include the Medicare non-facility rate for administration of an injection in our determination of the non-drug component payment rate based on CPT code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*). Consistent with the payment amounts for the non-drug component of other bundled payments for an episode of care, we also propose to continue to update the value of this non-drug component for GOTP2 by the GAF as described in § 410.67(d)(4)(ii), and by the MEI as described in § 410.67(d)(4)(iii).

We welcome comments on these proposals to establish payment for the weekly and monthly formulations of the new injectable buprenorphine drug, Brixadi®.

5. Clarification To Require an Opioid Use Disorder Diagnosis on Claims for OUD Treatment Services

Section 1861(s)(2)(HH) of the Act, as amended by section 2005 of the SUPPORT Act, implemented Medicare coverage for ''opioid use disorder treatment services.'' Section 1861(jjj)(1) of the Act describes opioid use disorder treatment services as items and services that are furnished by an opioid treatment program for the treatment of opioid use disorder. Section 1834 of the Act specifies payments to OTPs for providing opioid use disorder treatment services. We interpreted these statutory provisions to mean that services paid to OTPs under Medicare Part B must be for the treatment of opioid use disorder. Consequently, at § 410.67(a) we reflect that those statutory provisions provide for coverage and payment to OTPs for OUD treatment services, which we define at § 410.67(b).

In August of 2023, an Office of Inspector General (OIG) report (A–09–

[450] *https://www.cms.gov/files/document/chapter-39-opioid-treatment-programs-otps.pdf.*

22–03005) found that Medicare made over $1.3 million in payments to 70 OTPs for OUD treatment services that were claimed without an OUD diagnosis.[451] Of the claims paid without an OUD diagnosis code, 39 percent were for alcohol dependence, uncomplicated (F1020), 7 percent were for cocaine dependence, uncomplicated (F1420), and 5 percent were for generalized anxiety disorder (F411). As a result of these findings, OIG recommended that CMS ''develop billing requirements for OTPs to include OUD diagnosis codes on claims for OUD treatment services to indicate that enrollees have OUD diagnoses and consider working with MACs to implement a system edit to ensure that OTP payments are made for enrollees only when OUD diagnosis codes are included on claims.'' OIG also stated that ''requiring OTPs to include OUD diagnosis codes on claims could be a way for CMS to monitor whether OTPs furnished OUD treatment services to enrollees who had an OUD.'' In our response to the OIG report, we raised that the lack of an OUD diagnosis code on a claim is not conclusive evidence of an improper claim because an OUD diagnosis code is not required for payment when an OTP submits a claim for OUD treatment services. However, we agreed to explore ways to educate providers about including an OUD diagnosis on claims.

We continue to monitor claims paid by Medicare to OTPs for furnishing OUD treatment services, including for potential fraud and abuse. In analyzing our claims data at the beginning of CY 2024, we found data indicating that the majority of claims paid to OTPs have an OUD diagnosis code appended, meaning that only a small number of OTPs do not append an OUD diagnosis code to claims. However, we do intend to ensure that payments made to OTPs are in alignment with statutory requirements, which is that payments made must be for services furnished for the treatment of an OUD.

Therefore, we are clarifying that all claims submitted to Medicare, on Form CMS–1450 for institutional providers, and on Form CMS–1500 for professional providers, or the electronic equivalents, under the OTP benefit must include an OUD diagnosis. These diagnosis codes must apply to HCPCS G-codes representing both the bundled payments (G2067 through G2075) and add-on codes to the bundled payments (G2076–G2080, G2215–G2216, G1028, and G0137). Applicable diagnosis codes for an OUD that must be submitted on claims include ICD–10–CM codes in the F11 range for ''disorders related or resulting from abuse or misuse of opioids.'' [452] CMS plans to issue additional guidance on appending these diagnosis codes to claims. We believe clarifying these billing requirements is consistent with CMS's strategic pillars to be a responsible steward of public funds,[453] and that these requirements are consistent with statutory provisions under sections 1861(s)(2)(HH), 1861(jjj)(1), and 1834 of the Act.

G. Medicare Shared Savings Program

1. Executive Summary and Background

a. Purpose

Eligible groups of providers and suppliers, including physicians, hospitals, and other healthcare providers, may participate in the Medicare Shared Savings Program (Shared Savings Program) by forming or joining an accountable care organization (ACO) and in so doing agree to become accountable for the total cost and quality of care provided under Traditional Medicare to an assigned population of Medicare fee-for-service (FFS) beneficiaries. Under the Shared Savings Program, providers and suppliers that participate in an ACO continue to receive Traditional Medicare FFS payments under Parts A and B, and the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements, and in some instances may be required to share in losses if it increases health care spending.

As of January 1, 2024, the Shared Savings Program has 480 ACOs with over 634,000 health care providers and organizations providing care to over 10.8 million assigned beneficiaries, making it the largest value-based care program in the country.[454] [455] The policy changes to the Shared Savings Program finalized in the CY 2023 PFS final rule (87 FR 69777 through 69979) and CY 2024 PFS final rule (88 FR 79093 through 79232) are expected to grow participation in the program and increase the number of beneficiaries assigned to ACOs by up to four million in the next 10 years (that is, between 2024–2034).[456] These policies are expected to drive growth in participation, particularly in rural and underserved areas, promote equity, and advance alignment across accountable care initiatives, and are central to achieving CMS' goal of having 100 percent of people with Traditional Medicare in a care relationship with accountability for quality and total cost of care by 2030.[457] Of note, 19 newly formed ACOs in the Shared Savings Program are participating in a new, permanent payment option beginning in 2024 that is enabling these ACOs to receive more than $20 million in advance investment payments (AIPs) for caring for underserved communities.[458] ACOs are now delivering care to people with Traditional Medicare in 9,032 Federally Qualified Health Centers, Rural Health Clinics, and critical access hospitals, an increase of 27 percent from 2023.[459]

Section III.G. of this proposed rule addresses changes to the Shared Savings Program regulations to further advance Medicare's value-based care strategy of growth, alignment, and equity and includes changes to allow for timely improvements to program policies and operations.

We are proposing modifications to the Shared Savings Program to require ACOs, beginning in performance year 2025 and subsequent performance years, to report the APM Performance Pathway (APP) Plus quality measure set proposed in section III.G.4. of this proposed rule. The APP Plus quality measure set would incrementally grow to comprise of eleven measures, consisting of the six measures in the existing APP quality measure set and five newly proposed

[451] *https://oig.hhs.gov/oas/reports/region9/92203005.asp.*

[452] *https://www.icd10data.com/ICD10CM/Codes/F01–F99/F10-F19/F11-.*

[453] *https://www.cms.gov/about-cms/what-we-do/cms-strategic-plan.*

[454] Refer to CMS, Shared Savings Program Fast Facts—As of January 1, 2024, available at *https://www.cms.gov/files/document/2024-shared-savings-program-fast-facts.pdf.*

[455] See CMS Press Release, ''Participation Continues to Grow in CMS' Accountable Care Organization Initiatives in 2024'', January 29, 2024, available at *https://www.cms.gov/newsroom/press-releases/participation-continues-grow-cms-accountable-care-organization-initiatives-2024.*

[456] Refer to 87 FR 69889. See also, CMS Press Release, ''CMS Announces Increase in 2023 in Organizations and Beneficiaries Benefiting from Coordinated Care in Accountable Care Relationship'', January 17, 2023, available at *https://www.cms.gov/newsroom/press-releases/cms-announces-increase-2023-organizations-and-beneficiaries-benefiting-coordinated-care-accountable.*

[457] For a description of CMS' strategic vision and objectives, see Seshamani M, Fowler E, Brooks-LaSure C. ''Building On The CMS Strategic Vision: Working Together For A Stronger Medicare''. Health Affairs. January 11, 2022. Available at *https://www.healthaffairs.org/content/forefront/building-cms-strategic-vision-working-together-stronger-medicare.* See also, CMS, Innovation Center Strategy Refresh, available at *https://innovation.cms.gov/strategic-direction-whitepaper* (Innovation Center Strategic Objective 1: Drive Accountable Care, pages 13–17).

[458] Refer to CMS Press Release, ''Participation Continues to Grow in CMS' Accountable Care Organization Initiatives in 2024'', January 29, 2024, available at *https://www.cms.gov/newsroom/press-releases/participation-continues-grow-cms-accountable-care-organization-initiatives-2024.*

[459] Ibid.

measures from the Adult Universal Foundation measure set that would be incrementally incorporated into the APP Plus quality measure set over performance years 2025 through 2028. We are also proposing to focus the collection types available to Shared Savings Program ACOs for reporting the APP Plus quality measure set to eCQMs and Medicare CQMs. In adopting the APP Plus quality measure set, we are also proposing several changes to the methodology for calculating the MIPS Quality performance category score for Shared Savings Program ACOs reporting the APP Plus quality measure set. These include proposing that Shared Savings Program ACOs that report the APP Plus quality measure set and MIPS eligible clinicians, groups, and APM Entities that choose to report the APP Plus quality measure set, will be required to report on all measures in the APP Plus quality measure set, as applicable; establishing a Complex Organization Adjustment for Virtual Groups and APM Entities, including Shared Savings Program ACOs, when reporting eCQMs; and scoring Medicare CQMs using flat benchmarks in their first 2 performance periods in MIPS. Additionally, we are proposing to extend the eCQM reporting incentive for meeting the Shared Savings Program quality performance standard to performance year 2025 and subsequent performance years. Collectively, these proposals aim to align the quality measures that Shared Savings Program ACOs would be required to report with the quality measures under the Adult Universal Foundation measure set incrementally beginning in performance year 2025 and prioritize the eCQM collection type as the gold standard collection type that underlies CMS' Digital Quality Measurement Strategic Roadmap while using Medicare CQMs as the transition step on our building block approach for ACOs' progress to adopt digital quality measurement.

We propose to establish a new ''prepaid shared savings'' option to assist eligible ACOs with a history of earning shared savings. Eligible ACOs that apply and are approved to receive prepaid shared savings will receive advances of earned shared savings that they can use to make investments that would aid beneficiaries, such as investments in direct beneficiary services and investments to improve care coordination through staffing or healthcare infrastructure. At least 50 percent of prepaid shared savings would be reserved to be spent on direct beneficiary services not otherwise payable in Traditional Medicare, such as meals, dental, vision, hearing, and Part B cost-sharing support. Additionally, up to 50 percent of the prepaid shared savings can be spent on staffing and infrastructure. Further, we propose refinements to advance investment payment policies to allow ACOs receiving advance investment payments to voluntarily terminate from the payment option while remaining in the Shared Savings Program, and to specify that if CMS terminates an ACO's participation agreement, the ACO must repay any outstanding advance investment payments it received.

We propose modifications to the Shared Savings Program's financial methodology to encourage ACO participation in the Shared Savings Program by removing barriers for ACOs serving underserved communities, and by providing greater specificity and clarification on how CMS would perform certain financial calculations in the Shared Savings Program. We would ensure the benchmarking methodology includes sufficient incentive for ACOs serving underserved communities [460] to enter and remain in the program through the application of a proposed health equity benchmark adjustment. We propose to specify a calculation methodology to account for the impact of improper payments in recalculating expenditures and payment amounts used in Shared Savings Program financial calculations, upon reopening a payment determination pursuant to § 425.315(a). We propose to establish a methodology for excluding payment amounts for HCPCS and CPT codes exhibiting significant, anomalous, and highly suspect billing activity during CY 2024 or subsequent calendar years that warrant adjustment. We also propose modifications to provide clarity on the methodology for capping the ACO's risk score growth and regional risk score growth. Additionally, building off of a comment solicitation in CY 2024 PFS rulemaking, through a new request for information in this proposed rule, we are seeking comments on financial arrangements that could allow for higher risk and potential reward under a revised ENHANCED track within the Shared Savings Program, including the designs of and trade-offs between financial model features.

We are proposing changes in connection with Shared Savings Program eligibility requirements and application procedures. To better align program policies with our goal of increasing the number of beneficiaries in an accountable care relationship with a health care provider, we propose to sunset the requirement that CMS terminates the participation agreement if the ACO's population is not at least 5,000 by the end of the performance year specified by CMS in its request for a Corrective Action Plan (CAP) while continuing to require ACOs to meet the minimum threshold of 5,000 assigned beneficiaries to begin a new agreement. We are proposing to update provisions of the Shared Savings Program regulations on application procedures to reflect the latest approach Antitrust Agencies (the Department of Justice and the Federal Trade Commission [461]) use to evaluate ACOs and enforce the antitrust laws. We are proposing changes to the Shared Savings Program beneficiary assignment methodology, to revise the definition of primary care services to align with payment policy proposals described elsewhere in this proposed rule, and to broaden the existing exception to the program's voluntary alignment policy to allow for beneficiaries to be assigned to entities participating in certain Innovation Center ACO models.

We propose modifications to the beneficiary information notification requirements under § 425.312(a)(2)(v)(A) to reduce administrative burden on ACOs while maintaining beneficiary protections. First, we propose to modify the requirements for the timing of the follow-up communication to a beneficiary who has received the standardized written notice under § 425.312(a)(2)(iii) or (iv). Under the proposed approach, an ACO would be required to provide the follow-up communication within 180 days from the date the standardized written notice was provided, as opposed to no later than the earlier of the beneficiary's next primary care service visit or 180 days

[460] As described in the *CMS Framework for Health Equity* and consistent with Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (86 FR 7009), the term ''underserved communities'' refers to populations sharing a particular characteristic, including geographic communities that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life, as exemplified in the definition of ''equity.''

[461] Refer to Withdrawn Final Policy Statement, ''Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program,'' available at *https://www.justice.gov/sites/default/files/atr/legacy/2011/10/20/276458.pdf*. See also, FTC Press Release, ''Federal Trade Commission Withdraws Health Care Enforcement Policy Statements'', July 14, 2023, available at *https://www.ftc.gov/news-events/news/press-releases/2023/07/federal-trade-commission-withdraws-health-care-enforcement-policy-statements*.

from the date the standardized written notice was provided. In addition, we propose to modify § 425.312(a)(2)(iii) to require ACOs under preliminary prospective assignment with retrospective reconciliation to provide the standardized written notification to a subset of the Medicare FFS beneficiary population that is more likely to be assigned to the ACO, when compared to the population of beneficiaries who must receive the written notification under current § 425.312(a)(2)(iii). If finalized, this proposal would reduce the burden on ACOs and confusion for beneficiaries resulting from the current requirement under which ACOs are required to send this notification to a greater number of beneficiaries who may not ultimately be assigned to the ACO.

b. Statutory and Regulatory Background on the Shared Savings Program

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted, followed by enactment of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) on March 30, 2010, which amended certain provisions of the Patient Protection and Affordable Care Act (hereinafter collectively referred to as ''the Affordable Care Act''). Section 3022 of the Affordable Care Act amended Title XVIII of the Act (42 U.S.C. 1395 *et seq.*) by adding section 1899 of the Act to establish the Medicare Shared Savings Program to facilitate coordination and cooperation among healthcare providers to improve the quality of care for Medicare FFS beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. (See 42 U.S.C. 1395jjj.)

Section 1899 of the Act has been amended through subsequent legislation. The requirements for assignment of Medicare FFS beneficiaries to ACOs participating under the program were amended by the 21st Century Cures Act (the CURES Act) (Pub. L. 114–255). The Bipartisan Budget Act of 2018 (Pub. L. 115–123), further amended section 1899 of the Act to provide for the following: expanded use of telehealth services by physicians or practitioners participating in an applicable ACO to furnish services to prospectively assigned beneficiaries; greater flexibility in the assignment of Medicare FFS beneficiaries to ACOs by allowing ACOs in tracks under retrospective beneficiary assignment a choice of prospective assignment for the agreement period; permitting Medicare FFS beneficiaries to voluntarily identify an ACO professional as their primary care provider and requiring that such beneficiaries be notified of the ability to make and change such identification, and mandating that any such voluntary identification will supersede claims-based assignment; and allowing ACOs under certain two-sided models to establish CMS-approved beneficiary incentive programs.

The Shared Savings Program regulations are codified at 42 CFR part 425. The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (76 FR 67802) (hereinafter referred to as the ''November 2011 final rule'')). A subsequent major update to the program rules appeared in the June 9, 2015 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (80 FR 32692) (hereinafter referred to as the ''June 2015 final rule'')). The final rule entitled ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations,'' which addressed changes related to the program's financial benchmark methodology, appeared in the June 10, 2016 **Federal Register** (81 FR 37950) (hereinafter referred to as the ''June 2016 final rule''). A final rule, ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program—Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program—Accountable Care Organizations—Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act'', appeared in the November 23, 2018 **Federal Register** (83 FR 59452) (hereinafter referred to as the ''November 2018 final rule'' or the ''CY 2019 PFS final rule''). In the November 2018 final rule, we finalized a voluntary 6-month extension for existing ACOs whose participation agreements would otherwise expire on December 31, 2018; allowed beneficiaries greater flexibility in designating their primary care provider and in the use of that designation for purposes of assigning the beneficiary to an ACO if the clinician they align with is participating in an ACO; revised the definition of primary care services used in beneficiary assignment; provided relief for ACOs and their clinicians impacted by extreme and uncontrollable circumstances in performance year 2018 and subsequent years; established a new Certified Electronic Health Record Technology (CEHRT) use threshold requirement; and reduced the Shared Savings Program quality measure set from 31 to 23 measures (83 FR 59940 through 59990 and 59707 through 59715).

A final rule redesigning the Shared Savings Program appeared in the December 31, 2018 **Federal Register** (Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Uncontrollable Circumstances Policies for Performance Year 2017; final rule (83 FR 67816) (hereinafter referred to as the ''December 2018 final rule'')). In the December 2018 final rule, we finalized a number of policies for the Shared Savings Program, including a redesign of the participation options available under the program to encourage ACOs to transition to two-sided models; new tools to support coordination of care across settings and strengthen beneficiary engagement; and revisions to ensure rigorous benchmarking.

In the interim final rule with comment period (IFC) entitled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,'' which was effective on the March 31, 2020 date of display and appeared in the April 6, 2020 **Federal Register** (85 FR 19230), we removed the restriction that prevented the application of the Shared Savings Program extreme and uncontrollable circumstances policy for disasters that occur during the quality reporting period if the reporting period is extended to offer relief under the Shared Savings Program to all ACOs that may be unable to completely and accurately report quality data for 2019 due to the PHE for COVID–19 (85 FR 19267 and 19268).

In the IFC entitled ''Medicare and Medicaid Programs; Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program,'' which was effective on May

8, 2020, and appeared in the May 8, 2020 **Federal Register** (85 FR 27573 through 27587) (hereinafter referred to as the ''May 8, 2020 COVID–19 IFC''), we modified Shared Savings Program policies to: (1) allow ACOs whose agreement periods expired on December 31, 2020, the option to extend their existing agreement period by 1-year, and allow ACOs in the BASIC track's glide path the option to elect to maintain their current level of participation for performance year 2021; (2) adjust program calculations to remove payment amounts for episodes of care for treatment of COVID–19; and (3) expand the definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication. We also clarified the applicability of the program's extreme and uncontrollable circumstances policy to mitigate shared losses for the period of the PHE for COVID–19 starting in January 2020.

We have also made use of the annual CY PFS rules to address quality reporting for the Shared Savings Program and certain other issues. For summaries of certain policies finalized in prior PFS rules, refer to the CY 2020 PFS proposed rule (84 FR 40705), the CY 2021 PFS final rule (85 FR 84717), the CY 2022 PFS final rule (86 FR 65253 and 65254), the CY 2023 PFS final rule (87 FR 69779 and 69780), and the CY 2024 PFS final rule (88 FR 79094 and 79095). In the CY 2024 PFS final rule (88 FR 79093 through 79232), we finalized changes to Shared Savings Program policies, including to: continue to move ACOs toward digital measurement of quality by revising the quality performance standard and reporting requirements under the APP within the Quality Payment Program (QPP); add a third step to the step-wise beneficiary assignment methodology under which we use an expanded period of time to identify whether a beneficiary has met the requirement for having received a primary care service from a physician who is an ACO professional in the ACO to allow additional beneficiaries to be eligible for assignment, as well as related changes to how we identify assignable beneficiaries used in certain Shared Savings Program calculations; update the definition of primary care services used for purposes of beneficiary assignment to remain consistent with billing and coding guidelines; refine the financial benchmarking methodology for ACOs in agreement periods beginning on January 1, 2024, and in subsequent years to (1) cap the risk score growth in an ACO's regional service area when calculating regional trends used to update the historical benchmark at the time of financial reconciliation for symmetry with the cap on ACO risk score growth, (2) apply the same CMS–HCC risk adjustment methodology applicable to the calendar year corresponding to the performance year in calculating risk scores for Medicare FFS beneficiaries for each benchmark year, (3) further mitigate the impact of the negative regional adjustment on the benchmark to encourage participation by ACOs caring for medically complex, high-cost beneficiaries, and (4) specify the circumstances in which CMS would recalculate the prior savings adjustment for changes in values used in benchmark calculations due to compliance action taken to address avoidance of at-risk beneficiaries, or as a result of the issuance of a revised initial determination of financial performance for a previous performance year following a reopening of ACO shared savings and shared losses calculations; refine our policies for the newly established advance investment payments (AIP); make updates to other programmatic areas including the program's eligibility requirements; and make timely technical changes to the regulations for clarity and consistency. Further, we also summarized comments received in response to a comment solicitation on potential future developments to Shared Savings Program policies, including incorporating a track with higher risk and potential reward than the ENHANCED track.

Policies applicable to Shared Savings Program ACOs for purposes of quality reporting for other programs have also continued to evolve based on changes in the statute. For instance, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) established the Quality Payment Program. In the CY 2017 Quality Payment Program final rule with comment period (81 FR 77008), we established regulations for the MIPS and Advanced APMs and related policies applicable to eligible clinicians who participate in APMs, including the Shared Savings Program. We have also made updates to policies under the Quality Payment Program through the annual CY PFS rules.

c. Summary of Shared Savings Program Proposals

In sections III.G.2. through III.G.8. of this proposed rule, we propose modifications to the Shared Savings Program's policies, and describe comment solicitations. As a general summary, we are proposing the following changes to Shared Savings Program policies to:

- Update Shared Savings Program eligibility requirements and application procedures, including the following (section III.G.2 of this proposed rule):

++ Update compliance obligations for the requirement that ACOs maintain at least 5,000 assigned beneficiaries by the end of the performance year specified by CMS in its request for a CAP (section III.G.2.b of this proposed rule).

++ Revise the requirement that newly formed ACOs must agree to allow CMS to share a copy of their application with the Antitrust Agencies (section III.G.2.c of this proposed rule).

- Revise the policies for determining beneficiary assignment, including the following (section III.G.3 of this proposed rule):

++ Update the definition of primary care services used in beneficiary assignment at § 425.400(c) (section III.G.3.a of this proposed rule).

++ Revise the Shared Savings Program regulations to broaden a limited exception to the program's voluntary alignment policy and allow a voluntarily aligned Shared Savings Program beneficiary to be claims-based assigned to an entity participating in a disease- or condition-specific CMS Innovation Center model when that model uses claims-based assignment that is based on primary care and/or other services and the Secretary has determined that a waiver is necessary solely for purposes of testing the model, in order for beneficiaries with certain diseases or conditions to benefit from the focused attention and care coordination related to the disease or condition that an entity participating in such a model can offer (section III.G.3.b of this proposed rule).

- Revise the quality reporting and the quality performance standard requirements, including the following (section III.G.4. of this proposed rule):

++ Propose to require Shared Savings Program ACOs to report the APP Plus quality measure set (section III.G.4.b.(2)(a) of this proposed rule).

++ Propose to focus the collection types available to Shared Savings Program ACOs for reporting the APP Plus quality measure set to eCQMs and Medicare CQMs (section III.G.4.b.(2)(b) of this proposed rule).

++ Propose that Shared Savings Program ACOs that report the APP Plus quality measure set and MIPS eligible clinicians, groups, and APM Entities that choose to report the APP Plus quality measure set, will be required to report on all measures in the APP Plus

quality measure set, as applicable (section III.G.4.c.(2)(a) of this proposed rule).

++ Propose to establish a Complex Organization Adjustment for Virtual Groups and APM Entities, including Shared Savings Program ACOs, when reporting eCQMs (section III.G.4.c.(2)(b) of this proposed rule).

++ Propose to score Medicare CQMs using flat benchmarks in their first two performance periods in MIPS (section III.G.4.c.(2)(c) of this proposed rule).

++ Propose to extend the eCQM reporting incentive for meeting the Shared Savings Program quality performance standard to performance year 2025 and subsequent performance years (section III.G.4.d of this proposed rule).

• Allow eligible ACOs to receive prepaid shared savings (section III.G.5 of this proposed rule).

• Refine AIP policies, including the following (section III.G.6 of this proposed rule):

++ Allow ACOs receiving advance investment payments to voluntarily terminate from the payment option while remaining in the Shared Savings Program (section III.G.6.a of this proposed rule).

++ Codify a policy for recouping advance investment payments from ACOs whose participation agreements are terminated by CMS (section III.G.6.b of this proposed rule).

• Revise the policies on the Shared Savings Program's financial methodology, including the following (section III.G.7 of this proposed rule):

++ Apply a health equity benchmark adjustment (HEBA) which would adjust upward an ACO's historical benchmark, based on the number of beneficiaries they serve who are dually eligible or enrolled in the Medicare Part D Low-Income Subsidy (LIS). This would encourage and sustain participation by ACOs serving underserved populations that do not benefit from existing benchmark adjustments for regional efficiency or from generating prior savings (section III.G.7.b of this proposed rule).

++ Establish a calculation methodology to account for the impact of improper payments in recalculating expenditures and payment amounts used in Shared Savings Program financial calculations upon reopening a payment determination pursuant to § 425.315(a) (section III.G.7.c of this proposed rule).

++ Establish an approach to identify significant, anomalous, and highly suspect (SAHS) billing activity occurring in CY 2024 or subsequent calendar years, and specify approaches to mitigating the impact of the SAHS billing activity on Shared Savings Program financial calculations in CY 2024 or subsequent calendar years. Under the proposed approach we would exclude payment amounts from expenditure and revenue calculations for the relevant calendar year for which the SAHS billing activity is identified, as well as from historical benchmarks used to reconcile the ACO for a performance year corresponding to the calendar year for which the SAHS billing activity is identified (section III.G.7.d of this proposed rule).

++ Seek comment on establishing a higher risk/reward option than the current ENHANCED track (section III.G.7.e of this proposed rule).

++ Propose technical changes, for consistency and clarity in provisions of the Shared Savings Program regulations on financial calculations, to align and clarify the language used to describe weights applied to the growth in ACO and regional risk scores for each Medicare enrollment type, as part of the calculation for capping ACO and regional risk score growth, respectively. The weight for a given enrollment type would be equal to the product of the ACO's historical benchmark expenditures after the application any adjustment applied under § 425.652(a)(8) of the regulations (that is, the regional adjustment, prior savings adjustment or proposed HEBA (if finalized), or no adjustment) for that enrollment type and the ACO's performance year assigned beneficiary person years for that enrollment type (section III.G.7.f of this proposed rule).

• Modify beneficiary notification requirements, including the following (section III.G.8 of this proposed rule):

++ ACOs must provide the follow-up beneficiary communication no later than 180 days after the date that the ACO provided the standardized written notice to the beneficiary (section III.G.8.a of this proposed rule).

++ For ACOs that select preliminary prospective assignment with retrospective reconciliation, limit the distribution of the standardized written beneficiary information notification to beneficiaries who are more likely to be assigned to the ACO, when compared to the beneficiaries who must receive the written notification under current regulations (section III.G.8.b of this proposed rule).

Taken together, the Shared Savings Program proposals in this proposed rule are anticipated to improve ACOs' incentives to join the program and continue participating in future years and earn shared savings. The proposals are projected to reduce program spending by $260 million in total over the 10-year period 2025 through 2034. These changes are anticipated to support the goals outlined in the CY 2023 PFS final rule (87 FR 69777 through 69978) and CY 2024 PFS final rule (88 FR 79093 through 79232) for growing the program, with a particular focus on including underserved communities.

Certain policies, including both existing policies and the proposed new policies described in this proposed rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, and that do not result in program expenditures greater than those that would result under the statutory payment model. The following proposals require the use of our authority under section 1899(i) of the Act: the proposal to allow eligible ACOs to receive prepaid shared savings; the proposal to use a calculation methodology to account for the impact of improper payments in recalculating expenditures and payment amounts for certain Shared Savings Program financial calculations, upon reopening an ACO's payment determination and issuing a revised initial determination pursuant to § 425.315(a); the proposal to use a methodology for certain Shared Savings Program financial calculations to mitigate the impact of SAHS billing activity occurring in CY 2024 or subsequent calendar years; and the proposed technical changes to the provision describing how we calculate the weights applied when capping growth in regional risk scores as part of the regional component of the three-way blended benchmark update factor. As described in the Regulatory Impact Analysis in section VII. and elsewhere in this proposed rule, these proposed changes to our payment methodology are expected to improve the quality and efficiency of care and are not expected to result in a situation in which the payment methodology under the Shared Savings Program, including all policies adopted under the authority of section 1899(i) of the Act, results in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act. We will continue to reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. In the event

that we later determine that the payment model that includes policies established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

2. Eligibility Requirements and Application Procedures

a. Overview

We are proposing two modifications to the Shared Savings Program eligibility and application procedures that will be implemented for performance years beginning on or after January 1, 2025. Specifically, we propose the following, which are discussed in more detail in sections (b) and (c) below:

- Sunset the requirement after January 1, 2025, at § 425.110(b)(2) that CMS terminates the participation agreement and the ACO is not eligible to share in savings for that performance year if the ACO's assigned population is not at least 5,000 by the end of the performance year specified by CMS in its request for a CAP and
- Revise the antitrust language in the application procedures at §§ 425.202(a)(3) and 425.224(a)(3) for the Shared Savings Program.

b. Monitoring Compliance With the Requirement That ACOs Maintain at Least 5,000 Assigned Beneficiaries

Section 1899(b)(2)(D) of the Act requires participating ACOs to include primary care ACO professionals that are sufficient for the number of Medicare FFS beneficiaries assigned to the ACO and that at a minimum, the ACO shall have at least 5,000 such beneficiaries assigned to it. In the November 2011 final rule (76 FR 67808), in alignment with the statutory requirement at section 1899(b)(2)(D) of the Act, CMS established that, at a minimum, an ACO shall have at least 5,000 such beneficiaries assigned to it to be eligible to participate in the Shared Savings Program under § 425.110. We described the importance of maintaining at least 5,000 assigned beneficiaries with respect to both eligibility of the ACO to participate in the program and the statistical stability for purposes of calculating per capita expenditures and assessing financial and quality performance. We noted, however, that we understood circumstances may change during the agreement period, and that an ACO's assigned population may vary accordingly.

To enforce program requirements under § 425.110, while still recognizing that variations may occur for an ACO's assigned population, CMS generally issues a warning notice and request the ACO submit a Corrective Action Plan (CAP) should the ACO's assigned population fall below 5,000 beneficiaries. Few ACOs have had a beneficiary population that fell below 5,000. Between calendar year 2020 and 2023, based on the program's compliance monitoring review, 24 ACOs have been below this assignment threshold at the start of one or more performance years within an agreement period, which led CMS to issue compliance actions. Approximately 55 percent of these ACOs opted to voluntarily terminate ahead of the CAP deadline imposed by CMS, while approximately 40 percent were able to increase their beneficiary assignment over the threshold and remain in the program. Given additional time, more ACOs likely would be able to increase their beneficiary assignment, keeping more beneficiaries in accountable care relationships, and maintain their participation in the Shared Savings Program.

Separately, we had established a policy in the December 2018 final rule (83 FR 67925) providing for an ACO to select the Minimum Savings Rate (MSR)/Minimum Loss Rate (MLR) that CMS would use when performing shared savings and shared losses calculations for the ACO. As we have previously discussed, the MSR/MLR protects against an ACO earning shared savings or being liable for shared losses when the change in expenditures represents normal, or random, variation rather than an actual change in performance (see, for example, 83 FR 67923 through 67926).

In the December 2018 final rule (83 FR 67925 through 67929), we revised § 425.110(b) to provide for the use of a variable MSR/MLR when performing shared savings and shared losses calculations if an ACO's assigned beneficiary population fell below 5,000 for the performance year regardless of whether the ACO had previously selected a fixed or variable MSR/MLR. This policy protects the statistical stability of the program's expenditure calculations. As an ACO's assigned beneficiary population decreases, variability in the population's expenditures increases. We thus expressed concern that the reduction in the size of the ACO's assigned beneficiary population would cause shared savings payments made to the ACO to not reflect true cost savings, but normal expenditure fluctuations (83 FR 67926). The use of a variable MSR/MLR thus made it more difficult for an ACO under performance-based risk that falls below the 5,000-beneficiary threshold to earn shared savings or be responsible for shared losses to ensure that the savings or losses reflected the ACO's actual performance and not merely statistical noise. This policy provided additional protection to the Medicare Trust Funds and greater protection for ACOs against owing shared losses.

As described above, an ACO's failure to maintain at least 5,000 assigned beneficiaries may result in compliance actions, up to and including termination of the ACO from the Shared Savings Program. When originally developed, this program policy was intended in part to protect both CMS and the ACO from variability in the expenditure calculations caused by a small assigned beneficiary population. With the MSR and MLR adjustments finalized in the December 2018 final rule, we developed protections against issues with the benchmark calculation for ACOs with fewer assigned beneficiaries, which provide adequate protection against variability in the short term. The MSR and MLR sliding scale varies based on the number of beneficiaries assigned to the ACO from 1 up to 60,000. Currently, this adjustment to the MSR/MLR protects both CMS and the ACO from inappropriate over or underpayments, reducing the financial risk of allowing ACOs to continue to participate in the Shared Savings Program if they experience a reduction in assigned beneficiaries.

In light of the effectiveness of the variable MSR/MLR policy described above, we are proposing to sunset the requirement at § 425.110(b)(2) that CMS will terminate an ACO's participation agreement and determine that an ACO is not eligible to share in savings for that performance year if an ACO's assigned population is not at least 5,000 by the end of the performance year specified by CMS in its request for a CAP. Specifically, we propose to revise § 425.110(b)(2) to limit its application to performance years starting before January 1, 2025. Thus, for performance years beginning on or after January 1, 2025, if the ACO's assigned population is not at least 5,000 by the end of the performance year specified by CMS in its request for a CAP, CMS will not be required to terminate the participation agreement.

This proposal would not modify the requirement at § 425.110(a), which implements the statutory requirement at section 1899(b)(2)(D) of the Act that ACOs have 5,000 beneficiaries at critical points in CMS's determination of the

ACO's eligibility to participate in the Shared Savings Program, including: at the time of application in order to be eligible for the Shared Savings Program, and at any point when an ACO elects to renew its participation in the program. As discussed in the November 2011 final rule (76 FR 67808), CMS has found ''[a] minimum threshold is important with respect to both the eligibility of the ACO to participate in the program and to the statistical stability for purposes of calculating per capita expenditures and assessing quality performance''. A 5,000 beneficiary minimum, paired with a variable MSR/MLR, enables ACOs to have their work of improving beneficiary care best reflected in their financial performance and shared savings results. Additionally, we would retain § 425.110(b), which states that an ACO may be subject to actions under §§ 425.216 and 425.218 if its assigned population falls below 5,000 at any time during the performance year. This proposed approach provides CMS with additional flexibility in the compliance actions that we take in working with ACOs to help them return to the 5,000 beneficiary threshold.

The proposed modification aligns with CMS's broader goals to expand the number of beneficiaries in accountable care relationships. We anticipate this flexibility will provide ACOs with additional time and opportunities to recruit additional providers and suppliers to increase their assigned beneficiary population rather than being required to exit the Shared Savings Program due to their beneficiary attribution. We seek comment on this proposal. If finalized, this proposed change would be effective beginning on January 1, 2025.

c. Update Antitrust Language

Section 425.202(a)(3) requires that ACOs that are newly formed after March 23, 2010, agree to allow CMS to share a copy of their application with the Antitrust Agencies (the Federal Trade Commission (FTC) and the Department of Justice (DOJ), as defined in the Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program). This policy has been in effect since the enactment of the November 2011 final rule (76 FR 67822). We stated at the time that this policy was in the public interest to harmonize the eligibility criteria for ACOs that wished to participate in the Shared Savings Program with similar antitrust criteria on clinical integration, because competition among ACOs was expected to have significant benefits for Medicare beneficiaries.

In 2023, both the DOJ and the FTC withdrew the outdated Antitrust Enforcement Policy Statement because the policy no longer served its intended purpose of providing useful guidance to market participants.[462] Instead, both Antitrust Agencies have stated that they will continue to vigorously enforce the antitrust laws in the health care markets by evaluating mergers and conduct that harm competition on a case-by-case basis.

As a result, we propose to modify the Shared Savings Program eligibility requirements that will be implemented on January 1, 2025, by removing the reference to the Antitrust Enforcement Policy Statement in § 425.202(a)(3), and also in § 425.224(a)(3). This proposal aligns the Shared Savings Program with the Antitrust Agencies' decisions to withdraw the Antitrust Enforcement Policy Statement. We propose to edit § 425.202(a)(3) to state, ''An ACO that seeks to participate in the Shared Savings Program must agree that CMS can share a copy of their application with the Antitrust Agencies.'' Similarly, we propose to edit § 425.224(a)(3) to state, ''An ACO that seeks to enter a new participation agreement under the Shared Savings Program must agree that CMS can share a copy of its application with the Antitrust Agencies.'' We also plan to remove guidance from the Shared Savings Program website detailing how an ACO could calculate their share of services in each applicable Primary Service Area (PSA), as described in the Antitrust Policy Statement, as this is no longer useful to ACOs.

As we stated in 76 FR 67822, we intend to coordinate closely with the Antitrust Agencies throughout the application process and the operation of the Shared Savings Program to ensure there are no detrimental impacts to competition. CMS will share application and participation information including aggregate claims data regarding allowed charges and fee-for-service payments for all ACOs accepted in the Shared Savings Program, with the Antitrust Agencies needed to further any investigations or support their enforcement of the antitrust laws.

We seek comment on this proposal. If finalized, this proposed change would be effective beginning on January 1, 2025.

3. Beneficiary Assignment Methodology

a. Proposed Revisions to the Definition of Primary Care Services

(1) Background

Section 1899(c)(1) of the Act, as amended by the CURES Act and the Bipartisan Budget Act of 2018, provides that for performance years beginning on or after January 1, 2019, the Secretary shall assign beneficiaries to an ACO based on their utilization of primary care services provided by a physician who is an ACO professional and all services furnished by Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs). However, the statute does not specify a list of services considered to be primary care services for purposes of beneficiary assignment.

In the November 2011 final rule (76 FR 67853), we established the initial list of services, identified by Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes, that we considered to be primary care services. In that final rule, we indicated that we intended to monitor CPT and HCPCS codes and would consider making changes to the definition of primary care services to add or delete codes used to identify primary care services if there were sufficient evidence that revisions were warranted. We have updated the list of primary care service codes in subsequent rulemaking (refer to 80 FR 32746 through 32748; 80 FR 71270 through 71273; 82 FR 53212 and 53213; 83 FR 59964 through 59968; 85 FR 27582 through 27586; 85 FR 84747 through 84756; 85 FR 84785 through 84793; 86 FR 65273 through 65279; 87 FR 69821 through 69825; 88 FR 79163 through 79174) to reflect additions or modifications to the codes that have been recognized for payment under the PFS and to incorporate other changes to the definition of primary care services for purposes of the Shared Savings Program. For the performance year beginning on January 1, 2024, and subsequent performance years, we defined primary care services for purposes of assigning beneficiaries to ACOs under § 425.402 in § 425.400(c)(1)(viii).

(2) Proposed Revisions

Based on feedback from ACOs and our further review of the HCPCS and CPT codes that are currently recognized

[462] U.S. Department of Justice, Press Release, *Justice Department Withdraws Outdated Enforcement Policy Statements* (Feb. 3, 2023), available at *https://www.justice.gov/opa/pr/justice-department-withdraws-outdated-enforcement-policy-statements;* Federal Trade Commission, Press Release, *Federal Trade Commission Withdraws Health Care Enforcement Policy Statements* (July 14, 2023), available at *https://www.ftc.gov/news-events/news/press-releases/2023/07/federal-trade-commission-withdraws-health-care-enforcement-policy-statements.*

for payment under the PFS or that we are proposing to recognize for payment starting in CY 2025, we believe it would be appropriate to amend the definition of primary care services used in the Shared Savings Program assignment methodology to include certain additional codes for the performance year starting on January 1, 2025, and subsequent performance years, in order to remain consistent with billing and coding under the PFS.

We propose to specify a revised definition of primary care services used for assignment in a new provision of the Shared Savings Program regulations at § 425.400(c)(1)(ix) to include the list of HCPCS and CPT codes specified in § 425.400(c)(1)(viii), as well as the following additions: (1) Safety Planning Interventions (HCPCS code GSPI1) when the base code is also a primary care service code, if finalized under Medicare FFS payment policy; (2) Post-Discharge Telephonic Follow-up Contacts Intervention (HCPCS code GFCI1), if finalized under Medicare FFS payment policy; (3) Virtual Check-in Service (CPT code 9X091), if finalized under Medicare FFS payment policy; (4) Advanced Primary Care Management Services (HCPCS GPCM1, GPCM2, and GPCM3), if finalized under Medicare FFS payment policy; (5) Cardiovascular Risk Assessment and Risk Management Services (HCPCS codes GCDRA and GCDRM), if finalized under Medicare FFS payment policy; (6) Interprofessional Consultation Services (CPT codes 99446, 99447, 99448, 99449, 99451, 99452); (7) Direct Care Caregiver Training Services (HCPCS codes GCTD1, GCTD2 and GCTD3), if finalized under Medicare FFS payment policy; and (8) Individual Behavior Management/Modification Caregiver Training Services (HCPCS codes GCTB1 and GCTB2), if finalized under Medicare FFS payment policy.

We propose that the new provision at § 425.400(c)(1)(ix) would be applicable for use in determining beneficiary assignment for the performance year starting on January 1, 2025, and subsequent performance years.

The following provides additional information about the CPT and HCPCS codes that we are proposing to add to the definition of primary care services used for purposes of beneficiary assignment:

• *Safety Planning Interventions (SPI) (HCPCS code GSPI1 (Safety planning interventions, including assisting the patient in the identification of the following personalized elements of a safety plan: recognizing warning signs of an impending suicidal crisis; employing internal coping strategies; utilizing social contacts and social settings as a means of distraction from suicidal thoughts; utilizing family members, significant others, caregivers, and/or friends to help resolve the crisis; contacting mental health professionals or agencies; and making the environment safe; (List separately in addition to an E/M visit or psychotherapy)):* In section II.I of this proposed rule, we are proposing under the PFS to create an add-on G-code that would be billed along with an E/M visit or psychotherapy visit when safety planning interventions are personally performed by the billing practitioner in a variety of settings. Safety planning interventions involve a person working with a clinician to develop a personalized list of coping strategies and sources of support that the person could use in the event of experiencing thoughts of harm to themselves or others. This is not a suicide risk assessment, but rather, an intervention provided to people determined to have elevated risk. Safety planning interventions have also been used to reduce the risk of suicide. The basic components of a safety plan include the following: (1) recognizing warning signs of an impending suicidal crisis or actions that increase the risk of overdose; (2) employing internal coping strategies; (3) utilizing social contacts and social settings as a means of distraction from suicidal thoughts and/or taking steps to reduce the risk of suicide; (4) utilizing family members or friends to help resolve the crisis; (5) contacting mental health professionals, crisis services, or agencies; and (6) making the environment safe, including restricting access to lethal means, if applicable.

Refer to section II.I of this proposed rule for detailed, technical discussion regarding the proposed description, payment, and utilization of this HCPCS code.

In the CY 2019 PFS final rule (83 FR 59965 through 59966), we finalized the addition of prolonged evaluation and management or psychotherapy service(s) beyond the typical service time of the primary procedure (CPT codes 99354 and 99355) to the definition of primary care services used for purposes of assignment because these two codes are ''add-on codes'' that describe additional resource components of a broader service furnished in the office or other outpatient setting that are not accounted for in the valuation of the base codes. For the same reason, we believe it would be appropriate to also include HCPCS code GSPI1, if finalized under Medicare FFS policy since GSPI1 is being proposed as an add-on service to an E/M or psychotherapy visit. Evaluation and management visits are included in the definition of primary care services used for purposes of assignment and so we believe it would be appropriate to also include GSPI1, when billed with an E/M visit, in the definition of primary care services used for purposes of assignment to assign beneficiaries more accurately to ACOs participating in the Shared Savings Program. We further believe the services billed under this code reflect the types of services we expect primary care providers to provide in order to improve continuity of care. Including Safety Planning Intervention services in the definition of primary care services used for purposes of assignment would also align with the CMS Behavioral Health Strategy, the mission of which is to ensure that high-quality behavioral health services and supports are accessible to Medicare beneficiaries.

We note that, as proposed, HCPCS code GSPI1 could also be billed with psychotherapy services, which are not considered for purposes of beneficiary assignment under § 425.400(c). Therefore, we propose to include the allowed charges for HCPCS code GSPI1, for purposes of assigning beneficiaries to ACOs, only when billed with a service which is also included in the definition of primary care services.

• *Post-Discharge Telephonic Follow-up Contacts Intervention (FCI) (HCPCS code GFCI1: Post discharge telephonic follow-up contacts performed in conjunction with a discharge from the emergency department for behavioral health or other crisis encounter, per calendar month).* In section II.I of this proposed rule, we describe FCI as a specific protocol of services for individuals with suicide risk involving a series of telephone contacts between a provider and person in the weeks and sometimes months following discharge from the emergency department and other relevant care settings, that occurs when the person is in the community and is designed to reduce the risk of subsequent adverse outcomes. FCI calls are typically 10–20 minutes in duration and aim to encourage use of the Safety Plan (as needed in a crisis) and updating it to optimize effectiveness, expressing psychosocial support, and helping to facilitate engagement in any indicated follow-up care and services. We are proposing to create a monthly billing code to describe the specific protocols involved in furnishing post-discharge telephonic follow-up contacts that are performed in conjunction with a discharge from the emergency department for a crisis encounter, as a

bundled service describing four calls in a month, each lasting between 10–20 minutes. We are proposing to price this service based on a direct crosswalk to CPT code 99426 (*Principal care management; first 30 minutes of clinical staff time directed by a physician or other qualified healthcare professional*) because we believe the work would be similar in nature and intensity.

Refer to section II.I. of this proposed rule for detailed, technical discussion regarding the proposed description, payment, and utilization of this HCPCS code.

These services are similar to TCM services (CPT codes 99495 and 99496), which are included in the definition of primary care services used for purposes of assignment under § 425.400(c), in that these services help eligible people transition back to a community setting after a stay at certain facility types like TCM. Similar to the rationale described December 2014 proposed rule (79 FR 72792) and later finalized in the June 2015 final rule (80 FR 32746 through 32748) where we finalized the inclusion of TCM services in the definition of primary care services used for purposes of assignment, providing separate payment for the work of community physicians and practitioners in treating a patient following discharge from a hospital or nursing facility would ensure better continuity of care for these patients and help reduce avoidable readmissions. Therefore, we believe that FCI services should also be included in the definition of primary care services used for beneficiary assignment since FCI services are designed to assist in the transition from the emergency department into the community. We believe the services billed under this code reflect the types of services we expect primary care providers to provide in order to improve care coordination and care management. Thus, we believe that FCI services should also be included.

Further, in determining the recommended pricing for HCPCS code GFCI1, we recommend pricing this service based on a direct crosswalk to Principal Care Management (PCM) service (CPT code 99426) because we believe the work would be similar in nature, as well as time and intensity. In the CY 2021 PFS final rule (85 FR 84749), we finalized the inclusion of HCPCS codes G2064 and G2065 in the definition of primary care services used for purposes of assignment since we expect that most services billed under these codes will be billed by specialists who are focused on managing patients with a single complex chronic condition requiring substantial care management. These HCPCS codes were replaced by CPT codes 99424, 99425, 99426, and 99427 in the CY 2022 PFS final rule (86 FR 65275). PCM services (CPT codes 99424, 99425, 99426, and 99427 and HCPCS codes G2064 and G2065) are included in the definition of primary care services used for purposes of assignment and since FCI services are similar in nature, time, and intensity to PCM services, we believe it would be appropriate to include these services in the definition of primary care services used for purposes of assignment. Including FCI services in the definition of primary care services used for purposes of assignment would also align with the CMS Behavioral Health Strategy as the FCI services are designed to support beneficiaries with follow-up care related to suicide risk.

- *Virtual Check-in Service (CPT code 9X091):*

++ CPT code 9X091 (*Brief communication technology-based service (e.g., virtual check-in) by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related evaluation and management service provided within the previous 7 days nor leading to an evaluation and management service or procedure within the next 24 hours or soonest available appointment, 5–10 minutes of medical discussion*).

The CPT Editorial Panel established a new CPT code 9X091 describing a brief virtual check-in encounter that is intended to evaluate the need for a more extensive visit. The code descriptor for CPT code 9X091 mirrors that of existing HCPCS code G2012 (*Brief communication technology-based service, e.g., virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion*) and, per the CPT Editorial Panel materials, is intended to replace that code. HCPCS code G2012 is included in the Shared Savings Program definition of primary care services used for purposes of assignment.

In section II.E of this proposed rule, we are proposing separate payment for CPT code 9X091. Because the code description for CPT code 9X091 mirrors HCPCS code G2012 and because, per CPT Editorial Panel materials, is intended to replace HCPCS code G2012, we are proposing to make CPT code 9X091 separately payable under Medicare. We note we are proposing to delete HCPCS code G2012 for purposes of Medicare PFS payment policy, however, HCPCS code G2012 will continue to be included in the definition of primary care services used for purposes of assignment, consistent with how deleted CPT and HCPCS codes have been handled historically and to allow for consistency with calculating historical benchmarks.

We propose that we would include CPT code 9X091 in the definition of primary care services used for purposes of assignment as the code description of brief communication technology-based service mirrors the description of HCPCS code G2012, which is included in the definition of primary care services used for purposes of assignment since these services are furnished to established patients by physicians or qualified health care professionals that can report E/M services in lieu of an in person primary care visit (85 FR 84753). Since CPT code 9X091 is a direct replacement of HCPCS code G2012, 9X091 would be included in the definition of primary care services used for purposes of assignment, under proposed § 425.400(c)(1)(ix)(C). In the CY 2022 Physician Fee Schedule file rule (86 FR 65277 through 65279), we finalized a policy wherein we would incorporate into the definition of primary care services a permanent CPT code when it directly replaces another CPT code or a temporary HCPCS code (for example, a G-code) that is already included in the definition of primary care services for purposes of determining beneficiary assignment under the Shared Savings Program. Additionally, CPT code 9X091, per the CPT Editorial Panel materials, is intended to be reported instead of HCPCS code G2012, which is already included in the definition of primary care services used for purposes of assignment. We further believe the services billed under this code reflect the types of services we expect primary care providers to provide in order to improve care coordination and care management.

We explained that this approach would help to ensure the appropriate identification of primary care services used in the Shared Savings Program's assignment methodology by allowing for the immediate inclusion of replacement CPT codes in the determination of beneficiary assignment and lead to continuity in the assignment of beneficiaries receiving those services based on current coding. This continuity would improve predictability for ACOs, while also increasing the

consistency of care coordination for their assigned beneficiaries. We further finalized that such replacement codes would be incorporated into the definition of the primary care services for purposes of determining beneficiary assignment for the performance year, when the assignment window for a benchmark or performance year (as defined in § 425.20) includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare. CPT code 9X091 has an effective date of January 1, 2025.

• *Advanced Primary Care Management (HCPCS codes GPCM1, GPCM2, and GPCM3);*

(1) HCPCS code GPCM1: (*Advanced primary care management services provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the following elements, as appropriate:*

• Consent;

++ Inform the patient regarding availability of the service; that only one practitioner can furnish and be paid for the service during a calendar month; of the right to stop the services at any time (effective at the end of the calendar month); and that cost sharing may apply.

++ Document in patient's medical record that consent was obtained.

• *Initiation during a qualifying visit for new patients or patients not seen within 3 years;*

• *Provide 24/7 access for urgent needs to care team/practitioners, including providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent needs regardless of the time of day or day of week;*

• *Continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments;*

• *Deliver care in alternative ways to traditional office visits to best meet the patient's needs, such as home visits, and/or expanded hours;*

• *Overall comprehensive care management;*

++ Systematic needs assessment (medical and psychosocial).

++ System-based approaches to ensure receipt of preventive services.

++ Medication reconciliation, management and oversight of self-management.

• *Development, implementation, revision, and maintenance of an electronic patient-centered comprehensive care plan;*

++ Care plan is available timely within and outside the billing practice as appropriate to individuals involved in the beneficiary's care, can be routinely accessed and updated by care team/practitioner, and copy of care plan to patient/caregiver.

• *Coordination of care transitions between and among health care providers and settings, including referrals to other clinicians and follow-up after an emergency department visit and discharges from hospitals, skilled nursing facilities or other health care facilities as applicable;*

++ Ensure timely exchange of electronic health information with other practitioners and providers to support continuity of care.

++ Ensure timely follow-up communication (direct contact, telephone, electronic) with the patient and/or caregiver after an emergency department visit and discharges from hospitals, skilled nursing facilities, or other health care facilities, within 7 calendar days of discharge, as clinically indicated.

• *Ongoing communication and coordinating receipt of needed services from practitioners, home- and community-based service providers, community-based social service providers, hospitals, and skilled nursing facilities (or other health care facilities), and document communication regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors, in the patient's medical record;*

• *Enhanced opportunities for the beneficiary and any caregiver to communicate with the care team/practitioner regarding the beneficiary's care through the use of asynchronous non-face-to-face consultation methods other than telephone, such as secure messaging, email, internet, or patient portal, and other communication-technology based services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with patients, as appropriate;*

++ Ensure access to patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits).

• *Analyze patient population data to identify gaps in care and offer additional interventions, as appropriate;*

• *Risk stratify the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients;*

• *Be assessed through performance measurement of primary care quality, total cost of care, and meaningful use of Certified EHR Technology.*

(2) HCPCS code GPCM2 (*Advanced primary care management services for a patient with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the elements included in GPCM1, as appropriate*), and

(3) HCPCS code GPCM3 (*Advanced primary care management services for a patient who is a Qualified Medicare Beneficiary with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the elements included in GPCM1, as appropriate*).

In section II.G. of this proposed rule, we are proposing to establish coding and make payment under the PFS for a newly defined set of APCM services as described and defined by three HCPCS codes (GPCM1, GPCM2, and GPCM3) to recognize the resource costs associated with furnishing services using an ''advanced primary care approach'' supported by a team-based care structure under the PFS. Delivery of care using an advanced primary care model involves restructuring of the primary care team, which includes the billing practitioner and the auxiliary personnel under their general supervision, within practices. This restructuring creates several advantages for patients, and provides more broad accessibility and alternative methods for patients to communicate with their care team/practitioner about their care outside of in-person visits (for example, virtual, asynchronous interactions, such as online chat), which can lead to more timely and efficient identification of, and responses to, health care needs (for example, practitioners can route patients to the optimal clinician and

setting—to a synchronous visit, an asynchronous chat, or a direct referral to the optimal site of care). Practitioners using an advanced primary care delivery model can more easily collaborate across clinical disciplines through remote interprofessional consultations with specialists, as well as standardize condition management into evidence-based clinical workflows, which allow for closed-loop follow-up and more real-time management for patients with acute or evolving complex issues, partner on complex decisions, and personalize their patients' care plans.

Specifically, we are proposing to adopt specific coding and payment policies for APCM services for use by practitioners who are providing services under this specific model of advanced primary care, when the practitioner is the continuing focal point for all needed health care services and responsible for all primary care services.

Providing care using an advanced primary care delivery model involves resource costs associated with maintaining certain practice capabilities and continuous readiness and monitoring activities to support a team-based approach to care, where significant resources are used on virtual, asynchronous patient interactions, collaboration across clinical disciplines, and real-time management of patients with acute and complex concerns that are not fully recognized or paid for by the existing care management codes. As the delivery of primary care has evolved to embrace advanced primary care more fully, we believe that it is prudent to now adopt specific coding and payment policies to better recognize the resources involved in care management under an advanced primary care delivery model.

We are seeking to ensure that the APCM codes would fully and appropriately capture the care management and CTBS services that are characteristic of the changes in medical practice toward advanced primary care, as demonstrated in select CMS Innovation Center models. As we do for CCM and PCM services, we propose to require for APCM services that the practitioner provide an initiating visit and obtain beneficiary consent (see section II.G.2.c.(1) and II.G.2.c.(2) of this proposed rule). We are proposing to incorporate as elements of APCM services ''Management of Care Transitions'' and ''Enhanced Communications Opportunities.'' For the ''Management of Care Transitions'' APCM service element, we are proposing to specify timely follow-up during care transitions (see section II.G.2.c.(6) of this proposed rule). For the ''Enhanced Communications Opportunities'' APCM service element, we are proposing to incorporate digital access through CTBS services, such as virtual check-ins and remote evaluation of images, to maintain ongoing communication with the patient (see section II.G.2.c.(8) of this proposed rule). We are also proposing to specify for APCM services the practice-level characteristics and capabilities that we believe to be inherent to, and necessarily present when a practitioner is providing covered services using, the ''advanced primary care'' model. Included in the service descriptors for GPCM1, GPCM2, and GPCM3 are proposed practice-level capabilities that reflect care delivery using an advanced primary care model that focused around 24/7 access and continuity of care (see section II.G.2.c.(3) of this proposed rule), patient population-level management (see section II.G.2.c.(9) of this proposed rule), and performance measurement (see section II.G.2.c.(10) of this proposed rule). We believe these practice capabilities are indicative of, and necessary to, care delivery using the advanced primary care model.

Refer to section II.G. of this proposed rule for detailed, technical discussion regarding the proposed description, payment and utilization of these HCPCS codes as well as information about requirements for billing providers participating in ACOs.

As described in section II.G., HCPCS codes GPCM1 through GPCM3 would describe APCM services furnished per calendar month, following the initial qualifying visit (see section II.G.2.c.(1) for more on the initiating visit). Physicians and NPPs, including nurse practitioners (NPs), physician assistants (PAs), certified nurse midwives (CNMs) and clinical nurse specialists (CNSs), could bill for APCM services. As we describe in more detail in section II.G.2.c., within the code descriptors for GPCM1, GPCM2, and GPCM3, we are including the elements of the scope of service for APCM as well as the capabilities and requirements that we believe to be inherent to care delivery by the practitioner using an advanced primary care model, and necessary to fully furnish and, therefore, bill for APCM services.

We are proposing that the practitioner who bills for APCM services must intend to be responsible for the patient's primary care and serve as the continuing focal point for all needed health care services. We anticipate that most practitioners furnishing APCM services would be managing all the patient's health care services over the month and have either already been providing ongoing care for the patient or have the intention of being responsible for the patient's primary care and serving as the continuing focal point for all of the patient's health care services. As detailed in sections II.G.2.b. through II.G.2.d., this proposed coding and payment will incorporate elements of several specific, existing care management and communication technology-based services (CTBS) into a bundle of services, that reflects the essential elements of the delivery of advanced primary care, for payment under the PFS starting in 2025.

These new codes are designed to bundle the individual utilization of codes that are already included in the definition of primary care services used for purposes of assignment, specifically CCM (CPT codes 99437, 99487, 99489, 99490, 99491, and 99439 and HCPCS codes G0506 and G2058), PCM (CPT codes 99424, 99425, 99426, and 99427 and HCPCS codes G2064 and G2065), TCM (CPT codes 99495 and 99496), remote evaluation of patient videos/images (HCPCS code G2010), and virtual check-in and e-visits (HCPCS codes G2012 and G2252). These new codes also bundle IPC (CPT Codes 99446, 99447, 99448, 99449, 99451, 99452), which we are proposing to include in the definition of primary care services used for purposes of assignment in this section of the rule. Further, as proposed, this new APCM bundle represents a broader application of advanced primary care and incorporates elements included in care management and CTBS services. We believe the services billed under these codes reflect the types of services we expect primary care providers to provide in order to improve care coordination and care management and so it would be appropriate to include HCPCS codes GPCM1, GPCM2, and GPCM3 in the definition of primary care services used for purposes of assignment since these HCPCS codes bundle services furnished under CPT and HCPCS codes already included in the definition of primary care services used for purposes of assignment.

As described in section II.G, we anticipate that these codes would mostly be used by primary care specialties, such as general medicine, geriatric medicine, family medicine, internal medicine, and pediatrics, or in some instances, certain specialists functioning as primary care practitioners—for example, an OB/GYN or a cardiologist. Since primary care specialties, such as general medicine, geriatric medicine, family medicine, internal medicine, and pediatrics are primary care physicians (as defined in

§ 425.20) and OB/GYN or a cardiologist are two of the specialty designations (as described in § 425.402(c)) used for purposes of assignment we believe it would be appropriate to include HCPCS codes GPCM1, GPCM2, and GPCM3 in the definition of primary care services used for purposes of assignment. Inclusion of these APCM services in the definition of primary care services used for purposes of assignment would also strengthen and invest in primary care in alignment with the goals of the U.S. Department of Health and Human Services (HHS) Initiative to Strengthen Primary Care.[463] We also believe that updating the definition of primary care services used for purposes of assignment to include the APCM bundle would increase the accuracy of assignment based on the provision of primary care.

• *Cardiovascular Risk Assessment and Risk Management—*

++ *Cardiovascular Disease Risk Assessment HCPCS code GCDRA (Administration of a standardized, evidence-based Atherosclerotic Cardiovascular Disease (ASCVD) Risk Assessment for patients with ASCVD risk factors on the same date as an E/M visit, 5–15 minutes, not more often than every 12 months):* As described in section II.G. of this proposed rule, we are proposing a new stand-alone HCPCS code, GCDRA, to identify and value the work involved in administering an *ASCVD risk* assessment when medically reasonable and necessary in relation to *an E/M visit.* Atherosclerotic Cardiovascular Disease (ASCVD) Risk Assessment refers to a review of the individual's demographic factors, modifiable risk factors for CVD, and risk enhancers for CVD.

We are proposing that the ASCVD risk assessment must be furnished by the practitioner on the same date they furnish an E/M visit, as the ASCVD risk assessment would be reasonable and necessary when used to inform the patient's diagnosis, and treatment plan established during the visit. ASCVD risk assessment is reasonable and necessary for a patient who has at least one predisposing condition to cardiovascular disease that may put them at increased risk for future ASCVD diagnosis.

++ *Atherosclerotic Cardiovascular Disease Prevention Risk Management Services HCPCS code GCDRM (Atherosclerotic Cardiovascular Disease (ASCVD) risk management services with the following required elements: patient is without a current diagnosis of ASCVD, but is determined to be at medium or high risk for CVD (>15 percent in the next 10 years) as previously determined by the ASCVD risk assessment; ASCVD-Specific care plan established, implemented, revised, or monitored that addresses risk factors and risk enhancers and must incorporate shared decision-making between the practitioner and the patient; clinical staff time directed by physician or other qualified health care professional; per calendar month).* As described in section II.G of this proposed rule, over the past several years, we have worked to develop payment mechanisms under the PFS to improve the accuracy of valuation and payment for the services furnished by physicians and other healthcare professionals, especially in the context of evolving changes in medical practice using evidence-based models of care, such as the Million Hearts® model. We are proposing to establish a G-code, GCDRM, for ASCVD risk management services which refers to the development, implementation, and monitoring of individualized care plans for reducing cardiovascular risk, including shared decision-making and the use of the ''ABCS'' of cardiovascular risk reduction, as well as counseling and monitoring to improve diet and exercise.

We believe that ASCVD risk management services include continuous care and coordination to reduce or eliminate further elevation of ASCVD risk over time, and potentially prevent the development of future cardiovascular disease diagnoses or first-time heart attacks or strokes. Physicians and Non-Physician Practitioners (NPPs) who can furnish E/M services could bill for ASCVD risk management services. We anticipate that ASCVD risk management services would ordinarily be provided by clinical staff incident to the professional services of the billing practitioner in accordance with our regulation at § 410.26. We are proposing that ASCVD risk management services would be considered a ''designated care management service'' under § 410.26(b)(5) and, as such, could be provided by auxiliary personnel under the general supervision of the billing practitioner.

Refer to section II.G of this proposed rule for detailed, technical discussion regarding the proposed description, payment and utilization of HCPCS codes GCDRA and GCDRM.

Because HCPCS codes GCDRA and GCDRM are proposed to be care management services similar to CCM (CPT codes 99437, 99439, 99487, 99489, 99490, and 99491) which are included in the Shared Savings Program definition of primary care services used for purposes of assignment, we believe it would be consistent and appropriate to include GCDRA and GCDRM in the definition of primary care services used for purposes of assignment. In earlier rulemaking, we finalized the inclusion of CCM CPT codes 99487, 99489, 99490, and 99491 (codes for chronic care management) in the definition of primary care services for the Shared Savings Program. Refer to the June 2015 final rule (80 FR 32746 through 32748), CY 2018 PFS final rule (82 FR 53212 through 53213), and CY 2021 PFS final rule (85 FR 84749 through 84750 and 84754). ''Complex'' CCM services (CPT codes 99487 and 99489) and ''non-complex'' CCM services (CPT codes 99490 and 99491) share a common set of service elements, including the following: (1) Initiating visit, (2) structured recording of patient information using certified electronic health record technology (EHR), (3) 24/7 access to physicians or other qualified health care professionals or clinical staff and continuity of care, (4) comprehensive care management including systematic assessment of the patient's medical, functional, and psychosocial needs, (5) comprehensive care plan including a comprehensive care plan for all health issues with particular focus on the chronic conditions being managed, and (6) management of care transitions.

Elements of care management services include: (1) an initial visit, which can be an E/M service, Annual Wellness Visit (AWV) or initial preventive physical exam (IPPE or ''Welcome to Medicare''); (2) continuity of care with a designated practitioner; (3) comprehensive care management; (4) comprehensive care plan; (5) management of care transitions; and (6) care coordination. In the November 2011 final rule (76 FR 67852 through 67853), we finalized the inclusion of E/M services, the AWV, and the IPPE since those services aligns the definition of primary care services with the definition in section 5501 of the Affordable Care Act. Because care management, E/M services, the AWV, and the IPPE are all included in the definition of primary care services used for purposes of assignment, we believe GCDRA and GCDRM reflect the types of services we expect primary care providers to provide in order to improve care coordination and care management. Additionally, GCDRA and GCDRM are care and risk management services that

[463] Refer to: U.S. Department of Health and Human Services. (2023). HHS is Taking Action to Strengthen Primary Care. *https://www.hhs.gov/sites/default/files/primary-care-issue-brief.pdf.*

include elements of continuous and coordinated care, which the Shared Savings Program is intended to promote.

• *Interprofessional Consultation (IPC) (CPT codes 99446, 99447, 99448, 99449, 99451, 99452):* In the CY 2019 PFS final rule (83 FR 59489), CMS finalized six codes:

++ 99446 (*Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 5–10 minutes of medical consultative discussion and review*);

++ 99447 (*Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 11–20 minutes of medical consultative discussion and review*);

++ 99448 (*Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 21–30 minutes of medical consultative discussion and review*);

++ 99449 (*Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 31 minutes or more of medical consultative discussion and review*);

++ 99451 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a consultative physician including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 or more minutes of medical consultative time*); and

++ 99452 (*Interprofessional telephone/internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified health care professional, 30 minutes*).

These CPT codes describe assessment and management services conducted through telephone, internet, or electronic health record consultations furnished when a patient's treating physician or other qualified healthcare professional requests the opinion and/or treatment advice of a consulting physician or qualified healthcare professional with specific specialty expertise to assist with the diagnosis and/or management of the patient's problem without the need for the patient's face-to-face, in-person contact with the consulting physician or qualified healthcare professional. We believe that payment for these interprofessional consultations performed via communications technology such as telephone or internet is consistent with our ongoing efforts to recognize and reflect medical practice trends in primary care and patient-centered care management within the PFS. Accordingly, because these CPT codes 99446, 99447, 99448, 99449, 99451, and 99452 recognize and reflect medical practice trends in primary care and patient-centered care, we believe they should be included in the definition of primary care services used for purposes of assignment.

Beginning in the CY 2012 PFS proposed rule (76 FR 42793), we recognized the changing focus in medical practice toward managing patients' chronic conditions, many of which particularly challenge the Medicare population, including heart disease, diabetes, respiratory disease, breast cancer, allergies, Alzheimer's disease, and factors associated with obesity. Current E/M coding does not adequately reflect the changes that have occurred in medical practice, and the activities and resource costs associated with the treatment of these complex patients in the primary care setting In the years since 2012, we have acknowledged the shift in medical practice away from an episodic treatment-based approach to one that involves comprehensive patient-centered care management, and have taken steps through rulemaking to better reflect that approach in payment under the PFS. In the CY 2013 PFS final rule (77 FR 68979), we established new codes to pay separately for TCM services. Next, in the CY 2015 PFS final rule (79 FR 67715), we finalized new coding and separate payment beginning in CY 2015 for CCM services provided by clinical staff. In the CY 2017 PFS final rule (81 FR 80225), we established separate payment for complex CCM services, an add-on code to the visit during which CCM is initiated to reflect the work of the billing practitioner in assessing the beneficiary and establishing the CCM care plan and established separate payment for Behavioral Health Integration (BHI) services (81 FR 80226 through 80227). As part of this shift in medical practice, and with the proliferation of team-based approaches to care that are often facilitated by electronic medical record technology, we believe that making separate payment for interprofessional consultations undertaken for the benefit of treating a patient would contribute to payment accuracy for primary care and care management services. Refer to the CY 2019 PFS Final rule (83 FR 59489) for detailed, technical discussion regarding the description, payment and utilization of these CPT codes.

Since the services associated with CPT codes 99446, 99447, 99448, 99449, 99451, and 99452 include TCM, CCM, and BHI services, which are included in our definition of primary care services and are included in the proposed APCM bundle that we propose to be included in the definition of primary care services used for purposes of assignment, we believe that the services associated with CPT codes 99446, 99447, 99448, 99449, 99451, and 99452 should be included in the definition of primary care services for purposes of assignment. We additionally believe the services billed under this code reflect the types of services we expect primary care providers to provide in order to improve care coordination and care management. These IPC services were also designed to reimburse for comprehensive patient-centered care management and primary care, which the Shared Savings Program is intended to promote.

• *Direct Care Caregiver Training Services (HCPCS codes GCTD1, GCTD2, and* GCTD3*):* GCTD1 (*Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to-face; initial 30 minutes)*), GCTD2 (*Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service) (Use GCTD2 in conjunction with GCTD1)*), and GCTD3 (*Group caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to-face with multiple sets*

of caregivers). In section II.E. of this proposed rule, we are proposing to establish new coding and payment for caregiver training services (CTS) for direct care services and supports. The topics of training could include, but would not be limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control. Refer to section II.E. of this proposed rule for detailed, technical discussion regarding the proposed description, payment, and utilization of this HCPCS code.

Unlike other caregiver training codes that are currently paid under the PFS, the caregiver training codes for direct care services and support focus on specific clinical skills aimed at the caregiver effectuating hands-on treatment, reducing complications, and monitoring the patient. Like other codes describing caregiver training services, these proposed new codes would reflect the training furnished to a caregiver, in tandem with the diagnostic and treatment services furnished directly to the patient, in strategies and specific activities to assist the patient to carry out the treatment plan. We believe that CTS may be reasonable and necessary when they are integral to a patient's overall treatment and furnished after the treatment plan is established. The CTS themselves need to be congruent with the treatment plan and designed to effectuate the desired patient outcomes. Direct care training for caregivers of Medicare beneficiaries should be directly relevant to the person-centered treatment plan for the patient in order for the services to be considered reasonable and necessary under the Medicare program. We believe that since CTS may be integral to a patient's overall treatment and furnished after the treatment plan is established, these services should be included in the definition of primary care services for purposes of beneficiary assignment in support of the Shared Savings Program's goal to promote coordinated, high quality care to an ACO's assigned beneficiaries. In the CY 2024 PFS final rule (88 FR 79168 through 79169), we finalized the inclusion of other caregiver training services (CPT codes 96202, 96203, 97550, 97551, and 97552) in the definition of primary care services used for purposes of assignment in the Shared Savings Program. These new caregiver training services codes (HCPCS GCTD1, GCTD2, and GCTD3) are similar to the caregiver training services currently included in the Shared Savings Program definition of primary care services in that these codes allow treating practitioners to report the training furnished to a caregiver, in tandem with the diagnostic and treatment services furnished directly to the patient, in strategies and specific activities to assist the patient to carry out the treatment plan. We also believe the services billed under these codes reflect the types of services we expect primary care providers to provide in order to improve care coordination and care management.

- *Individual Behavior Management/Modification Caregiver Training Services (HCPCS codes GCTB1 and GCTB2):* GCTB1 (*Caregiver training in behavior management/modification for caregiver(s) of a patient with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; initial 30 minutes*) and GCTB2 (*Caregiver training in behavior management/modification for caregiver(s) of a patient with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service) (Use GCTB2 in conjunction with GCTB1)*). In section II.E of this proposed rule, we are proposing to establish new coding and payment for caregiver behavior management and modification training that could be furnished to the caregiver(s) of an individual patient. Behavior management/modification training for caregivers of Medicare beneficiaries should be directly relevant to the person-centered treatment plan for the patient in order for the services to be considered reasonable and necessary under the Medicare program. Each training activity should be clearly identified and documented in the treatment plan. All other policies and procedures surrounding CPT 96202 and 96203 will also apply to these services (88 FR 78914–78920). Refer to section II.E. of this proposed rule for detailed, technical discussion regarding the proposed description, payment and utilization of this HCPCS code.

We believe that, since CTS may be reasonable and necessary when they are integral to a patient's overall treatment and furnished after the treatment plan is established especially in the case of medical treatment scenarios where assistance by the caregiver receiving the CTS is necessary to ensure a successful treatment outcome for the patient, (for example when the patient cannot follow through with the treatment plan for themselves), these services should be included in the definition of primary care services for purposes of beneficiary assignment in support of the Shared Savings Program's goal to promote coordinated, high quality care to an ACO's assigned beneficiaries. In the CY 2024 PFS final rule (88 FR 79168 through 79169), we finalized the inclusion of other caregiver training services (CPT codes 96202, 96203, 97550, 97551, and 97552) in the definition of primary care services used for purposes of assignment in the Shared Savings Program. These new caregiver training services codes (HCPCS codes GCTD1, GCTD2, GCTD3, GCTB1, and GCTB2) are similar to the caregiver training services currently included in the Shared Savings Program definition of primary care services in that these codes allow treating practitioners to report the training furnished to a caregiver, in tandem with the diagnostic and treatment services furnished directly to the patient, in strategies and specific activities to assist the patient to carry out the treatment plan, which is integral to care coordination. We also believe the services billed under these codes reflect the types of services we expect primary care providers to provide in order to improve care coordination and care management.

As part of this revised definition of primary care services used for assigning beneficiaries under § 425.402, we propose to incorporate a provision in § 425.400(c)(1)(ix)(C), specifying that the primary care service codes for purposes of assigning beneficiaries include a CPT code identified by CMS that directly replaces a CPT code specified in § 425.400(c)(1)(ix)(A) or a HCPCS code specified in § 425.400(c)(1)(ix)(B), when the assignment window or expanded assignment window (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

We seek comment on these proposed changes to the definition of primary care services used for assigning beneficiaries under § 425.400(c)(1)(ix) to Shared Savings Program ACOs for the performance year starting on January 1, 2025, and subsequent performance years. We also welcome comments on any other existing HCPCS or CPT codes and new HCPCS or CPT codes proposed elsewhere in this proposed rule that we should consider adding to the definition of primary care services for purposes of assignment in future rulemaking.

b. Proposed Revisions to Criteria for ACO Models To Waive Shared Savings Program Statutory Requirements Giving Precedence for Assignment Based on Beneficiary Voluntary Alignment

(1) Background

Section 50331 of the Bipartisan Budget Act of 2018 amended section 1899(c) of the Act to add a new paragraph (2)(B) that requires the Secretary, for performance year 2018 and each subsequent performance year, to permit a Medicare FFS beneficiary to voluntarily identify an ACO professional as the primary care provider of the beneficiary for purposes of assigning such beneficiary to an ACO. A voluntary identification by a Medicare FFS beneficiary under this provision supersedes any claims-based assignment. In earlier rulemaking (81 FR 80501 through 80510 and 83 FR 59959 through 59964) CMS finalized modifications to the Shared Savings Program regulations at § 425.402(e) to implement the statutory requirements governing voluntary alignment.

In the November 2018 final rule (83 FR 59959 through 59964), we finalized changes to the beneficiary voluntary alignment policies (refer to § 425.402(e)) to revise the requirements previously established for the voluntary alignment process. We explained that it could be appropriate, in limited circumstances, to align a beneficiary to an entity participating in certain specialty and disease-specific CMS Innovation Center models to test a new system of payment and service delivery that CMS believes would lead to better health outcomes for Medicare beneficiaries while lowering costs to Medicare Parts A and B. Additionally, we explained that it could be difficult for the CMS Innovation Center to conduct a viable test of a specialty or disease-specific model, if we were to require that beneficiaries who have previously designated an ACO professional as their primary clinician remain assigned to the Shared Savings Program ACO under all circumstances. We applied this exception for the Comprehensive ESRD Care (CEC) model, which assigned beneficiaries to entities participating in the model through the beneficiaries' first treatment at a participating dialysis facility.

Currently, under § 425.402(e)(2)(ii)(D), we would not assign a beneficiary who has voluntarily identified a Shared Savings Program ACO professional to a Shared Savings Program ACO when the beneficiary is also eligible for claims-based assignment to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on claims for services other than primary care services and for which there has been a determination by the Secretary that a waiver under section 1115A(d)(1) of the Act of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the model.

(2) Proposed Revisions

Since finalization of this limited exception to the Shared Savings Program's voluntary alignment policy, disease-specific CMS Innovation Center models have been developed that use claims for both primary care services and services other than primary care in determining claims-based assignment to entities participating in these models. We believe it would be appropriate to propose to broaden this limited exception and allow a voluntarily aligned Shared Savings Program beneficiary to be claims-based assigned to an entity participating in a disease- or condition-specific CMS Innovation Center model when that model uses claims-based assignment that is based on primary care and/or other services. Disease- or condition-specific CMS Innovation Center models are designed to support condition management, coordination, and services for patients that have a specific disease or condition that often requires coordination of care across specialties and settings. For example, the CMS Innovation Center has tested disease- and condition-based episode payment models, such as those focused on oncology and kidney disease.[464] Doing so would help beneficiaries with certain diseases or conditions benefit from the focused attention and care coordination related to the disease or condition that an entity participating in such a model could provide. We would identify models for which the exception would apply in our Shared Savings and Losses and Assignment Methodology and Quality Performance Specifications document, which is located on the Shared Savings Program website, *https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos*. This proposed expanded exception would be applicable to beneficiaries assigned to entities participating in CMS Innovation Center models under which assignment is based solely on (1) claims for primary care and/or other services related to treatment of one or more specific diseases or conditions targeted by the model, or (2) claims for services other than primary care services, when the Secretary has determined that a waiver is necessary solely for purposes of testing the model.

An example of a CMS Innovation Center model whose assigned beneficiaries may be impacted by the proposed expanded exception is the Kidney Care Choices (KCC) model,[465] which is designed to help health care providers reduce the cost and improve the quality of care for patients with late-stage chronic kidney disease and ESRD. The KCC model builds on the previous CEC model [466] by adding strong financial incentives for health care providers to manage the care for Medicare beneficiaries with chronic kidney disease (CKD) stage 4 and ESRD, to delay the onset of dialysis and to incentivize kidney transplantation. Under the CEC model, the CMS Innovation Center worked with groups of health care providers, dialysis facilities, and other suppliers involved in the care of ESRD beneficiaries to improve the coordination and quality of care that these individuals received. We determined that an ESRD beneficiary, who was otherwise eligible for assignment to an entity participating in the CEC model, could benefit from the focused attention on and increased care coordination for their ESRD available under the CEC model. As described above, we created a narrow exception to the general policy that a beneficiary who had voluntarily aligned to a Shared Savings Program ACO professional would supersede their alignment to a CMS Innovation Center model. Specifically, we did not assign a beneficiary to the ACO when the beneficiary was also eligible for alignment to an entity participating in the CEC model.

KCC is more complex than CEC and is designed to capture multiple care relationships and uses a mix of E/M codes for alignment of beneficiaries with CKD and managing clinician Monthly Capitation Payments for aligning ESRD beneficiaries. The existing exception is not applicable to KCC in part because claims for primary care and other services related to the treatment of one or more specific diseases or conditions targeted by the model (chronic kidney disease (CKD) stage 4 and ESRD) are considered as part of the model's beneficiary alignment

[464] Refer to Innovation Models website: *https://www.cms.gov/priorities/innovation/models#views=models&cat=disease-specific%20&%20episode-based%20models*.

[465] Refer to *https://www.cms.gov/priorities/innovation/innovation-models/kidney-care-choices-kcc-model*.

[466] Refer to *https://www.cms.gov/priorities/innovation/innovation-models/comprehensive-esrd-care*.

methodology, which takes into consideration where a beneficiary receives the majority of their kidney care as well as the beneficiary's diagnosis of CKD stages 4 or ESRD receiving maintenance dialysis. KCC's alignment methodology could align beneficiaries receiving primary care services that are also considered for Shared Savings Program assignment if furnished and billed under one of the HCPCS/CPT codes included in § 425.400(c) by ACO professionals who are primary care physicians, physicians with one of the primary specialty designations in § 425.402(c), NPs, PAs, and/or CNSs. We note that outpatient/office E/M services are included in § 425.400(c) and that nephrology is one of the primary specialty designations under § 425.402(c) so we anticipate that, if this proposal is finalized, most, if not all, beneficiaries who voluntarily align to a physician that participates in a Shared Savings Program ACO and meet the KCC alignment criteria would be claims-based align to the KCC model, assuming there is a determination by the Secretary that waiver of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the model.

We propose expanding upon current Shared Savings Program regulations to broaden the existing exception to the program's voluntary alignment policy, which would allow the exception to apply to beneficiaries assigned to entities in a CMS Innovation Center model under which claims-based assignment is based solely on (1) claims for primary care and/or other services related to treatment of one or more specific diseases or conditions targeted by the model, or (2) claims for services other than primary care services, and for which there has been a determination by the Secretary that waiver of the requirement in section 1899(c)(2)(B) of the Act is necessary for purposes of testing the model. Under the proposed revisions, if a beneficiary voluntarily aligns to a Shared Savings Program ACO under § 425.402(e), we would not assign the beneficiary to that Shared Savings Program ACO when the beneficiary is also eligible for claims-based assignment to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on (1) claims for primary care and/or other services related to treatment of one or more specific diseases or conditions targeted by the model or (2) claims for services other than primary care service, and for which there has been a determination by the Secretary that waiver of the requirement in section 1899(c)(2)(B) of the Act is necessary for purposes of testing the model. We would not supersede voluntary alignment for CMS Innovation Center models that are not designed to target a specific disease or condition, such as ACO REACH. While ACO REACH contains design features for organizations serving high needs beneficiaries, it is designed more broadly, and not for beneficiaries with a specific disease or condition. Such models do not target a specific disease or condition. Therefore, a beneficiary's claims-based assignment to an entity participating in such a model would not supersede their voluntary alignment to a Shared Savings Program ACO under our proposal.

For example, under the KCC model, alignment is based on where a beneficiary receives the majority of their nephrology services and/or dialysis management services. Claims for those kidney care services could include claims for services that, under the Shared Savings Program's claims-based assignment policies, would lead a beneficiary to be assigned to a Shared Savings Program ACO. Since under the KCC model, claims-based assignment is based solely on claims for primary care and/or other services (kidney care services) related to the treatment of one or more specific diseases or conditions targeted by the model (chronic kidney disease (CKD) stage 4 and ESRD), our proposed exception would apply and a beneficiary who voluntarily aligned to a Shared Savings Program ACO and who received kidney care services from an entity participating in the KCC model would nonetheless be claims-based assigned to the KCC model, if there is a determination by the Secretary that waiver of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the KCC model. This proposed expansion of the voluntary alignment exception would support assignment of beneficiaries to entities participating in CMS Innovation Center models, which would reduce barriers for the CMS Innovation Center to conduct viable tests of disease-or condition-specific models and thereby improve access to high-quality, value-based specialty care, such as that provided by an entity participating in a model focused on diabetes care or care provided by specific specialists, such as cardiologists or gastroenterologists.

This proposal would also support CMS's goals of improving patient care, lowering costs, and better aligning payment systems to promote patient-centered practices through accountable and value-based care. We believe that specific subpopulations of Medicare beneficiaries who are otherwise eligible for assignment to an entity participating in a disease or condition-specific CMS Innovation Center model, but who may not be captured by § 425.402(e)(2)(ii)(D) because their models consider primary care services for purposes of assignment, could benefit from the focused attention and increased care coordination offered by an entity participating in a disease or condition-specific model. Application of this exception would require a determination from the Secretary to waive the voluntary alignment provision.

Under this proposal, if a beneficiary designated an ACO professional participating in a Shared Savings Program ACO as the physician or practitioner they consider responsible for coordinating their overall care (that is, their primary clinician), but the beneficiary is also eligible for assignment to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on (1) claims for primary care and/or other services related to treatment of one or more specific diseases or conditions targeted by the model, or (2) claims for services other than primary care services, and for which there has been a determination that a waiver of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the model, the CMS Innovation Center or its designee would notify the beneficiary of their assignment to an entity participating in the model. Additionally, although such a beneficiary may still voluntarily identify an ACO professional participating in a Shared Savings Program ACO as their primary clinician and seek care from any clinician, the beneficiary would not be assigned to a Shared Savings Program ACO even if the designated primary clinician is an ACO professional in a Shared Savings Program ACO.

For PY 2024, there are approximately 152,000 beneficiaries with a primary clinician selection who is a Shared Savings Program ACO professional as defined at § 425.20, and approximately 83,000 are voluntarily aligned to a Shared Savings Program ACO after meeting all the assignment eligibility criteria as described at § 425.401(a). Overall, this represents an exceedingly small share of the overall Shared Savings Program assigned beneficiary population, currently 10.8 million [467]

[467] Refer to *https://www.cms.gov/files/document/2024-shared-savings-program-fast-facts.pdf*.

beneficiaries. Additionally, simulating our proposed § 425.402(e)(2)(ii)(D) using PY 2024 data, less than 1 percent (703) of beneficiaries who are voluntarily aligned to a Shared Savings Program ACO would instead be claims-based assigned to an entity participating in a CMS Innovation Center model.

The benefit of allowing beneficiaries who voluntarily align to a Shared Savings Program ACO to be claims-based assigned to an entity participating in a CMS Innovation Center tailored to the needs of their specific disease or condition far outweighs any cost to the Shared Savings Program. The impact of assigning these beneficiaries to a CMS Innovation Center model notwithstanding their voluntary designation would be minimal because so few beneficiaries would be impacted by this proposed expansion of the exception (for PY 2024, less than 1 percent of all beneficiaries who voluntarily align to a Shared Savings Program ACO). As explained earlier in this section, this proposal would enable us to better test CMS Innovation Center models and ultimately improve health outcomes for Medicare beneficiaries with the specific diseases and conditions targeted by CMS Innovation Center models. We also recognize the importance of continuing to allow beneficiaries to voluntarily identify an ACO professional as their primary clinician for purposes of assignment to a Shared Savings Program ACO, and we reiterate that, based on PY 2024 data, this proposal would impact very few beneficiaries who voluntarily align to Shared Savings Program ACOs (less than .01 percent of all such beneficiaries). Beneficiaries who voluntarily align to a Shared Savings Program ACO but are, pursuant to our proposal, ultimately claims-based assigned to an entity participating in a CMS Innovation Center model would be notified of this in accordance with the CMS Innovation Center model's participation agreement. We propose to apply these modifications to our policies under the Shared Savings Program regarding voluntary alignment beginning for performance year 2025, and subsequent performance years. We propose to incorporate these new requirements into new regulations at § 425.402(e)(2)(iii). We solicit comments on this proposal.

Accordingly, since the new proposed provisions § 425.402(e)(2)(iii) will supersede the existing provisions at § 425.402(e)(2)(ii) for performance year 2025 and subsequent performance years, we propose to revise the introductory text at § 425.402(e)(2)(ii) to designate that provision's applicability for performance years starting on January 1, 2019, through 2024.

4. Quality Performance Standard & Other Reporting Requirements

a. Background

Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care. As we stated in the November 2011 final rule establishing the Shared Savings Program (76 FR 67872), our principal goal in selecting quality measures for ACOs has been to identify measures of success in the delivery of high-quality health care at the individual and population levels. In the November 2011 final rule, we established a quality measure set spanning four domains: patient experience of care and wherever practicable, caregiver experience of care, care coordination/patient safety, preventative health, and at-risk population (76 FR 67872 through 67891). We have subsequently updated the measures that comprise the quality performance measure set for the Shared Savings Program through rulemaking in the CY 2015, 2016, 2017, 2019, 2023, and 2024 PFS final rules (79 FR 67907 through 67921, 80 FR 71263 through 71268, 81 FR 80484 through 80489, 83 FR 59708 through 59715, 87 FR 69860 through 69863, and 88 FR 79112 through 79114, respectively).

b. Proposal to Require Shared Savings Program ACOs to Report the Alternative Payment Model (APM) Performance Pathway (APP) Plus Quality Measure Set

(1) Background

In the CY 2021 PFS final rule, we finalized modifications to the Shared Savings Program quality reporting requirements and quality performance standard for performance year 2021 and subsequent performance years (85 FR 84720 through 84743). For performance year 2021 and subsequent years, ACOs are required to report quality data via the APP codified at § 414.1367. Pursuant to policies finalized under the CY 2022 and CY 2023 PFS (86 FR 65685; 87 FR 69858), to meet the quality performance standard under the Shared Savings Program through performance year 2024, ACOs must report the ten CMS Web Interface measures or the three electronic clinical quality measures (eCQMs)/Merit-based Incentive Payment System (MIPS) clinical quality measures (CQMs), and administer the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey. In performance year 2025 and subsequent performance years, ACOs must report the three eCQMs/MIPS CQMs and administer the CAHPS for MIPS survey. In the CY 2024 PFS final rule, we established the Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs) as a new collection type for Shared Savings Program ACOs reporting on the Medicare CQMs within the APP quality measure set for performance year 2024 and subsequent performance years (88 FR 79107). Shared Savings Program ACOs have the option to report on Medicare CQMs, which are reported on an ACO's eligible Medicare fee-for-service beneficiaries, instead of the ACO's all payer/all patient population. Medicare CQMs are aligned with MIPS standards for data completeness, measure benchmarking, and scoring (88 FR 79099 and 88 FR 79108). In the CY 2024 PFS final rule, we stated that Medicare CQMs would serve as a transition collection type to help some ACOs build the infrastructure, skills, knowledge, and expertise necessary to report all payer/all patient eCQMs/MIPS CQMs and support ACOs in the transition to digital quality measure reporting (88 FR 79097 through 79098).

Since the CY 2021 PFS final rule was issued, ACOs and other interested parties have continued to express concerns about requiring ACOs to report all payer/all patient eCQMs/MIPS CQMs due to the cost of purchasing and implementing a system wide infrastructure to aggregate data from multiple ACO participant taxpayer identification numbers (TINs) and varying electronic health record (EHR) systems (86 FR 65257). In the CY 2022 PFS final rule, commenters supported our acknowledgement of the complexity of the transition to all payer/all patient eCQMs/MIPS CQMs (86 FR 65259). In public comments on the CY 2023 PFS proposed rule, some commenters expressed multiple concerns regarding the requirement to report all payer/all patient eCQMs/MIPS CQMs beginning in performance year 2025, such as issues related to meeting all payer data requirements, data completeness requirements, data aggregation and deduplication issues, and interoperability issues among different EHRs (87 FR 69837).

ACOs face continued difficulties in aggregating data on the three all payer/all patient eCQMs/MIPS CQMs that are

part of the existing APP quality measure set. The Shared Savings Program continues to receive feedback from ACOs and other stakeholders about the difficulties with reporting on the three all payer/all patient eCQMs/MIPS CQMs and meeting data management requirements given their muti-practice/multi EHR structure. Additionally, we continue to receive feedback on the challenges of aggregating data due to the health information technology (IT) infrastructure in use by ACOs and the current state of interoperability. Building on our goal to provide technical support to ACOs and help ACOs build the skills necessary to aggregate and match patient data to report all payer/all patient eCQMs/MIPS CQMs, in December 2022, we hosted a webinar to support ACOs in the transition to reporting all payer/all patient eCQMs/MIPS CQMs and released a guidance document on the topic. Resources from the ''Reporting MIPS CQMs and eCQMs in the APM Performance Pathway'' webinar are available at *https://youtu.be/LDrpoGnnRQs*. The guidance document, entitled ''Medicare Shared Savings Program: Reporting MIPS CQMs and eCQMs in the Alternative Payment Model Performance Pathway (APP)'' is available in the Quality Payment Program Resource Library at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2179/APP%20Guidance%20Document%20for%20ACOs.pdf*. Over the past 2 years, we have learned that there are complexities and hurdles concerning ACOs adopting the all payer/all patient collection types; as a result, the widespread adoption of the all payer/all patient collection types require further time and support. For example, our internal data indicate that in performance year 2021, 12 out of 475 ACOs reported eCQMs/MIPS CQMs under the APP, while 37 out of 482 ACOs reported eCQMs/MIPS CQMs in performance year 2022.[468] Submission data for performance year 2023 indicate that 73 out of 456 ACOs reported eCQMs/MIPS CQMs under the APP. Further, we have come to understand that additional maturation processes are needed to support large, complex organizations like ACOs that participate in the Shared Savings Program to fully and equitably participate in the all payer/all patient collection types.

CMS' goal, as stated in the CY 2024 PFS final rule, is to support ACOs in the adoption of all payer/all patient measures (88 FR 79098). In that rule, we described our intention to monitor the reporting of quality data utilizing the Medicare CQM collection type, which would include assessing if any Medicare CQMs qualify as topped out as described at § 414.1380(b)(1)(iv) (88 FR 79098). We also noted that, ''[s]eparately, we may specify higher standards, new measures, or both—up to and including proposing to sunset the Medicare CQM collection type in future rulemaking—to ensure that Medicare CQMs conform to the intent of section 1899(b)(3)(C) of the Act and the priorities established in the CMS National Quality Strategy'' (88 FR 79098).

Under the goals of the CMS National Quality Strategy to improve the quality and safety of healthcare for everyone, CMS is implementing a building-block approach and aligning the measures used to establish the Shared Savings Program quality performance standard with the Universal Foundation of quality measures and streamlining quality measures across CMS quality programs for measuring primary care clinician performance in the adult and pediatric populations.[469] In the CY 2024 PFS proposed rule, we stated that ''we intend to propose future policies aligning the APP measure set for Shared Savings Program ACOs with the quality measures under the 'Universal Foundation' beginning in performance year 2025'' (88 FR 52423). A few commenters were supportive of aligning the APP quality measure set with the Universal Foundation measures, while other commenters were opposed. Several commenters urged CMS to first test measures before making them required and scored measures for ACOs. Commenters were concerned about balancing the alignment of the Universal Foundation measures with efforts to reduce administrative burden, potential growth in the number of measures ACOs would have to report, and implementing multiple major changes to the APP quality measure set in performance year 2025. In the CY 2024 PFS final rule, we stated that we will take the comments under consideration in future rulemaking, as we evaluate the impact of aligning the APP quality measure set with the Universal Foundation measures (88 FR 79114).

(2) Proposed Revisions

(a) Proposal To Require Shared Savings Program ACOs To Report the APP Plus Quality Measure Set

To further advance Medicare's overall value-based care strategy and maintain alignment within and across CMS' quality programs, in section IV.A.4.c.(2) of this proposed rule, we are proposing to create the APP Plus quality measure set to align with the Adult Universal Foundation measures. Out of the ten Adult Universal Foundation measures, five of the measures are already in the APP quality measure set for performance year 2025 under policies finalized in the CY 2024 PFS final rule (88 FR 79112 through 79113). There is one measure—Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Measure # 484)—in the APP quality measure set that is not an Adult Universal Foundation measure, resulting in a total of six measures that are in the APP quality measure set.

Under the proposed approach, the APP Plus quality measure set would incrementally grow to comprise of eleven measures, consisting of the six measures in the existing APP quality measure set and five newly proposed measures from the Adult Universal Foundation measure set that would be incrementally incorporated into the APP Plus quality measure set over performance years 2025 through 2028. The proposed new measures and the timeline for incorporating the measures into the APP Plus quality measure set are described in section IV.A.4.c.(3) of this proposed rule and below. The proposal in section IV.A.4.c.(2) is to make the APP Plus quality measure set an optional measure set for APP reporters. For performance year 2025 and subsequent performance years, we are proposing to require Shared Savings Program ACOs to report the APP Plus quality measure set as proposed in section III.G.4.b.(2)(a) of this proposed rule. Consequently, the APP quality measure set would no longer be available for reporting by Shared Savings Program ACOs beginning in performance year 2025. Our proposal would align the quality measures that Shared Savings Program ACOs would be required to report with the quality measures under the Adult Universal Foundation measure set incrementally beginning in performance year 2025.

Creating alignment with the Adult Universal Foundation would better align the quality measures reported by Shared Savings Program ACOs with the Medicaid Core Sets and the Marketplace

[468] Counts based on internal analysis of ACOs' quality reporting in performance years 2021 and 2022.

[469] Centers for Medicare & Medicaid Services (2024). CMS National Quality Strategy. Accessed June 24, 2024. *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy*.

Quality Rating System, which have previously adopted the quality measures in the Universal Foundation.[470] As discussed in section IV.A.4.c.(2) of this proposed rule, alignment of quality measures across CMS programs allows practitioners to better focus their quality efforts, reduce administrative burden, and drive digital transformation and stratification of a focused quality measure set to assess impact on disparities.[471] Our proposed alignment with the Adult Universal Foundation would also better align the quality measures reported by Shared Savings Program ACOs with the Value in Primary Care MIPS Value Pathway (MVP), which contains the same Universal Foundation measures. This may create a smoother transition for clinicians from MIPS to the Shared Savings Program. Alignment would allow clinicians to leverage their familiarity and experience with the Adult Universal Foundation quality measures among primary care clinicians participating in this MVP as they transition to reporting the APP Plus quality measure set in the Shared Savings Program. Experience and familiarity with the same quality measures, redesigned care processes, and quality improvement activities that are commonplace in ACOs would streamline the pathway for clinicians to join ACOs in the future and is consistent with our goal to have all beneficiaries in an accountable care relationship by 2030.

Section 1899(b)(3)(C) of the Act requires CMS to seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care. In the November 2011 final rule, we finalized 33 quality measures for use in establishing the quality performance standard measure set for ACOs: including 22 measures that were actively reported by ACOs via the Group Practice Reporting Option (GPRO) Web Interface (76 FR 67889). As we stated in the November 2011 final rule establishing the Shared Savings Program, our principal goal in selecting quality measures for ACOs has been to identify measures of success in the delivery of high-quality health care at the individual and population levels, with a focus on outcomes (76 FR 67872). As we sought to improve the quality of care furnished by ACOs over time, we have subsequently updated this measure set through rulemaking in the CY 2015, 2016, 2017, 2019, and 2023 PFS final rules (79 FR 67907 through 67921, 80 FR 71263 through 71268, 81 FR 80484 through 80489, 83 FR 59707 through 59715, and 87 FR 69860 through 69763, respectively). We have also sometimes increased the number of measures reported by ACOs through rulemaking. For example, in the CY 2016 PFS final rule, we increased the Shared Savings Program quality measure set from 33 total measures to 34 total measures (80 FR 71265). In the CY 2016 PFS final rule, we noted that since the November 2011 Shared Savings Program final rule, we have continued to review the quality measures used for the Shared Savings Program to ensure that they are up to date with current clinical practice and aligned with other CMS quality reporting programs (80 FR 71264). Also, through rulemaking, we sometimes reduced the number of measures reported by ACOs. For example, in the CY 2019 PFS final rule, we finalized policies which reduced the Shared Savings Program quality performance measure set to 23 measures in PY 2019 (83 FR 59715). In developing our proposals in the CY 2019 PFS final rule, we stated that we considered the agency's efforts to streamline quality measures, reduce regulatory burden, and promote innovation as part of broader CMS initiatives (83 FR 59711). In the CY 2021 PFS final rule, we again reduced the total number of measures that ACOs must report (85 FR 84733). Specifically, through the adoption of the APP quality measure set, we reduced the total number of measures from 23 to either 6 or 13 measures (depending on the ACO's chosen reporting option) for PY 2021 (85 FR 84723).

Our proposal to adopt the APP Plus quality measure set for ACOs that participate in the Shared Savings Program would increase the number of measures reported by ACOs that currently report the eCQM/MIPS CQM measure set from three measures in performance year 2024 to five measures in performance year 2025. For ACOs that reported the CMS Web Interface measures, our proposal to adopt the APP Plus quality measure set would decrease the number of measures reported from ten measures in performance year 2024 to eight measures in performance year 2025. While we acknowledge that the increase in the number of measures for ACOs that currently report the eCQM/MIPS CQM measure set may be an increased burden for those ACOs, we are using a phased-in approach to expand the APP Plus quality measure set between performance years 2025 and 2028, which should help to minimize the impact of increased burden associated with reporting additional measures. The option for ACOs to report Medicare CQMs, which are MIPS CQMs that are reported on an ACO's fee-for-service population, may also alleviate the reporting burden for ACOs that report Medicare CQMs by focusing an ACO's patient matching and data aggregation efforts only on an ACO's eligible Medicare fee-for-service population. Additionally, we believe that the benefits of scoring an increased number of measures may offset the increased burden that some ACOs may face in adopting the additional measures. For example, as the number of measures in the measure set increases, the individual weight of each measure on the ACO's quality performance score decreases. Each measure in a six-measure set would account for roughly 16.67 percent of an ACO's MIPS Quality performance category score while each measure in an eight-measure set would account for 12.5 percent of an ACO's MIPS Quality performance category score. The scoring of more measures, in concert with the scoring policies proposed in sections IV.A.4.f.(1)(b)(iii) and IV.A.4.f.(1)(c)(i) of this proposed rule, may result in improved quality performance scores for the ACOs as each individual measure carries less weight.

The proposed APP Plus quality measure sets for Shared Savings Program ACOs for performance year 2025, performance years 2026 and 2027, and performance year 2028 and subsequent performance years are displayed in Tables 34, 35, and 36, respectively. Under our proposal, there would be eight measures (five eCQMs/Medicare CQMs, two administrative claims measures, and the CAHPS for MIPS Survey measure) in the APP Plus quality measure set for Shared Savings Program ACOs in performance year 2025 (Table 34), nine measures (six eCQMs/Medicare CQMs, two administrative claims measures, and the CAHPS for MIPS Survey measure) in performance years 2026 and 2027 (Table 35), and eleven measures (eight eCQMs/Medicare CQMs, two administrative claims measures, and the CAHPS for MIPS Survey measure) in performance years 2028 and subsequent performance years (Table 36). We intend to update

[470] Jacobs D, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher L. Aligning Quality Measures across CMS—The Universal Foundation. New England Journal of Medicine, February 1, 2023, available at *https://www.nejm.org/doi/full/10.1056/NEJMp2215539.*

[471] Jacobs D, et al., Update On The Medicare Value-Based Care Strategy: Alignment, Growth, Equity. Health Affairs Forefront (March 14, 2024), available at *https://www.healthaffairs.org/content/forefront/update-medicare-value-based-care-strategy-alignment-growth-equity.*

the APP Plus quality measure set as new measures are added to or removed from the Adult Universal Foundation measure set in the future.

(b) Proposed Collection Types Available for Shared Savings Program ACOs Reporting the APP Plus Quality Measure Set

We are proposing to streamline the collection types available for Shared Savings Program ACOs reporting the APP Plus quality measure set to the eCQM and Medicare CQM collection types for performance year 2025 and subsequent performance years. We believe that our proposal to establish the APP Plus quality measure set to align with the Adult Universal Foundation measure set should also aim to prioritize the eCQM collection type—the gold standard collection type that underlies the Digital Quality Measurement (dQM) Strategic Roadmap (available at *https://ecqi.healthit.gov/sites/default/files/CMSdQMStrategicRoadmap_032822.pdf*)—and use Medicare CQMs as the transition step on our building-block approach for ACOs' progress to adopt digital quality measurement. We are also seeking to reduce reporting burden on ACOs by using a phased-in approach to expand the APP Plus quality measure set between performance years 2025 and 2028. We will also continue to provide the Medicare CQM reporting option as ACOs increase their experience and overcome their challenges with reporting all payer/all patient measures. As discussed more fully below, we are proposing not to include the MIPS CQM collection type for Shared Savings Program ACOs reporting the APP Plus quality measure set to focus ACOs' efforts on the implementation of the APP Plus quality measure set, while continuing to encourage the adoption of eCQMs. We believe that our proposed approach would recognize the investments ACOs have made to report eCQMs and their benefits (that is, more efficient data collection, real time provider feedback, and less burden through the use of digital data) and allow ACOs that have invested in eCQMs to continue on that track and align with long term goals of digital quality measurement.[472]

Since Medicare CQMs are MIPS CQMs that are reported on an ACO's eligible Medicare fee-for-service population, ACOs that have invested in the infrastructure to report MIPS CQMs would be able to report Medicare CQMs on a subset of their all payer/all patient population. Furthermore, as noted in the CY 2024 PFS final rule, Medicare CQMs address ACO concerns related to the difficulty of matching and aggregating patient data across multiple EHR systems (88 FR 79106). Medicare CQMs also provide a transition path and alternative for ACOs that have difficulty reporting patient data by limiting the beneficiaries for which an ACO must match and aggregate data to only the ACO's eligible Medicare fee-for-service beneficiaries, instead of their all payer/all patient population (88 FR 79106). As a logical next step in the reporting of digital quality measures, this population is larger than the sample currently used in the CMS Web Interface, but not as large as the all payer/all patient population that must be reported for an eCQM or MIPS CQM (88 FR 79106).

We aim to fully transition to digital quality measurement in CMS quality reporting and value-based purchasing programs, and we are working to convert current eCQMs to the Fast Healthcare Interoperability Resources (FHIR) standard (86 FR 65379). Including eCQMs as a collection type for Shared Savings Program ACOs reporting the APP Plus quality measure set aligns with our goal to transition to digital quality measurement including the alignment and development of FHIR standards and tools for eCQM reporting in the dQM Strategic Roadmap. There are numerous benefits to using eCQMs, including their use of electronic standards that reduce the burden of manual extraction and reporting for measured entities, their use of clinical data to assess the outcomes of treatment by measured entities, and their fostering of access to real-time data for point of care quality improvement and decision support.[473] Furthermore, eCQMs align with the Meaningful Measures Framework 2.0 goal of improving quality reporting efficiency by transitioning to digital quality measures.[474] A recent study noted the resource intensity of quality reporting, underscoring the high cost of claims-based measures relative to others and recommended that policy makers shift to electronic metrics to ''optimize resources spent in the overall pursuit of higher quality.''[475] For these reasons, and to continue encouraging ACOs on their progress to adopt digital quality measurement, we are not modifying the availability of eCQMs as a collection type for ACOs that reported the APP quality measure set by including eCQMs as a collection type in the APP Plus quality measure set in performance year 2025 and subsequent performance years. In section III.G.7.e. of this proposed rule, we seek comment on a higher risk, higher reward track for Shared Savings Program ACOs participating in the ENHANCED track. In this request for information, we seek comment on questions relevant to our long-term goals of supporting ACOs in their transition to reporting all payer/all patient quality measures: How should a revised ENHANCED track with higher risk and potential reward also require additional accountability for quality? Should ACOs in this revised track be required to report all payer/all patient quality measures?

In the CY 2024 PFS final rule, we stated that ''Medicare CQMs are intended to serve as a transition to all payer/all patient reporting and not as a permanent collection type. We acknowledge that ACOs are at different stages of readiness to adopt all payer/all patient measures, and we intend for Medicare CQMs to be available to ACOs during their transition to all payer/all patient reporting.'' (88 FR 79106). In the CY 2024 PFS final rule, we also stated that ''[w]e expect that the sunsetting of the Medicare CQM collection type may be paced with the uptake of FHIR Application Programming Interface (API) technology, but this will be assessed on industry readiness and CMS requirements'' (88 FR 79106). Specifically, we anticipate that the increased use of FHIR API technology will facilitate ACOs' reporting of eCQMs and thus increase their uptake of them. Future advancements in FHIR API technology and its uptake among Shared Savings Program ACOs may accelerate our future plans to sunset Medicare CQMs. As discussed earlier in this section, we are proposing to streamline the collection types available for Shared Savings Program ACOs reporting the APP Plus quality measure set to the eCQM and Medicare CQM collection types for performance year 2025 and subsequent performance years and use Medicare CQMs as the transition step on our building-block approach for ACOs' progress to adopt digital quality measurement. As we continue to support ACOs in fully and equitably participating in all payer/all patient

[472] Centers for Medicare & Medicaid Services (2023). Electronic Clinical Quality Measure Basics (eCQM 101). Accessed June 24, 2024. *https://ecqi.healthit.gov/sites/default/files/eCQM-Basics-508.pdf*.

[473] eCQI Resource Center (2024). Get Started with eCQMs. *https://ecqi.healthit.gov/ecqms*.

[474] Centers for Medicare & Medicaid Services (2024). Meaningful Measures 2.0: Moving to Measure Prioritization and Modernization. *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/meaningful-measures-20*.

[475] Saraswathula, A., et al., The Volume and Cost of Quality Metric Reporting. *JAMA* (June 6, 2023), available at *https://jamanetwork.com/journals/jama/fullarticle/2805705*.

collection types with our proposed creation of the APP Plus quality measure set, our commitment to monitor ACOs' reporting of quality data using Medicare CQMs and to assess their appropriateness as a collection type remains the same.

As we stated in the CY 2024 PFS final rule, ACOs that include or are composed solely of FQHCs or RHCs must report quality data on behalf of the FQHCs or RHCs that participate in the ACO. To clarify, while FQHCs and RHCs that provide services that are billed exclusively under FQHC or RHC payment methodologies are exempt from reporting traditional MIPS, FQHCs and RHCs that participate in APMs, such as the Shared Savings Program, are considered APM Entity groups as described at § 414.1370 (88 FR 79099). If our proposal is finalized, FQHCs and RHCs that participate in Shared Savings Program ACOs would have to report the APP Plus quality measure set through their ACO for performance year 2025 and subsequent performance years.

We seek comment on all of the proposals described in this section.

(3) Proposed Changes to Regulation Text

As discussed in section III.G.4.b.(2)(a) of this proposed rule, for performance year 2025 and subsequent performance years, we are proposing to require Shared Savings Program ACOs to report the APP Plus quality measure set as proposed in section IV.A.4.c.(3) of this proposed rule. The APP Plus quality measure set would comprise of eleven measures, consisting of six measures from the APP quality measure set and five newly proposed measures from the Adult Universal Foundation measure set that would be incrementally incorporated into the APP Plus quality measure set over performance years 2025 through 2028. We are also proposing to focus the collection types available to Shared Savings Program ACOs for reporting the APP Plus quality measure set to eCQMs and Medicare CQMs. We refer readers to sections IV.A.4.c, IV.A.4.e.(1)(b)(i), IV.A.4.f.(1)(b)(iii), and IV.A.4.f.(1)(c)(i). of this proposed rule for changes to the regulation text at 42 CFR part 414. We are proposing conforming changes to the regulation text at 42 CFR part 425 as described below in this section. We seek comment on our proposed regulation text changes.

- We are proposing to sunset the requirement that ACOs must submit quality data via the APP to satisfactorily report on behalf of the eligible clinicians who bill under the TIN of an ACO participant for purposes of the MIPS Quality performance category of the Quality Payment Program, and to revise § 425.508(b) to indicate that the requirement will be applicable for performance years beginning in 2021–2024. We are also proposing to replace the phrase ''Alternative Payment Model Performance Pathway (APP)'' with the phrase ''APM Performance Pathway (APP)'' to conform with the phrase used at § 414.1367.
- We are adding a new paragraph (c) at § 425.508 to establish that, for performance years beginning on or after January 1, 2025, ACOs must submit quality data via the APM Performance Pathway (APP) on the quality measures contained in the APP Plus quality measure set established under § 414.1367 to satisfactorily report on behalf of the eligible clinicians who bill under the TIN of an ACO participant for purposes of the MIPS Quality performance category of the Quality Payment Program.
- We are proposing to revise the section heading at § 425.510 to ''Application of the APM Performance Pathway (APP) quality measure set or the APP Plus quality measure set (as applicable) to Shared Savings Program ACOs for performance years beginning on or after January 1, 2021.''
- We are proposing to sunset the requirement that ACOs must report quality data on the APP quality measure set according to the method of submission established by CMS and to revise § 425.510(b). We are adding a new paragraph (b)(1) at § 425.510 to indicate that the requirement will be applicable for performance years beginning in 2021–2024.
- We are adding a new paragraph (b)(2) at § 425.510 to establish that, for performance years beginning on or after January 1, 2025, ACOs must report quality data on the APP Plus quality measure set established under § 414.1367, according to the submission method established by CMS.
- We are revising § 425.512(a)(2)(iii) to establish that, for performance year 2025 and subsequent performance years, an ACO in the first performance year of the ACO's first agreement period under the Shared Savings Program will meet the quality performance standard if the ACO reports the APP Plus quality measure set and meets the data completeness requirement on all eCQMs/Medicare CQMs, and the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B)), and receives a MIPS Quality performance category score for the applicable performance year.
- We are revising the introductory paragraph (a)(5)(i) to § 425.512 to read as follows: ''Except as specified in paragraphs (a)(2) and (7) of this section, CMS designates the quality performance standard as:''.
- We are revising the introductory paragraph (a)(5)(i)(A) to read as follows: ''For performance year 2024, the ACO reporting quality data on the APP quality measure set established under § 414.1367 of this subchapter, according to the method of submission established by CMS and –''.
- We are revising the introductory paragraph (a)(5)(i)(B) to read as follows: ''For performance year 2025 and subsequent performance years, the ACO reporting quality data on the APP Plus quality measure set established under § 414.1367 of this subchapter, according to the method of submission established by CMS and –''.
- We are adding a new paragraph (a)(5)(ii)(A) to § 425.512 to indicate that an ACO will meet the alternative quality performance standard for performance year 2024 if the ACO reports quality data on the APP quality measure set established under § 414.1367 according to the method of submission established by CMS and achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP quality measure set.
- We are adding a new paragraph (a)(5)(ii)(B) to § 425.512 to establish that an ACO will meet the alternative quality performance standard for performance year 2025 and subsequent years if the ACO reports the quality data on the APP Plus quality measure set established under § 414.1367 according to the method of submission established by CMS and achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP Plus quality measure set.
- We are revising § 425.512(a)(5)(iii)(B) to indicate that for performance year 2025 and subsequent performance years, an ACO will not meet the quality performance standard or the alternative quality performance standard if the ACO does not report any of the eCQMs/Medicare CQMs in the APP Plus quality measure set and does not administer a CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B)).
- We are revising § 425.512(a)(7) introductory text and (a)(7)(i) and adding new paragraphs (a)(7)(i)(A) and (B) to indicate for performance year 2024, CMS will use the higher of the ACO's health equity adjusted Quality performance category score or the equivalent of the 40th percentile MIPS

Quality performance category score when an ACO reports all of the required measures, meeting the data completeness requirement for each measure in the APP quality measure set and receiving a MIPS Quality performance category score and the ACO meets either of the following:

++ The ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score are reduced under § 414.1380(b)(1)(vii)(A).

++ At least one of the eCQMs/MIPS CQMs/Medicare CQMs does not have a benchmark as described at § 414.1380(b)(1)(i)(A).

• We are revising § 425.512(a)(7)(ii) and adding new paragraphs (a)(7)(ii)(A) and (B) to indicate for performance year 2025 and subsequent performance years, an ACO will receive the higher of the ACO's health equity adjusted quality performance category score or the equivalent of the 40th percentile MIPS Quality performance category score when an ACO reports all of the required measures in the APP Plus quality measure set, meeting the data completeness requirement for each measure in the APP Plus quality measure set, and receiving a MIPS Quality performance category score, and the ACO meets either of the following:

++ The ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score are reduced under § 414.1380(b)(1)(vii)(A).

++ At least one of the eCQMs/Medicare CQMs does not have a benchmark as described at § 414.1380(b)(1)(i)(A).

• We are revising § 425.512(b)(1) and (2) and (b)(4)(i) by removing the phrase ''APP measure set'' and replacing with the phrase ''APP quality measure set'' to align naming conventions for the two quality measure sets within the APP: the APP quality measure set and the APP Plus quality measure set.

• We are revising § 425.512(b)(1) to update a renumbered cross reference.

• We are revising the heading for § 425.512(b)(2) by removing the phrase ''and subsequent performance years.''

• We are renumbering the current paragraph (b)(3) of § 425.512 to paragraph (b)(4) and revising the cross references therein to reflect this renumbering.

• We are adding a new paragraph (b)(3) to § 425.512 to establish for performance year 2025 and subsequent performance years that for an ACO that reports all of the eCQMs/Medicare CQMs in the APP Plus quality measure set, meeting the data completeness requirement for all of the eCQMs/Medicare CQMs, and administers the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B)), CMS calculates the ACO's health equity adjusted quality performance score as the sum of the ACO's MIPS Quality performance category score for all measures in the APP Plus quality measure set and the ACO's health equity adjustment bonus points. The sum of these values may not exceed 100 percent.

• We are renumbering the current paragraph (b)(4) of § 425.512 to paragraph (b)(5) and revising the cross references therein to reflect this renumbering.

• We are revising renumbered § 415.512(b)(5)(iv) to add reference to new paragraph (c)(3)(iv).

• We are revising § 425.512(c)(3) introductory text by removing the phrase ''via the APP'' and adding in its place the phrase ''on the APP quality measure set or APP Plus quality measure set (as applicable)''.

• We are revising § 425.512(c)(3)(iii) by removing the phrase ''and subsequent performance years'' after ''For performance year 2024''.

• We are adding new paragraph (c)(3)(iv) to § 425.512 to establish for performance year 2025 and subsequent performance years, if CMS determines the ACO meets the requirements of the Extreme and Uncontrollable Circumstances policy and the ACO reports the APP Plus quality measure set, meets the data completeness requirement, and receives a MIPS Quality performance category score, CMS will calculate the ACO's quality score as the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

c. Proposed Changes to the Methodology for Calculating the MIPS Quality Performance Category Score for Shared Savings Program ACOs Reporting the APP Plus Quality Measure Set

(1) Background

Consistent with the authority to establish the quality reporting and other reporting requirements for the Medicare Shared Savings Program set forth in section 1899(b)(3) of the Act and the statutory requirements for the Quality Payment Program set forth in section 1848(q) and (r) of the Act for MIPS and section 1833(z) of the Act for Advanced APMs, since the Shared Savings Program's alignment with the APP in performance year 2021, MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of an APM Entity participating in a MIPS APM—including ACOs that participate in the Medicare Shared Savings Program—that report data via the APP have been scored according to the APP scoring methodology described at § 414.1367. The MIPS Quality performance category score is calculated according to the APP scoring methodology at § 414.1367(c)(1) (85 FR 84864). Under the waiver authority at section 1115A(d)(1) of the Act for CMS Innovation Center APMs and at section 1899(f) of the Act for the Medicare Shared Savings Program, the Cost performance category weight is zero percent as described at § 414.1367(c)(2) (85 FR 84864) for MIPS eligible clinicians that report via the APP. As noted in section 1848(q)(5)(C)(ii) of the Act, a MIPS eligible clinician in an APM for a performance period automatically earns a minimum score of one half of the highest potential score for the MIPS Improvement activities category for their participation in an APM for the performance period. These baseline scores are automatically applied to the MIPS Improvement activities performance category score for MIPS eligible clinician in an APM—including ACOs that participate in the Medicare Shared Savings Program—that report via the APP as described at § 414.1367(c)(3) (85 FR 84865). The Promoting Interoperability performance category under the APP is reported and calculated in the same manner described at § 414.1375 (85 FR 84865).

As described in the CY 2021 PFS final rule, we waived the requirement to weight each MIPS performance category as described in section 1848(q)(5)(E) of the Act using the waiver authority in section 1899(f) of the Act for Medicare Shared Savings Program for MIPS eligible clinicians that report via the APP—including ACOs that participate in the Medicare Shared Savings Program (85 FR 84865). The performance category weights used to calculate the final score for a MIPS eligible clinician who is scored through the APP at § 414.1367(d)(1) are:

- Quality: 50 percent.
- Cost: 0 percent.
- Improvement Activities: 20 percent.
- Promoting Interoperability: 30 percent.

Additionally, in the CY 2021 PFS final rule, we also stated that under the authority provided in section 1848(q)(5)(F) of the Act, it may become necessary to reweight one or more performance categories (85 FR 84866).

As described at § 414.1367(d)(2), if CMS determines, in accordance with § 414.1380(c)(2), that a different scoring weight should be assigned to the Quality or Promoting Interoperability performance category, CMS will redistribute the performance category weights as follows:

- If CMS reweights the Quality performance category to 0 percent: Promoting Interoperability performance category is reweighted to 75 percent, and Improvement activities performance category is reweighted to 25 percent.
- If CMS reweights the Promoting Interoperability performance category to 0 percent: Quality performance category is reweighted to 75 percent, and Improvement activities performance category is reweighted to 25 percent.

Lastly, as codified at § 414.1367(e), final scoring for APM participants reporting to MIPS through the APP—including ACOs that participate in the Medicare Shared Savings Program—would follow the same methodology as established for MIPS generally at § 414.1380 (85 FR 84866).

In performance year 2024, ACOs are scored on either the three eCQMs/MIPS CQMs/Medicare CQMs or the ten CMS Web Interface measures, the CAHPS for MIPS survey, and two administrative claims-based measures. Under this methodology, an ACO's MIPS Quality performance category score is calculated according to MIPS scoring rules for the Quality performance category established at § 414.1380(b)(1) with exceptions for (1) measures that do not have a benchmark or do not meet the case minimum requirement and (2) measures that are identified as topped out. Specifically, each submitted measure that does not have a benchmark or does not meet the case minimum requirement is excluded from an ACO's total measure achievement points (numerator) and total available measure achievement points (denominator). Additionally, any measure that is identified as topped out is not subject to the scoring cap described at § 414.1380(b)(1)(iv). Under current APP scoring rules, each required measure of the APP quality measure set that is not submitted by an ACO via the APP receives zero measure achievement points.

(2) Proposed Revisions

(a) Proposal To Establish the Data Submission Criteria for the APP Plus Quality Measure Set

As discussed in section IV.A.4.e.(1)(b)(i) of this proposed rule, for the APP Plus quality measure set, we are proposing that Shared Savings Program ACOs that report the APP Plus quality measure set and MIPS eligible clinicians, groups, and APM Entities that choose to report the APP Plus quality measure set, will be required to report on all measures in the APP Plus quality measure set, as applicable. Specifically, in § 414.1335(b), we are proposing to establish the data submission criteria for the APP Plus quality measure set, which would require the reporting of all measures within the APP Plus quality measure set, except for administrative claims-based quality measures.[476]

The MIPS Quality performance category score is calculated according to the APP scoring methodology at § 414.1367(c)(1) (85 FR 84864 through 85 FR 84865). As such, an ACO's MIPS Quality performance category score is calculated according to MIPS scoring rules for the Quality performance category established at § 414.1380(b)(1) with exceptions for (1) measures that do not have a benchmark or do not meet the case minimum requirement and (2) measures that are identified as topped out. Consistent with our proposal described above, under § 414.1380(b)(1), for performance year 2025 and subsequent performance years, ACOs would be scored on all required measures in the APP Plus quality measure set.

We are proposing that the policies related to MIPS performance category scoring in the APP at § 414.1367(c) would apply to Shared Savings Program ACOs that report the APP Plus quality measure set for the purpose of meeting the Shared Savings Program's quality performance standard.[477] Specifically, we are proposing that the APP scoring policies at § 414.1367(c)(1) for the calculation of the ACO's MIPS Quality performance category, § 414.1367(c)(2) for the calculation of an ACO's MIPS Cost performance category, § 414.1367(c)(3) for the calculation of an ACO's MIPS Improvement activities performance category, and § 414.1367(c)(4) for the calculation of an ACO's MIPS Promoting Interoperability performance category would apply to ACOs that report the APP Plus quality measure set in performance year 2025 and subsequent performance years. Additionally, we are proposing that § 414.1367(d) for the performance category weights and § 414.1367(e) for the calculation of the final score would apply to Shared Savings Program ACOs that report the APP Plus quality measure set in performance year 2025 and subsequent performance years.

If our proposals are finalized, then in performance year 2025, ACOs would be scored on the required eight measures in the APP Plus quality measure set: five eCQMs/Medicare CQMs, the CAHPS for MIPS survey, and two administrative claims-based measures. In performance years 2026 and 2027, ACOs would be scored on the required nine measures: six eCQMs/Medicare CQMs, the CAHPS for MIPS survey, and two administrative claims-based measures. In performance year 2028 and subsequent performance years, ACOs would be scored on the required eleven measures: eight eCQMs/Medicare CQMs, the CAHPS for MIPS survey, and two administrative claims-based measures. We refer readers to Tables 34, 35, and 36 in Section III.G.4.f of this proposed rule for additional detail on the required measures in each performance year.

We refer readers to section IV.A.4.e.(1)(b)(i) of this proposed rule for a discussion of our proposal to establish the data submission criteria for the APP Plus quality measure set, specifically the proposal to require the reporting of all measures within the APP Plus quality measure set.

(b) Proposal To Establish a Complex Organization Adjustment for Virtual Groups and APM Entities

To account for the organizational complexities faced by Virtual Groups and APM Entities, including Shared Savings Program ACOs, when reporting eCQMs, in section IV.A.4.f.(1)(b)(iii) of this proposed rule, we are proposing to establish a Complex Organization Adjustment beginning in the CY 2025 performance period/2027 MIPS payment year. A Virtual Group and an APM Entity would receive one measure achievement point for each submitted eCQM that meets the case minimum requirement at § 414.1380(b)(1)(iii) and the data completeness requirement at § 414.1340. Each reported eCQM may not score more than 10 measure achievement points and the total achievement points (numerator) may not exceed the total available measure achievement points (denominator) for the quality performance category. The Complex Organization Adjustment for a Virtual Group or APM Entity may not

[476] As described at § 414.1325(a)(2)(i), there are no data submission requirements for administrative claims-based quality measures as performance on such measures is calculated by CMS using administrative claims data, which includes claims submitted with dates of service during the applicable performance period that are processed no later than 60 days following the close of the applicable performance period.

[477] This discussion describes standards under the APP, which are applicable to APM Entities. We refer throughout to ACOs in lieu of APM Entities as we are discussing the application of APP standards to ACOs participating in the Shared Savings Program, and thus ACOs are the sole relevant type of APM Entity.

exceed 10 percent of the total available measure achievement points in the quality performance category. The adjustment would be added for each measure submitted at the individual measure level.

Since Shared Savings Program ACOs are APM Entities, this proposal would be applicable to Shared Savings Program ACOs reporting the APP Plus quality measure set beginning in performance year 2025. We refer readers to section IV.A.4.f.(1)(b)(iii) of this proposed rule for discussion of our proposal to establish the Complex Organization Adjustment for Virtual Groups and APM Entities.

As the Adult Universal Foundation measures are phased into the APP Plus quality measure set, ACOs that participate in the Shared Savings Program would be required to report on a larger measure set relative to other eCQM reporters. Under our proposal as described in section III.G.4.f of this proposed rule, the APP Plus quality measure set for Shared Savings Program ACOs would include eight measures (five eCQMs/Medicare CQMs, two administrative claims measures, and the CAHPS for MIPS Survey measure) in performance year 2025 (Table 34); nine measures (six eCQMs/Medicare CQMs, two administrative claims measures, and the CAHPS for MIPS Survey measure) in performance years 2026 and 2027 (Table 35); and eleven measures (eight eCQMs/Medicare CQMs, two administrative claims measures, and the CAHPS for MIPS Survey measure) in performance years 2028 and subsequent performance years (Table 36).

(c) Proposal To Score Shared Savings Program ACOs Reporting Medicare CQMs Using Flat Benchmarks

In the CY 2024 PFS final rule, we finalized our proposal to establish new benchmarks for scoring ACOs on the Medicare CQMs under MIPS in alignment with MIPS benchmarking policies (88 FR 79110). As historical Medicare CQM data would not be available, we finalized that for performance years 2024 and 2025, we will score Medicare CQMs using performance period benchmarks. We also finalized that, for performance year 2026 and subsequent performance years, when baseline period data are available to establish historical benchmarks in a manner that is consistent with the MIPS benchmarking policies at § 414.1380(b)(1)(ii), we will score Medicare CQMs using historical benchmarks.

A few commenters noted in our proposal in the CY 2024 PFS proposed rule (88 FR 79109–79110) their concern about ACOs being compared only to other ACOs that report Medicare CQMs since the Medicare CQMs would be available only to Shared Savings Program ACOs. One commenter stated their preference to have their quality performance compared to all other participants on these measures, while another commenter stated that CMS should stop measuring ACOs against each other and instead measure ACOs on a national standard so that all ACOs can pass and do not lose out on savings due to arbitrary quality decile cut points. In our response to these comments, we stated that given that benchmarks are specific to each collection type and that we proposed to establish Medicare CQMs as a new collection type for only Shared Savings Program ACOs, only ACO data will be available to benchmark Medicare CQMs. Additionally, the health equity adjustment would be applicable to Medicare CQMs for purposes of determining shared savings payments/losses. The application of the health equity adjustment would help improve performance when ACOs deliver high quality care to underserved patient populations. For these reasons, it is appropriate to establish benchmarks for Medicare CQMs that are consistent with MIPS benchmarking policies. ACOs that prefer to be compared to clinicians at large may do so by reporting eCQMs or MIPS CQMs, for which CMS calculates a benchmark using data reported by MIPS eligible clinicians reporting under the chosen collection type.

In performance year 2022, ACOs had a higher average performance on quality measures they were required to report in order to share in savings compared to other similarly sized clinician groups not in the Shared Savings Program.[478] This includes statistically significant higher performance for quality measures related to diabetes and blood pressure control; breast cancer and colorectal cancer screening; tobacco screening and smoking cessation; and depression screening and follow-up.[479] In shifting to Medicare CQMs, ACO performance would be benchmarked against other ACOs only reporting Medicare CQMs. Since ACOs are high performers relative to comparably sized MIPS groups, benchmarking Medicare CQMs using only ACO data would lower some ACOs' MIPS measure achievement points on those measures. In other words, high-performing ACOs could earn lower measure achievement points relative to comparable MIPS groups because the Medicare CQM benchmarking pool is comprised of higher-than-average performance data–in effect, creating a ''tournament approach'' to scoring Medicare CQMs wherein ACOs must compete with other ACOs to earn measure achievement points. This could be particularly disadvantageous for ACOs that serve a high proportion of underserved populations because, while ACOs that report eCQMs and/or Medicare CQMs and serve a high proportion of underserved populations are eligible for health equity adjustment points, ACOs must score in the top or middle thirds of ACO measure performers to earn health equity adjustment points.

As described in section III.G.4.b.(2)(b) of this proposed rule, for performance year 2025 and subsequent performance years, we are proposing to streamline the collection types available for Shared Savings Program ACOs reporting the APP Plus quality measure set to the eCQM and Medicare CQM collection types. Therefore, as discussed in section IV.A.4.f.(1)(c)(i) of this proposed rule, we are proposing to add § 414.1380(b)(1)(ii)(F) to state that beginning in the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQM collection type would be scored using flat benchmarks for their first two performance periods in MIPS. Our proposal in section IV.A.4.f.(1)(c)(i) of this proposed rule would expand the use of flat benchmarks to Medicare CQMs in their first two performance periods in MIPS. The use of flat benchmarks would allow ACOs with high scores to earn maximum or near maximum achievement points while allowing room for quality improvement and rewarding that improvement in subsequent years. Use of flat benchmarks also helps to ensure that ACOs with high quality performance on a measure are not penalized as low performers. As discussed in section IV.A.4.f.(1)(c)(i) of this proposed rule, we are proposing to add § 414.1380(b)(1)(ii)(F) to incorporate this proposal. The use of historical benchmarks, when data are available, is consistent with MIPS benchmarking policies at § 414.1380(b)(1)(ii), allow ACOs to know benchmarks prior to start of the performance year, and create opportunities for improvement.

Table 30 lists the Medicare CQMs in the APP Plus quality measure set that would be eligible for flat benchmarks in

[478] Centers for Medicare & Medicaid Services (2023). *Medicare Shared Savings Program Saves Medicare More Than $1.8 Billion in 2022 and Continues to Deliver High-quality Care. [Press release]. https://www.cms.gov/newsroom/press-releases/medicare-shared-savings-program-saves-medicare-more-18-billion-2022-and-continues-deliver-high.*

[479] *Id.*

performance year 2025 through performance year 2029 under our proposal.

TABLE 30: Medicare CQMs Eligible for Flat Benchmarks in Performance Year 2025 through 2029

Performance Year	Quality #
2025	001, 134, 236, 112, 113
2026	112, 113, 305
2027	305
2028	487, 493
2029	487, 493

A quality performance benchmark is the performance rate an ACO must achieve to earn the corresponding quality points for each measure. Flat benchmarks assign a performance rate range to each decile. In flat benchmarks for non-inverse measures, any performance rate at or above 90 percent would be in the top decile; any performance rate between 80 percent and 89.99 percent would be in the second highest decile, and so on. For inverse measures, this would be reversed—any performance rate at or below 10 percent would be in the top decile; any performance rate between 10.01 percent and 20 percent would be in the second highest decile, and so on. The number of measure achievement points received for each measure is determined based on the applicable benchmark decile category and the percentile distribution.

For non-inverse measures, better quality performance is indicated by a higher performance rate. For example, Quality #: 001 Controlling High Blood Pressure is a non-inverse measure that measures the percentage of patients 18–85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period. Better quality performance on this measure is demonstrated by having a higher percentage of patients whose blood pressure was adequately controlled. Table 31 lists the flat benchmarks for a non-inverse Medicare CQM under our proposal described in section IV.A.4.f.(1)(c)(i) of this proposed rule.

TABLE 31: Flat Benchmarks for a Non-Inverse Medicare CQM in its First Two Performance Periods in MIPS in Performance Year 2025 and Subsequent Years

Decile	Performance Rate Range
1	< 10.00
2	10.00 – 19.99
3	20.00 – 29.99
4	30.00 – 39.99
5	40.00 – 49.99
6	50.00 – 59.99
7	60.00 – 69.99
8	70.00 – 79.99
9	80.00 – 89.99
10	>= 90.00

For example, if an ACO reports a non-inverse Medicare CQM in its first two performance periods in MIPS in performance year 2025 and earns a performance rate of 55.25 percent, then the ACO would score in the 6th decile on that measure.

For inverse measures, better quality performance is indicated by a lower performance rate. This is reflected in flat benchmark such that lower quality performance rates are found in higher deciles. For example, Quality #: 001 Diabetes: Hemoglobin A1c (HbA1c) Poor Control is an inverse quality measure that measures the percentage of patients 18–75 years of age with diabetes who had hemoglobin A1c >9.0 percent during the measurement period. Better quality performance on this measure is demonstrated by having a lower percentage of patients whose HbA1c was >9.0 percent. Table 32 lists the flat benchmarks for an inverse Medicare CQM under our proposal described in section IV.A.4.f.(1)(c)(i) of this proposed rule.

TABLE 32: Flat Benchmarks for an Inverse Medicare CQM in its First Two Performance Periods in MIPS in Performance Year 2025 and Subsequent Years

Decile	Performance Rate Range
1	99.00 – 90.01
2	90.00 – 80.01
3	80.00 – 70.01
4	70.00 – 60.01
5	60.00 – 50.01
6	50.00 – 40.01
7	40.00 – 30.01
8	30.00 – 20.01
9	20.00 – 10.01
10	<= 10.00

For example, if an ACO reports an inverse Medicare CQM in its first two performance periods in MIPS in performance year 2025 and earns a performance rate of 12.25 percent, then the ACO would score in the 9th decile on that measure. In performance year 2025, Quality #: 001 Diabetes: Hemoglobin A1c (HbA1c) Poor Control is the only inverse Medicare CQM measure.

There are scoring scenarios in which ACOs would earn higher measure achievement points under flat benchmarks compared to those they would earn under performance period benchmarks. Most notable are scenarios in which ACOs have a tight distribution of performance rates on a measure. For example, a non-inverse measure for which a performance rate of 90.00 percent is in the 8th decile. In this example, an ACO that reported a performance rate of 90.00 percent would be scored in the 8th decile when the hypothetical performance period benchmark is applied. Using the flat benchmarks described in Table 31 of this proposed rule, an ACO that reported a performance rate of 90.00 percent would be scored in the 10th decile, resulting in greater measure achievement points than under the hypothetical performance period benchmarks described in this example. For more details on the calculation of measure achievement points, we refer readers to the ''APM Performance Pathway (APP) Toolkit'' which is updated for each performance year and posted in the QPP Resource Library.

We seek comment on our proposal to score ACOs reporting Medicare CQMs using flat benchmarks in performance year 2025 and subsequent performance years.

(3) Proposed Changes to Regulation Text

As discussed in sections III.G.4.c.(2)(a), III.G.4.c.(2)(b), and III.G.4.c.(2)(c) of this proposed rule, we are proposing to establish scoring rules to calculate the MIPS Quality performance category score for ACOs reporting the APP Plus quality measure set for performance year 2025 and subsequent performance years. We believe that these proposed scoring rules would incentivize the reporting of eCQMs in the APP Plus quality measure set while continuing to support ACOs that report Medicare CQMs as they build the infrastructure, skills, knowledge, and expertise necessary to aggregate patient data to report digital quality measures. We refer readers to sections IV.A.4.e.(1)(b)(i), IV.A.4.f.(1)(b)(iii), and IV.A.4.f.(1)(c)(i) of this proposed rule for changes to the regulation text at 42 CFR part 414.

d. Proposal To Extend the eCQM Reporting Incentive for Meeting the Shared Savings Program Quality Performance Standard

(1) Background

In the CY 2023 PFS final rule, we extended the incentive for reporting eCQMs/MIPS CQMs through performance year 2024 to align with the timeline for sunsetting of the CMS Web Interface reporting option and to allow ACOs an additional year to gauge their performance on the eCQMs/MIPS CQMs before full reporting of the measures are required beginning in performance year 2025 (87 FR 69836 through 69838). We originally adopted this incentive in the CY 2022 PFS final rule to encourage ACOs to begin the transition to eCQM/MIPS CQM reporting in performance years 2022 and 2023 (86 FR 65269). We finalized an update to the incentive for performance year 2024 such that:

- If an ACO reports the three eCQMs/MIPS CQMs, meets the data completeness requirement at § 414.1340 and the case minimum requirement at § 414.1380 for all three eCQMs/MIPS CQMs, and:
- Achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and;
- Achieves a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set, the ACO will meet the quality performance standard used to determine eligibility for shared savings and to avoid maximum shared losses, if applicable.

We received a few comments on our proposal in the CY 2023 PFS proposed rule to extend the incentive for reporting eCQMs/MIPS CQMs through performance year 2024 suggesting that we extend the incentive beyond 2024 to facilitate the national shift towards eCQMs. In our response in the CY 2023 PFS final rule (87 FR 69836), we stated that ''We are not extending the incentive beyond performance year 2024 at this time because this policy is intended to align with the timeline for sunsetting of the CMS Web Interface reporting option at the end of performance year 2024. We will continue to monitor the impact of this policy as we gain more experience with ACOs reporting eCQMs/MIPS CQMs and may revisit the policy in future rulemaking.''

(2) Proposed Revisions

We are committed to continuing to support ACOs in the transition to all payer/all patient eCQMs and digital quality measurement reporting. As described in section III.G.4.b.(2)(a) of this proposed rule, for performance year 2025 and subsequent performance years, we are proposing to require Shared Savings Program ACOs to report the APP Plus quality measure set as

proposed in section IV.A.4.c.(3) of this proposed rule. The APP Plus quality measure set would incrementally grow to comprise of eleven measures, consisting of six measures from the APP quality measure set and five newly proposed measures from the Adult Universal Foundation measure set that would be incrementally incorporated into the APP Plus quality measure set over performance years 2025 through 2028. We are also proposing to focus the collection types available to Shared Savings Program ACOs for reporting the APP Plus quality measure set to all payer/all patient eCQMs and Medicare CQMs (while not adding the MIPS CQM as an available collection type for Shared Savings Program ACOs under the APP Plus quality measure set).

The Shared Savings Program continues to hear from ACOs and other stakeholders about the challenges with reporting on all payer/all patient measures and meeting data management requirements given their muti-practice/multi EHR structure, the challenges to aggregate data with the health IT infrastructure in use by ACOs and current state of interoperability. Shared Savings Program quality reporting data over the past two performance years indicate that ACOs have been slow to report eCQMs. In performance year 2021, 5 of 475 ACOs reported eCQMs under the APP. In performance year 2022, among ACOs that reported quality data under the APP, 24 out of 482 reported eCQMs with 7 of these ACOs reporting a combination of eCQMs and MIPS CQMs.[480] We encourage ACOs, especially those ACOs serving large, underserved populations, to leverage interoperability and digital data more fully and to more quickly transition to eCQMs. As such, we are proposing to extend the eCQM reporting incentive to performance year 2025 and subsequent performance years to support ACOs in meeting the Shared Savings Program quality performance standard for sharing in savings at the maximum rate under its track.

Specifically, we are proposing that for performance year 2025 and subsequent performance years, an ACO will meet the quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:

- If the ACO reports all of the eCQMs in the APP Plus quality measure set applicable for a performance year, meeting the data completeness requirement at § 414.1340 for all eCQMs, and;
- Achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP Plus quality measure set, and;
- Achieves a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining measures in the APP Plus quality measure set.

The eCQM reporting incentive would apply only to those ACOs that report all of the eCQMs in the APP Plus quality measure set applicable for a performance year and meet the data completeness requirement for all of the eCQMs. The reporting incentive would not apply to ACOs that report a combination of eCQMs/Medicare CQMs or report only Medicare CQMs. We will further assess the need for the eCQM reporting incentive in the future as ACOs continue the transition to adopting eCQMs and may make refinements as needed in future rulemaking. The proposed APP Plus quality measure set for Shared Savings Program ACOs for performance year 2025, performance years 2026 and 2027, and performance year 2028 and subsequent performance years are displayed in Tables 34, 35, and 36, respectively. We included the measure type in these tables for each measure in the APP Plus quality measure set to provide ACOs with a list of the outcome measures for purposes of qualifying for the eCQM reporting incentive.

(3) Proposed Changes to Regulation Text

We are proposing to add paragraphs (a)(5)(i)(B)(*1*) and (*2*) to § 425.512 to incorporate our proposal to extend the eCQM reporting incentive to performance year 2025 and subsequent performance years into the regulation text.

We seek comment on our proposal to extend the eCQM reporting incentive to performance year 2025 and subsequent performance years.

e. Summary of Proposals

In Table 33 of this proposed rule, we summarize the proposed changes to the regulation at § 425.512(a)(5) to reflect the changes we are proposing to the quality reporting requirements and quality performance standard for performance year 2025 and subsequent performance years.

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[480] Counts based on internal analysis of ACOs' quality reporting in performance year 2022 and 2021.

TABLE 33: Proposed APP Plus Quality Measure Set Reporting Requirements and Quality Performance Standard for Shared Savings ACOs for Performance Year 2025 and Subsequent Performance Years

	Performance Year 2025	Performance Years 2026 and 2027	Performance Year 2028 and Subsequent Performance Years
Shared Savings Program ACO Quality Reporting Requirements	ACOs are required to report the **5** eCQMs/Medicare CQMs in the APP Plus quality measure set and administer the CAHPS for MIPS survey. CMS will calculate 2 claims-based measures.	ACOs are required to report **6** eCQMs/Medicare CQMs in the APP Plus quality measure set and administer the CAHPS for MIPS survey. CMS will calculate 2 claims-based measures.	ACOs are required to report **8** eCQMs/Medicare CQMs in the APP Plus quality measure set and administer the CAHPS for MIPS survey. CMS will calculate 2 claims-based measures.
Shared Savings Program ACO Quality Performance Standard and Alternative Quality Performance Standard	**Quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:** 1. For ACOs that report eCQMs/Medicare CQMs and serve a high proportion of underserved beneficiaries, achieving a health equity adjusted quality performance score that is equivalent to or higher than the **40th** percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, or 2. Reporting the **5** eCQMs in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 for all 5 eCQMs, and achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set and a quality performance score equivalent to or higher than the **40th** percentile of the performance benchmark on at least 1 of the remaining **7** measures in the APP Plus quality measure set. **Alternative quality**	**Quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:** 1. For ACOs that report eCQMs/Medicare CQMs and serve a high proportion of underserved beneficiaries, achieving a health equity adjusted quality performance score that is equivalent to or higher than the **40th** percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, or 2. Reporting the **6** eCQMs in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 for all 6 eCQMs, and achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set and a quality performance score equivalent to or higher than the **40th** percentile of the performance benchmark on at least 1 of the remaining **8** measures in the APP Plus quality measure set. **Alternative quality**	**Quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:** 1. For ACOs that report eCQMs/Medicare CQMs and serve a high proportion of underserved beneficiaries, achieving a health equity adjusted quality performance score that is equivalent to or higher than the **40th** percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, or 2. Reporting the **8** eCQMs in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 for all 8 eCQMs, and achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set and a quality performance score equivalent to or higher than the **40th** percentile of the performance benchmark on at least 1 of the remaining **10** measures in the APP Plus quality measure set. **Alternative quality**

	Performance Year 2025	Performance Years 2026 and 2027	Performance Year 2028 and Subsequent Performance Years
	performance standard used to determine shared savings using the sliding scale methodology: An ACO that fails to meet the criteria above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1of the 4 outcome measures in the APP Plus quality measure set would share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's health equity adjusted quality performance score. If an ACO (1) does not report any of the **5** eCQMs /Medicare CQMs in the APP Plus quality measure set and (2) does not administer a CAHPS for MIPS survey, the ACO will not meet the quality performance standard or the alternative quality performance standard. This ACO will be ineligible to share savings and will owe maximum shared losses, if applicable.	**performance standard used to determine shared savings using the sliding scale methodology:** An ACO that fails to meet the criteria above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set would share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's health equity adjusted quality performance score. If an ACO (1) does not report any of the **6** eCQMs /Medicare CQMs in the APP Plus quality measure set and (2) does not administer a CAHPS for MIPS survey, the ACO will not meet the quality performance standard or the alternative quality performance standard. This ACO will be ineligible to share savings and will owe maximum shared losses, if applicable.	**performance standard used to determine shared savings using the sliding scale methodology:** An ACO that fails to meet the criteria above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set would share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's health equity adjusted quality performance score. If an ACO (1) does not report any of the **8** eCQMs /Medicare CQMs in the APP Plus quality measure set and (2) does not administer a CAHPS for MIPS survey, the ACO will not meet the quality performance standard or the alternative quality performance standard. This ACO will be ineligible to share savings and will owe maximum shared losses, if applicable.

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f. Proposed APP Plus Quality Measure Set

(1) Background

The APP quality measure set for performance year 2024 and subsequent performance years was finalized in the CY 2024 PFS final rule (88 FR 79112 through 79114). In that final rule, for performance year 2024 and subsequent performance years, we also finalized the addition to the APP quality measure set of the Medicare CQM collection type for Diabetes: Hemoglobin A1c (HbA1c) Poor Control (Quality #: 001), Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality #: 134), and Controlling High Blood Pressure (Quality #: 236).

(2) Proposed Revisions

As described in section III.G.4.b.(2)(a) of this proposed rule, for performance year 2025 and subsequent performance years, we are proposing to require Shared Savings Program ACOs to report the APP Plus quality measure set as proposed in section IV.A.4.c.(3) of this proposed rule. The APP Plus quality measure set would comprise of eleven measures, consisting of six measures from the APP quality measure set and five newly proposed measures from the Adult Universal Foundation measure set that would be incrementally incorporated into the APP Plus quality measure set over performance years 2025 through 2028. We are also proposing to focus the collection types available to Shared Savings Program ACOs for reporting the APP Plus quality measure set to all payer/all patient eCQMs and Medicare CQMs.

The proposed APP Plus quality measure set for Shared Savings Program ACOs for performance year 2025, performance years 2026 and 2027, and performance year 2028 and subsequent performance years are displayed in Tables 34, 35, and 36, respectively. In these tables, we also included the measure type for each measure in the APP Plus quality measure set to provide ACOs with a list of the outcome measures for purposes of qualifying for

the eCQM reporting incentive, as described in section III.G.4.d. of this proposed rule. This information is also relevant to the alternative quality performance standard under which ACOs that fail to meet the quality performance standard to qualify for the maximum sharing rate, but that achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP Plus quality measure set, may be eligible to share in savings on a sliding scale, as discussed in the current § 425.512(a)(4)(ii).

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TABLE 34: Measures Included in the APP Plus Quality Measure Set for Shared Savings Program ACOs for Performance Year 2025

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Person-Centered Care	Patient Engagement/Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Behavioral Health	Process
236	Controlling High Blood Pressure	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
113	Colorectal Cancer Screening	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
112	Breast Cancer Screening	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Wellness and Prevention	Process

^ Indicates this is an outcome measure for purposes of qualifying for the eCQM reporting incentive and the alternative quality performance standard.

TABLE 35: Measures Included in the APP Plus Quality Measure Set for Shared Savings Program ACOs for Performance Years 2026 and 2027

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Person-Centered Care	Patient Engagement/Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/Medicare CQM/	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Behavioral Health	Process
236	Controlling High Blood Pressure	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
113	Colorectal Cancer Screening	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
112	Breast Cancer Screening	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
305	Initiation and Engagement of Substance Use Disorder Treatment	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Behavioral health	Process

^ Indicates this is an outcome measure for purposes of qualifying for the eCQM reporting incentive and the alternative quality performance standard.

TABLE 36: Measures Included in the APP Plus Quality Measure Set for Shared Savings Program ACOs for Performance Year 2028 and Subsequent Performance Years

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Person-Centered Care	Patient Engagement/Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Behavioral Health	Process
236	Controlling High Blood Pressure	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
113	Colorectal Cancer Screening	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
112	Breast Cancer Screening	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
305	Initiation and Engagement of Substance Use Disorder Treatment	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Behavioral health	Process
487	Screening for Social Drivers of Health	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Equity	Process
493	Adult Immunization Status	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Wellness and Prevention	Process

^ Indicates this is an outcome measure for purposes of qualifying for the eCQM reporting incentive and the alternative quality performance standard.

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g. Survey Modes for the Administration of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey Request for Information

We seek public comment on the potential expansion of the survey modes of the CAHPS for MIPS Survey from a mail-phone protocol to a web-mail-phone protocol. During the 2023 CAHPS for MIPS Web Mode Field Test,[481] adding the web-based survey mode to the current mail-phone protocol of CAHPS for MIPS survey administration resulted in an increased response rate. Additional information on the CAHPS for MIPS Survey Request for Information is available in section IV.A.4.e.(1)(e) of this proposed rule.

5. Providing the Option of Prepaid Shared Savings

a. Background

In the CY 2023 PFS final rule (87 FR 69782 through 69805), CMS finalized a new payment option for eligible Shared Savings Program ACOs entering agreement periods beginning on or after January 1, 2024, to receive advance shared savings payments. This payment option is referred to as advance investment payment (AIP) and the payments themselves are referred to as advance investment payments.

These payments are intended to improve the quality and efficiency of items and services furnished to Medicare beneficiaries by reducing the barriers to participation in the Shared Savings Program by supporting investments in increased staffing, healthcare infrastructure, and the provision of accountable care for underserved beneficiaries. Accordingly, advance investment payments must be spent on one of the following categories: increased staffing, healthcare infrastructure, and the provision of accountable care for underserved beneficiaries, which may include addressing social determinants of health (42 CFR 425.630(e)(1)).

Advance investment payments are only available to ACOs newly entering the Shared Savings Program in their first agreement period (§ 425.630(b)(1)). Many commentors on the CY 2023 PFS final rule (87 FR 69782 through 69805) suggested that CMS should expand access to advance investment payments by expanding the eligibility criteria to include currently participating ACOs as well as high revenue ACOs. While we do not believe that it is appropriate to expand the eligibility criteria for advance investment payments at this time, as CMS still needs time to assess the impact of the new payment option, there is persuasive evidence that investment in staffing, healthcare infrastructure, and accountable care for underserved beneficiaries could be valuable for all ACOs, not just those that are new to the program. Investment in care coordination for beneficiaries reduces costs and improve the quality of care received.[482] [483] [484] Investment in health information technology can be leveraged to empower individuals, address patients' full range of health needs, promote healthy behaviors, and facilitate better health outcomes for individuals, families, and communities.[485] Additionally, there is evidence that investment in services not currently covered by Medicare may improve beneficiary health and reduce avoidable health care utilization costs over time, including coverage of dental [486] [487] [488] hearing [489] [490] and vision [491] care.

Furthermore, we have come to understand that, for beneficiaries, the benefits of receiving services from providers associated with ACOs—such as improvements in quality and coordinated care—may not be immediately apparent. By encouraging ACOs to invest in new services that beneficiaries otherwise would not receive, like hearing, vision and dental services, the benefits of receiving care from providers who are part of an ACO would become more tangible. This would encourage beneficiaries to receive care from providers participating in an ACO and may ultimately result in improved quality and efficiency of care for beneficiaries.

For ACOs that are currently participating in the Shared Savings Program and that reinvest their earned shared savings payments in activities that reduce costs and improve quality of care, it could be more valuable to gain access to those shared savings payments early in and/or throughout each performance year, instead of waiting months after the end of each performance year when any earned shared savings payments are distributed. Currently, CMS completes the financial reconciliation calculations for each ACO during the summer after the end of each performance year, which allows time for claims runout

[481] *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2893/2023_CAHPS_for_MIPS_WebMode_Field_Test.pdf.*

[482] Breckenridge ED, Kite B, Wells R, Sunbury TM. Population Health Management. Effect of Patient Care Coordination on Hospital Encounters and Related Costs. September 26, 2019. Available at *https://doi.org/10.1089/pop.2018.0176.*

[483] Elliott MN, Adams JL, Klein DJ, et al. Journal of General Internal Medicine. Patient-Reported Care Coordination is Associated with Better Performance on Clinical Care Measures. September 20, 2021. Available at *https://link.springer.com/article/10.1007/s11606-021-07122-8.*

[484] Figueroa JF, Feyman Y, Zhou X, et al. Hospital-level care coordination strategies associated with better patient experience. BMJ Quality & Safety. April 4, 2018. Available at *https://qualitysafety.bmj.com/content/27/10/844.*

[485] The Office of the National Coordinator for Health Information Technology. 2020–2025 Federal Health IT Strategic Plan. Available at *https://www.healthit.gov/sites/default/files/page/2020-10/Federal%20Health%20IT%20Strategic%20Plan_2020_2025.pdf.*

[486] Schenkein HA, Loos BG. Inflammatory mechanisms linking periodontal diseases to cardiovascular diseases. Journal of Clinical Periodontology. April 30, 2013. Available at *https://doi.org/10.1111/jcpe.12060.*

[487] Teeuw WJ, Gerdes VE, Loos BG. Effect of periodontal treatment on glycemic control of diabetic patients: a systematic review and meta-analysis. Diabetes Care. February 2010. Available at *https://pubmed.ncbi.nlm.nih.gov/20103557/.*

[488] Allareddy V, Rampa S, Lee MK, Allareddy V, Nalliah RP. Hospital-based emergency department visits involving dental conditions: Profile and predictors of poor outcomes and resource utilization. The Journal of the American Dental Association. November 19, 2014. Available at *https://doi.org/10.14219/jada.2014.7.*

[489] Choi JS, Adams ME, Crimmins EM, Lin FR, Ailshire JA. Association between hearing aid use and mortality in adults with hearing loss in the USA: a mortality follow-up study of a cross-sectional cohort. The Lancet Healthy Longevity. January 3, 2024. Available at *https://doi.org/10.1016/S2666-7568(23)00232-5.*

[490] Reed NS, Altan A, Deal JA, et al. Trends in Health Care Costs and Utilization Associated with Untreated Hearing Loss Over 10 Years. *JAMA Otolaryngology—Head and Neck Surgery.* November 8, 2018. Available at *https://jamanetwork.com/journals/jamaotolaryngology/fullarticle/2714049.*

[491] Lipton BJ, Decker SL. The effect of health insurance coverage on medical care utilization and health outcomes: Evidence from Medicaid adult vision benefits. Journal of Health Economics. November 11, 2015. Available at *https://doi.org/10.1016/j.jhealeco.2015.10.006.*

and other necessary data to become available. CMS compares the updated historical benchmark to an ACO's assigned beneficiaries' per capita expenditures during the performance year to determine whether the ACO may share in savings or losses, if owed. CMS then notifies the ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due. These payments are generally distributed to ACOs in the early fall following the end of each performance year. This is the sole payment CMS makes to an ACO in the Shared Savings Program and generally an ACO's sole source of revenue. Distributing prepaid shared savings during a performance year would allow ACOs to invest these payments in additional services for assigned beneficiaries, staffing, and healthcare infrastructure earlier and reap the benefits from that investment earlier.

The CMS Innovation Center tested a number of strategies for providing more experienced ACOs with advances of funding during each performance year. One of the innovations was the infrastructure payments available in the Next Generation ACO model, a CMS Innovation Center model that was intended for more experienced ACOs.[492] Most Next Generation ACOs (82 percent) that participated in the Next Generation ACO model in 2018 had prior experience as Medicare ACOs before starting in the model, and the majority (56 percent) previously participated in the Shared Savings Program.[493] ACOs selecting the infrastructure payment option received $6 per assigned beneficiary per month to support ACO Activities, which was later recouped during financial settlement following each performance year. The model defined ACO Activities as activities related to promoting accountability for the quality, cost, and overall care for the population of beneficiaries assigned to the Next Generation ACO, including managing, and coordinating care; encouraging investment in healthcare infrastructure and redesigned care processes for high quality and efficient service delivery; or carrying out any other obligation or duty of the ACO under the terms of the Next Generation ACO model. Examples of these activities included, but were not limited to, providing direct patient care in a manner that reduces costs and improves quality; promoting evidence-based medicine and patient engagement; reporting on quality and cost measures; coordinating care, such as through the use of telehealth, remote patient monitoring, and other enabling technologies; establishing and improving clinical and administrative systems for the ACO; meeting the quality performance standards; evaluating health needs; communicating clinical knowledge and evidence-based medicine; and developing standards for beneficiary access and communication, including beneficiary access to medical records. In interviews performed as part of the CMS Innovation Center's evaluation of the model, Next Generation ACO leaders described using these funds to support upfront operating costs and healthcare infrastructure and clinical process enhancements such as new staff, health information technology, data analytic capacity, population health management, or care coordination.[494]

Despite these ACOs' prior experience as Medicare ACOs and the meaningful investments many had made in their own healthcare infrastructure and providers, they still found value in access to funding during the performance year. Almost all Next Generation ACOs used the funds to develop workflows informed by data analytics and clinical staff input. Most Next Generation ACOs also reported using the funds to support care management, such as acquiring tools and developing healthcare infrastructure to support care coordination. Leaders from many Next Generation ACOs described how the payments facilitated new processes for seamless patient care handoffs between health care providers, enabled the creation of better workflows for scheduling follow-up visits, and supported provision of screenings and assessments. Data from a clinician survey suggested that the payments were likely helpful in improving the delivery or coordination of care, with 63 percent of providers agreeing that additional resources to support practice changes made their day-to-day work easier.[495] Separately, the ACO Investment Model (AIM), a model run by the CMS Innovation Center which informed development of the advance investment payments, gave participating ACOs upfront and quarterly funding to spend on ACO start-up costs. These ACOs primarily invested in staffing and healthcare infrastructure including care management, ACO administration, health IT and data analysis,[496] and these ACOs generated an estimated net aggregate reduction in spending by Medicare of $381.5 million after accounting for Medicare's payment of AIM funds and participating ACOs' earned shared savings.[497]

Section 1899(i)(3) of the Act authorizes the Secretary to use other payment models instead of the one-sided model described in section 1899(d) of the Act so long as the Secretary determines that the other payment model will improve the quality and efficiency of items and services furnished to Medicare beneficiaries without additional program expenditures. We are interested in building on experience from the Next Generation ACO model, and we agree, in part, with comments on the CY 2023 PFS final rule that encouraged CMS to expand AIP to additional ACOs. While we do not believe it is appropriate to expand the eligibility criteria for AIPs at this time as explained earlier in this section, we agree with commenters that additional ACOs could benefit from expanded access to performance year funding that encourages investment in staffing, healthcare infrastructure, and additional services for beneficiaries. Prepaid shared savings would be required to be spent at least partially on direct beneficiary services, improving the quality of care beneficiaries receive.

Consequently, under the authority provided to the Secretary by section 1899(i)(3) of the Act, we are proposing to provide prepaid shared savings to certain ACOs that meet the eligibility criteria described in section III.G.5.b of this proposed rule. Such payments would be made pursuant to the standards we propose to establish in new § 425.640. This new payment

[492] Refer to ''Next Generation ACO Model'' available at *https://www.cms.gov/priorities/innovation/innovation-models/next-generation-aco-model.*

[493] NORC at the University of Chicago. Next Generation Accountable Care Organization Model Third Evaluation Report. September 2020. Available at *https://www.cms.gov/priorities/innovation/data-and-reports/2020/nextgenaco-thirdevalrpt-fullreport.*

[494] NORC at the University of Chicago. Evaluation of the Next Generation Accountable Care Organization (NGACO) Model—Final Report. January 2024. Available at *https://www.cms.gov/priorities/innovation/data-and-reports/2024/nextgenaco-sixthevalrpt.*

[495] NORC at the University of Chicago. Next Generation Accountable Care Organization (NGACO) Model Evaluation Third Evaluation Report. 2020. Available at *https://www.cms.gov/priorities/innovation/data-and-reports/2020/nextgenaco-thirdevalrpt-fullreport.*

[496] Abt Associates, Evaluation of the Accountable Care Organization Investment Model, AIM Implementation and Impacts over Two Performance Years (September 2019), page 55. Available at *https://www.cms.gov/priorities/innovation/aim-second-annrpt.pdf.*

[497] Abt Associates, Evaluation of the Accountable Care Organization Investment Model, Final Report (September 2020), page 39. Available at *https://innovation.cms.gov/data-and-reports/2020/aim-final-annrpt.*

option would provide prepaid shared savings to ACOs with a history of earning shared savings while participating in the Shared Savings Program. These payments would be distributed on a quarterly basis and would be recouped from shared savings CMS determines the ACO to have earned during the annual financial reconciliation cycle. Prepaid shared savings would be the advance payment of shared savings that are expected to be earned by the ACO and are covered under the Shared Savings Distribution Waiver (76 FR 66726). If the ACO does not earn sufficient shared savings to offset the advanced payment of shared savings during the applicable performance year, CMS may withhold or terminate the ACO's prepaid shared savings under proposed § 425.640(h)(1)(iii).

We have determined that the other payment model CMS has adopted under section 1899(i)(3) of the Act would continue to improve the quality and efficiency of care should this proposal be finalized. Section 1899(i)(3)(A) of the Act requires CMS determine that the other payment model will improve the quality and efficiency of items furnished under the Medicare program. Based on the evidence for direct beneficiary services noted above, our experience administering the Shared Savings Program, and the CMS Innovation Center's experience with the ACO Investment Model and infrastructure payments in the Next Generation ACO model, we have determined that allowing ACOs access to funding earlier than currently available, in the form of prepaid shared savings, would allow ACOs to more rapidly achieve the benefits of investing in staffing, healthcare infrastructure, and direct beneficiary services. Improvement in these areas would improve the quality and efficiency of beneficiary care therefore meeting the standard of section 1899(i)(3)(A) of the Act. As we explained earlier in this section, ACOs have expenditures throughout the PY, particularly when implementing care coordination and beneficiary management strategies, and having access to their shared savings early can help ensure the ACO has adequate funding to perform these services throughout the year.

Section 1899(i)(3)(B) of the Act requires CMS to determine that prepaid shared savings, when implemented in combination with existing modifications made to the Shared Savings Program payment model specified in section 1899(d) of the Act, will not result in additional program expenditures. The addition of prepaid shared savings meets this standard in part because the eligibility criteria for prepaid shared savings have been selected to only permit ACOs that CMS estimates are most likely to earn shared savings to receive payments. Additionally, any payments the ACO receives under this proposal must be repaid to CMS, and CMS would be protected by the ACOs' repayment mechanisms in the event that an ACO does not earn shared savings or cannot otherwise repay the amount owed to CMS. Based on this design, we estimate that there would be no additional program expenditures stemming from the implementation of prepaid shared savings under this proposal. Please review section VII of this proposed rule for a more complete discussion of the financial impact of the Shared Savings Program payment model, including the findings necessary to demonstrate compliance with section 1899(i)(3)(B) of the Act.

We intend to periodically reassess whether a payment model established under section 1899(i)(3) of the Act, including the payment of prepaid shared savings, continues to improve the quality and efficiency of items and services furnished to Medicare beneficiaries without resulting in additional program expenditures. If we determine that the payment model no longer satisfies the requirements of section 1899(i)(3) of the Act (for example if the payment model results in net program costs), we would undertake additional notice and comment rulemaking to adjust our payment methodology to assure continued compliance with the statutory requirements.

b. Eligibility

To ensure that prepaid shared savings are provided only to ACOs that are well-positioned to use prepaid shared savings to improve the quality and efficiency of care to their assigned beneficiaries while minimizing the risk of an ACO being unable to repay prepaid shared savings, we propose to limit the availability of prepaid shared savings to those ACOs that have a track record of success in the Shared Savings Program. This approach is also consistent with our compliance with section 1899(i)(3)(B) of the Act as such ACOs are most likely to be able to repay the upfront funding through earned shared savings.

We propose to establish the eligibility criteria for prepaid shared savings in § 425.640(b). CMS must determine that an ACO meets all of the following criteria for the ACO to be eligible to receive prepaid shared savings during an agreement period:

- The ACO is a renewing ACO as defined under § 425.20 entering an agreement period beginning on January 1, 2026, or in subsequent years.
- The ACO must have received a shared savings payment for the most recent performance year that:

(A) Occurred prior to the agreement period for which the ACO has applied to receive prepaid shared savings; and

(B) CMS has conducted financial reconciliation.

- The ACO must have a positive prior savings adjustment as calculated per § 425.658 at application disposition for the agreement period in which they would receive prepaid shared savings.
- The ACO does not have any outstanding shared losses or advance investment payments that have not yet been repaid to CMS after reconciliation for the most recent performance year for which CMS completed financial reconciliation.
- If the ACO received prepaid shared savings in the current agreement period or a prior agreement period, the ACO must have fully repaid the amount of prepaid shared savings received through the most recent performance year for which CMS has completed financial reconciliation.
- The ACO is participating in Levels C–E of the BASIC track or the ENHANCED track during the agreement period in which they would receive prepaid shared savings.
- The ACO has in place an adequate repayment mechanism in accordance with § 425.204(f) that can be used to recoup outstanding prepaid shared savings.
- During the agreement period immediately preceding the agreement period in which the ACO would receive prepaid shared savings, the ACO:

(A) Met the quality performance standard as specified under § 425.512; and

(B) Has not been determined by CMS to have avoided at-risk beneficiaries as specified under § 425.316(b)(2).

These eligibility criteria have been selected to allow only ACOs with a record of meeting the quality performance standard, not avoiding at risk beneficiaries, and recent success in earning shared savings to receive prepaid shared savings. This is for the protection of both CMS and the ACOs, as CMS does not want to overestimate an ACO's ability to earn future shared savings and burden an ACO with debt that they would not be able to repay. Our experience administering the Shared Savings Program leads us to determine that ACOs with prior success in the program—that is, ACOs with a record of meeting the quality

performance standard, not avoiding at risk beneficiaries, and recent success in earning shared savings—are well positioned to identify beneficiary needs and invest prepaid shared savings to improve beneficiary care and are therefore most likely to benefit from prepaid shared savings. These ACOs would also be reasonably confident they will be able to repay CMS through their earned shared savings and would therefore be comfortable spending the funding they receive. Accordingly, CMS would only permit ACOs that are currently participating in the Shared Savings Program, that have earned shared savings in the most recent performance year for which financial reconciliation has been completed, and that have a positive prior savings adjustment at application disposition to receive prepaid shared savings, as they have the history of success that provides CMS with a more reasoned expectation that they will earn shared savings in the future. New ACOs would not be eligible for prepaid shared savings, as they do not have a recent performance history we can use to estimate future performance. Many new ACOs are eligible to receive advance investment payments, which are not available to ACOs currently participating in the Shared Savings Program. Advance investment payments are more tailored to the needs of a new ACO as there is more flexibility in the use of funding and advance investment payments do not need to be repaid in the event that the ACO does not earn shared savings.

Additionally, ACOs that did not meet the quality performance standard as specified under § 425.512 or were subject to a pre-termination action from CMS after determining an ACO avoided at-risk beneficiaries as specified under § 425.316(b)(2) in the agreement period preceding the agreement period in which they would receive prepaid shared savings would be prohibited from participating in the prepaid shared savings payment option, as these compliance issues can prevent an ACO from earning shared savings that would be used to repay the prepaid shared savings.

CMS also proposes to limit participation in the prepaid shared savings payment option to ACOs that have fully repaid all shared losses they may owe and any advance investment payments they may have received in a prior agreement period, and to ACOs that participate in a two-sided risk track (Levels C–E of the BASIC track or the ENHANCED track), as these tracks require a repayment mechanism in accordance with § 425.204(f), which could be used to recoup prepaid shared savings. CMS also proposes these criteria in part to limit participation to ACOs that are most likely to be able to repay any prepaid shared savings they receive. Similarly, if the ACO received prepaid shared savings in a current or previous agreement period, they must have fully repaid the amount of prepaid shared savings received though the most recent performance year for which CMS has completed financial reconciliation before they would be able to renew their participation in prepaid shared savings for another agreement period. For example, if an ACO is in the fifth year of its 5-year agreement period during which they have been receiving prepaid shared savings and is in the process of renewing for a new agreement period, CMS would ensure they have fully repaid the prepaid shared savings received from the first four performance years of their current agreement period through earned shared savings before they are approved to receive prepaid shared savings in a new agreement period. As CMS intends to provide prepaid shared savings to ACOs if they improve and maintain performance and continue to see success in the program on an annual basis, ACOs that are not initially eligible would have the option to participate in the prepaid shared savings payment option in future years if they demonstrate a more recent history of success in the program and meet the other eligibility criteria. These criteria also provide an additional incentive for ACOs to improve their performance in the program. CMS would also continue to review the eligibility criteria over time and may expand eligibility in future years if we determine that doing so is in the interests of the Shared Savings Program, participating ACOs, and their beneficiaries, and all requirements under section 1899(i)(3) of the Act are satisfied. Additionally, to standardize timelines for payment, spending, and recoupment of prepaid shared savings, ACOs would only be eligible for prepaid shared savings if they renew or early renew to begin a new agreement period. The proposed policies for the calculation, spending and recoupment of prepaid shared savings allow for up to five years for ACOs to receive, spend and repay the funding through earned shared savings. We propose to create a new paragraph in § 425.100(e) to establish that an ACO may receive prepaid shared savings if it meets the criteria under § 425.640(b). We propose in § 425.640(b) to specify the eligibility criteria for an ACO to receive prepaid shared savings. We seek comments on these proposals.

c. Application Procedure & Contents

We propose to establish the process for an ACO to apply for prepaid shared savings in § 425.640(c). Specifically, we propose that an ACO must submit to CMS supplemental application information sufficient for CMS to determine whether the ACO is eligible to receive prepaid shared savings. The application cycle for prepaid shared savings would be conducted as part of, and in conjunction with, the Shared Savings Program application process under § 425.202, with instructions and timelines published on the Shared Savings Program website. We propose the initial application cycle to apply for prepaid shared savings would be for a January 1, 2026, start date. We intend to provide further information regarding the process, including the application contents and specific requirements such as the deadline for submitting applications and all supplemental application information that would be required, through subregulatory guidance. The prepaid shared savings application procedure would also include a process by which CMS provides an applicant with feedback and an opportunity to clarify or revise their application.

CMS would provide preliminary information to the applicant ACO about its eligibility to receive prepaid shared savings during the Phase 1 application cycle requests for information, and a final determination about its eligibility to receive prepaid shared savings at the time of final application dispositions. For example, for ACOs applying in 2025 for an agreement period beginning in 2026, we would provide preliminary information identifying whether an ACO is likely to earn shared savings in the 2024 performance year and have a positive prior savings adjustment as calculated per § 425.658 at application disposition.

We propose at § 425.640(d)(1) that an ACO would be required to submit a spend plan as part of its application for prepaid shared savings. We propose that the plan must describe how the ACO would spend the prepaid shared savings during the first performance year of the agreement period during which the ACO would receive prepaid shared savings, including the breakdown of how the funding would be spent consistent with the allowable uses as described in section III.G.5.d of this proposed rule and information about: (1) direct beneficiary services that would be provided to ACO beneficiaries; and (2) investments that would be made in the ACO with prepaid shared savings. ACOs must also

include their communication strategy for informing both CMS and any impacted beneficiaries if the ACO will no longer be providing any direct beneficiary services (as described in section III.G.5.d of this proposed rule) that had previously been provided by the ACO using prepaid shared savings. This communication strategy must include when and how the ACO intends to notify CMS and the impacted beneficiaries as well as any available alternatives for impacted beneficiaries to access similar services. ACOs would be able to limit the distribution of direct beneficiary services to subgroups of assigned beneficiaries including those with specific medical conditions or specific socioeconomic needs. ACOs would be required to attest that they will not discriminate on the basis of race, color, religion, sex, national origin, disability, or age with respect to their use of prepaid shared savings. ACOs would have flexibility to alter their use of prepaid shared savings from their submitted spend plans during each performance year but would be required to ensure than any changes to proposed spending aligns with the restrictions on spending discussed in section III.G.5.d of this proposed rule. CMS would review mid-year changes of the use of prepaid shared savings at the end of each performance year. CMS would also be able to review an ACO's spend plan at any time and require the ACO to modify its spend plan to comply with the requirements of § 425.640(d) and (i).

As discussed in greater detail in section III.G.5.h of this proposed rule, we would reserve the right to withhold or terminate an ACO's ability to receive the prepaid shared savings if it is not in compliance with the requirements of the Shared Savings Program codified in part 425 of our regulations, pursuant to proposed § 425.640(h)(1)(i). In addition, by certifying their application under § 425.202(a)(2), the ACO certifies that the information contained in the application, including information related to the intended use of prepaid shared savings, is accurate, complete, and truthful.

We propose at § 425.640(d) that we would review the information submitted in the ACO's prepaid shared savings application to determine whether an ACO meets the criteria for prepaid shared savings and would approve or deny the application accordingly. We would review the ACO's Shared Savings Program renewal application simultaneously with the prepaid shared savings application.

As discussed in section III.G.5.g of this proposed rule, we are also proposing to update our public reporting requirements under § 425.308 by adding new paragraph (b)(10) to require an ACO to publicly report its spend plan. We propose to require that the ACO post on its dedicated public reporting web page: (1) the total amount of prepaid shared savings received from CMS for each performance year; (2) the ACO's spend plan; and (3) an itemization of how the prepaid shared savings were actually spent during each performance year, including expenditure categories, the dollar amounts spent on the various categories, information about which groups of beneficiaries received direct beneficiary services that were purchased with prepaid shared savings and investments that were made in the ACO with prepaid shared savings, how these direct beneficiary services were provided to beneficiaries and how the direct beneficiary services and investments supported the care of beneficiaries, any changes to the spend plan as submitted under § 425.640(d)(2) (if applicable), and such other information as may be specified by CMS. Additionally, we are proposing that the ACO would be required to report the same information to CMS under § 425.640(i) to facilitate efficient monitoring. This would help ensure that CMS efficiently obtains information in a consistent manner from all ACOs receiving prepaid shared savings and thereby support CMS's monitoring and analysis of the use of prepaid shared savings. CMS will also make this data publicly available through a public use file. Further, we expect to use the submitted data as the template that ACOs can use to populate their public reporting web page early in each performance year to minimize administrative burden for ACOs. We also intend to use the information submitted to CMS to generate a public use file that can be used to quickly review the use of prepaid shared savings across all participating ACOs.

We propose to add § 425.640(c) and (d) to establish standards for the contents of an application to be determined eligible for prepaid shared savings as well as the procedures for filing such an application. We seek comments on these proposals.

d. Allowable and Prohibited Uses of Prepaid Shared Savings

We propose in § 425.640(e) to specify how an ACO may use prepaid shared savings. Similar to advance investment payments, prepaid shared savings are intended to improve quality and efficiency of items and services furnished to Medicare beneficiaries. We recognize that there are many ways to do this, and that the most effective ways would vary by ACO. Our proposal intends to provide ACOs with flexibility to use payments consistent with broad allowable uses. However, as prepaid shared savings are only available to ACOs that are currently successfully participating in the Shared Savings Program, we intend to place restrictions on the amount of total annual prepaid shared savings that can be spent on each category of spending. Financially successful ACOs are likely to have already made significant investments in staffing and healthcare infrastructure, as they are necessary for the functioning of an ACO, and we intend to encourage ACOs receiving prepaid shared savings to invest in direct beneficiary services that are not already offered by the ACO. Direct beneficiary services like vision, hearing and dental, and other services that have a reasonable expectation of improving or maintaining the health or overall function of ACO beneficiaries, have the potential to further improve beneficiary outcomes, reduce costs, and improve beneficiary engagement and willingness to receive care from a provider affiliated with an ACO. However, staffing and healthcare infrastructure are still important expenses that can have positive impacts on healthcare costs, ACO efficiency, the quality of beneficiary care, regardless of an ACO's experience in the Shared Savings Program. Accordingly, we also intend to allow ACOs to use some of their prepaid shared savings to invest in these areas. For each performance year, ACOs would be permitted to use up to 50 percent of their estimated annual prepaid shared savings on staffing and healthcare infrastructure and up to 100 percent of their estimated annual prepaid shared savings on direct beneficiary services. ACOs must use a minimum of 50 percent of their prepaid shared savings on direct beneficiary services.

We note that an ACO may use prepaid shared savings for staffing, healthcare infrastructure and direct beneficiary services in a manner that complies with the beneficiary incentives provision at § 425.304(a), (b), and newly proposed (d) as discussed in section III.G.5.i of this proposed rule, and all other applicable laws and regulations. Permitted uses for ''staffing and healthcare infrastructure'' include but are not limited to the following:

- *Staffing.* Examples could include, but are not limited to, hiring physicians, physicians' assistants, nurse practitioners, clinical nurse specialists, nutrition professionals, case managers, licensed clinical social workers, community health workers, patient

navigators, health equity officers, psychiatrists, clinical psychologists, therapists, mental health counselors, licensed professional counselors, substance use counselors, peer support specialists, and other behavioral health clinicians, or staff education.

- *Healthcare Infrastructure:* Examples could include, but are not limited to, investments in or improvements to existing case or practice management systems, clinical data registries, electronic quality reporting, health information exchange participation, certified electronic health record technology (CEHRT), health IT to support behavioral health or dental services, IT-enabled screening tools, closed-loop referral tools, audiovisual interpreter technology, or practice physical accessibility improvements. Investments can be made for individual ACO providers/suppliers (as defined in § 425.20) or ACO wide.
- Direct beneficiary services include in-kind items or services provided to an ACO beneficiary that are not otherwise covered by Traditional Medicare but have a reasonable expectation of improving or maintaining the health or overall function of ACO beneficiaries. Direct beneficiary services can also include cost sharing support including the reduction of beneficiary copay or deductibles for Traditional Medicare beneficiaries. In advance of the application deadline for agreement periods beginning on January 1, 2026, we intend to release sub regulatory guidance with more specific information about permitted uses of funding for direct beneficiary services. Permitted uses for direct beneficiary services could include, but are not limited to the following: beneficiary meals, nutrition support, tenancy support and sustaining services, housing assistance, utility support, caregiver support services, services to address social isolation, home visits, transportation services, home or environmental modifications like air conditioners, bathroom safety devices, personal emergency response systems or medical alert systems, and vision, hearing or dental care directly provided by ACO providers/suppliers (as defined in § 425.20) or covered under a health insurance plan purchased by the ACO on behalf of the beneficiary. While some of these services are covered in some form by Traditional Medicare, prepaid shared savings funding reserved for direct beneficiary services would only be permitted to be used for those services if the version of the service offered by the ACO is not currently covered by Traditional Medicare and there is a reasonable expectation that those services will improve or maintain the health or overall function of ACO beneficiaries. For example, some types of home visits are covered by Traditional Medicare, but an ACO would be able to extend the number of home visits offered to beneficiaries beyond the number covered by Traditional Medicare with prepaid shared savings. Direct beneficiary services would also include cost-sharing support, including the reduction of beneficiary copay or deductibles for Traditional Medicare beneficiaries for Part B primary care services. ACOs would be able to provide cost-sharing support for primary care services (as defined in § 425.20) with respect to which coinsurance applies under Part B.

As discussed in section III.G.5.i of this proposed rule, if this rulemaking is finalized, CMS expects to make a determination that the anti-kickback statute safe harbor for CMS-sponsored model patient incentives (§ 1001.952(ii)(2)) is available to protect direct beneficiary services that are made in compliance with this policy and the conditions for use of the antikickback statute safe harbor set out at § 1001.952(ii)(2). As noted earlier in this preamble, ACOs that wish to provide direct beneficiary services beneficiaries through prepaid shared savings will need to submit a spend plan with information including the groups of beneficiaries they intend to provide with direct beneficiary services, how the direct beneficiary services will be provided to beneficiaries and how such services support the care of beneficiaries, and attest that they will not discriminate on the basis of race, color, religion, sex, national origin, disability, or age with respect to how they propose to spend prepaid shared savings. As proposed, ACOs will also be required to report their actual use of prepaid shared savings after the end of each performance year, including which groups of beneficiaries received direct beneficiary services, how such services were provided to beneficiaries, and how these services supported the care of beneficiaries.

Many direct beneficiary services may be provided by staff working for an ACO or its participating providers or suppliers. If a staff member is hired or directed to provide these services, ACOs may use dollars designated for direct beneficiary services to cover the percentage of their salary that aligns with the percentage of time the staff member spends providing direct beneficiary services that are not otherwise covered by Traditional Medicare. This funding may also be used to contract with a community-based organization (CBO) or other external entity to pay their staff to provide direct beneficiary services. Additionally, ACOs should take care to ensure that a direct beneficiary service that is provided to a beneficiary does not impact other Federal, state, or local means-tested benefits a beneficiary is already receiving and should provide beneficiaries with any necessary documentation regarding their receipt of the direct beneficiary service. If CMS finalizes this proposal, we would include additional information in our sub regulatory guidance regarding the approved uses for direct beneficiary services and potential impacts on beneficiary eligibility for other Federal means tested programs.

We propose in § 425.640(e)(2) that an ACO may not use prepaid shared savings for any expense other than those allowed under paragraph (e)(1). Prohibited uses of prepaid shared savings would include management company or parent company profit, performance bonuses, provision of medical services covered by Traditional Medicare, cash or cash equivalent payments to patients, and items or activities unrelated to the management and operations of an ACO or care of beneficiaries. Similar to advance investment payments, prepaid shared savings are intended to help an ACO put care processes in place to directly care for the unique needs of the ACO's beneficiary population, it is not intended to solely increase profits or to be spent on items unrelated to the management and operations of the ACO or the beneficiaries it serves. Additionally, we propose that an ACO participating in Levels C–E of the BASIC track or the ENHANCED track may not use any prepaid shared savings to pay back any shared losses that it would have incurred as specified in a written notice from CMS under § 425.605(e)(2) or § 425.610(h)(2), respectively.

To the extent that an ACO is addressing unmet social needs, including food insecurity and transportation problems, through direct beneficiary services, we encourage ACOs to coordinate with a community-based organization to provide these services. As explained in the CY 2023 PFS proposed rule (87 FR 46102), where we refer to CBO, we mean public or private not-for-profit entities that provide specific services to the community or targeted populations in the community to address the health and social needs of those populations. They may include community-action agencies, housing agencies, area agencies on aging, or other non-profits that apply for grants to perform social

services. They may receive grants from other agencies in the U.S. Department of Health and Human Services, including Federal grants administered by the Center for Disease Control and Prevention (CDC), Administration for Children and Families (ACF), Administration for Community Living (ACL), or other Federal or State funded grants to provide social services.

Generally, such organizations know the populations they serve and their communities and may have the infrastructure or systems in place to help coordinate supportive services that address social determinants of health or serve as a source from which ACOs can receive information regarding community needs. Since CBOs have developed such an expertise, we believe it would be impactful for ACOs in the delivery of high-quality direct beneficiary services to contract with CBOs in the provision of these services. CMS further encourages ACOs to work with community care hubs, which are community-focused entities supporting a network of CBOs that provide services addressing health-related social needs and centralize administrative functions and operational infrastructure. Working directly with a community care hub can help connect the ACO with multiple smaller CBOs in the provision of direct beneficiary services. If an ACO works with a CBO to provide these types of services and this is reflected in its plan to address the needs of its population, we would consider them to be in compliance with the requirement at § 425.112(b)(2)(iii)(A), which requires an ACO to, in its plan to address the needs of its population, describe how it intends to partner with community stakeholders to improve the health of its population.

We also propose in § 425.640(f)(6) to allow ACOs receiving prepaid shared savings to request a smaller quarterly payment amount from CMS. For example, if an ACO is eligible for a maximum quarterly prepaid shared savings amount of one million dollars, we would estimate their annual prepaid shared savings to be four million dollars. This allows the ACO to spend up to two million dollars on staffing and healthcare infrastructure and up to their full $4 million payment amount on direct beneficiary services. However, the ACO may request a lower quarterly payment of $500,000 that results in the ACO only receiving two million dollars over the full performance year. This would also reduce the amount the ACO can spend on staffing and healthcare infrastructure as an ACO may not spend more than 50 percent of the prepaid shared savings they receive on staffing and healthcare infrastructure. In the event that CMS stops or reduces an ACOs quarterly payments during the performance year below the quarterly payment amount previously requested by the ACO, the reduction does not impact the total maximum amount they are permitted to spend on each category of allowable uses identified at the start of each year, as it would not be appropriate to subject ACOs to mid-year spend plan changes when they may have entered into contracting or other arrangements with staff or suppliers which could impact continuity of care. We would monitor how ACOs are spending these funds and, as necessary, revisit these guidelines in future rulemaking if changes are required.

We seek comment on these proposals.

e. Calculation of Prepaid Shared Savings

As noted in section III.G.5.a of this proposed rule, we have determined that prepaid shared savings would not result in additional program expenditures. While ACOs would be required to repay the prepaid shared savings they receive through earned shared savings, it is also important for CMS to avoid paying ACOs an amount of prepaid shared savings that they are unlikely to be able to repay through earned shared savings. While prepaid shared savings would be helpful in providing successful ACOs with additional cash flow that would encourage their investment in activities that could potentially reduce ACOs' costs and improve the quality of care that ACOs provide to their beneficiaries, overpaying ACOs might result in a level of outstanding debt for some ACOs that could disrupt their operations and potentially their participation in the Shared Savings Program as well as generate unnecessary financial risk for CMS. Our proposed policies on the calculation and distribution of the prepaid shared savings payments are intended to balance the benefit for the ACOs of receiving funding earlier with the risk of overpayment both for CMS and the ACO, while helping to ensure that prepaid shared savings do not result in additional program expenditures.

We are proposing a new § 425.640(f) to provide an ACO that CMS determines meets the eligibility criteria described in section III.G.5.b of this proposed rule with a prepaid shared savings payment for each quarter of an agreement period that they are determined to be eligible for prepaid shared savings equal to the maximum quarterly payment amount calculated pursuant to the methodology outlined in § 425.640(f)(2) (as further explained elsewhere in this section), the ACO elects to receive a lesser amount as described in § 425.640(f)(6) (as further explained in section III.G.5.d. of this proposed rule) or the payment is withheld or terminated pursuant to § 425.640(h). If an ACO's quarterly payment is withheld or terminated (as further explained in section III.G.5.f.(2) of this proposed rule), we would not provide ACOs with additional or catch-up payments if quarterly payments of prepaid shared savings are later resumed. We propose that under new § 425.640(f), CMS would notify in writing each ACO of its determination of the amount of prepaid shared savings. The notice would inform the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of our regulations. If CMS does not make any prepaid shared savings payment, the notice would specify the reason(s) why and inform the ACO of its right to request reconsideration review in accordance with the standards specified in subpart I of our regulations. Thus, prior to each quarterly payment, we propose to provide the ACO with the notice described above in the form of a report that shows our calculation of the ACO's quarterly prepaid shared savings amount. We propose to coincide the timing of these notices with the timing of existing report packages sent to ACOs for informational purposes, in December (after initial assignment prior to a given performance year), May (after quarter 1 assignment for a given performance year), and August (after quarter 2 assignment for a given performance year). Accordingly, notice regarding the first and second quarterly payments that an eligible ACO would receive in a given performance year would be provided in December of the immediately preceding year. Subsequent notices regarding the third and fourth quarterly payments that an eligible ACO would receive in a given performance year would then be provided in May and August, respectively, of that performance year.

We are also proposing a new § 425.640(f)(2) to specify the calculation of an ACO's maximum quarterly prepaid shared savings payment. To calculate this payment, we propose calculating a prepaid shared savings multiplier, adjusting it by several factors explained later in this section, and then multiplying one-fourth of the adjusted multiplier by an ACO's assigned beneficiary person years. We propose to calculate the prepaid shared savings multiplier as the simple average of per capita savings or losses generated by the ACO during the two most recent performance years that have been

financially reconciled at the time of the ACO's renewal application disposition, which constitute benchmark year (BY) 1 and BY2 of the agreement period in which the ACO may receive prepaid shared savings (''current agreement period,'' hereafter). That is, we would exclude BY3 from the calculation of an ACO's average per capita savings or losses because the performance year that constitutes BY3 of the ACO's current agreement period would not have been financially reconciled at the time of the ACO's application disposition. Accordingly, the per capita savings for each performance year would be determined as the quotient of the ACO's total updated benchmark expenditures minus total performance year expenditures divided by performance year assigned beneficiary person years. For purposes of calculating the simple average of per capita savings or losses generated by the ACO during the two most recent performance years that have been financially reconciled, we would use all savings generated during each of the 2 performance years in the prepaid shared savings multiplier, not just savings that met or exceeded the ACO's minimum savings rate (MSR) for that prior performance year.

Under new § 425.640(f)(2)(iii), we propose to apply a proration factor to the prepaid shared savings multiplier to account for situations where an ACO's assigned beneficiary population is larger in BY1 and BY2 when calculated using the ACO's certified ACO participant list and assignment methodology for a given performance year within the current agreement period, as compared to the ACO's assigned beneficiary population when the ACO was reconciled for the performance years that constitute BY1 and BY2 of the current agreement period. Mathematically, to apply this proration factor we would calculate the ratio between: (1) the ACO's average assigned beneficiary person years for the 2 performance years that constitute BY1 and BY2 for the ACO's current agreement period (regardless of whether these performance years occurred over one or multiple prior agreement periods, which would occur if the ACO early renews immediately before the current agreement period) and (2) the average assigned beneficiary person years in BY1 and BY2 for the ACO's current agreement period calculated using the ACO's certified ACO participant list and assignment methodology for a given performance year within the current agreement period. Increases in the size of the ACO's assigned beneficiary population during the current agreement period would therefore result in a ratio less than 1, while decreases in the assigned beneficiary population would result in a ratio greater than 1. This ratio would be capped at 1 to avoid increasing the adjusted prepaid shared savings multiplier if the average number of beneficiaries assigned to the ACO across the 2 benchmark years of its current agreement period is lower than the average number of beneficiaries assigned during the 2 performance years that constitute BY1 and BY2. Prorating for growth in assignment would ensure that the prepaid shared savings amount does not exceed the amount of cumulative savings generated by the ACO during the performance years that constitute BY1 and BY2 for its current agreement period.

It is necessary to calculate a proration factor at the start of the ACO's current agreement period to account for several possible circumstances in which the ACO's assigned beneficiary population may be different in BY1 and BY2 when calculated using the ACO's certified ACO participant list and assignment methodology for a given performance year within the current agreement period, as compared to the ACO's assigned beneficiary population when the ACO was reconciled for the performance years that constitute BY1 and BY2 of the current agreement period. Specifically, changes in the size of the ACO's assigned beneficiary population at the start of the ACO's current agreement period could be due to the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), or changes to the beneficiary assignment methodology specified in 42 CFR part 425, subpart E.

Additionally, these circumstances could potentially arise after the start of the ACO's current agreement period. In turn, changes in the size of the ACO's assigned beneficiary population could potentially occur throughout the course of the current agreement period. Therefore, we propose in new § 425.640(f)(3)(ii) that for the second and each subsequent performance year during the term of the current agreement period, we would redetermine this proration factor.

In addition to pro-rating the prepaid shared savings multiplier, we also propose to adjust it in two ways. First, under new § 425.640(f)(2)(iv), we would apply a sharing rate scaling factor of ½ (or 50 percent). This sharing rate scaling factor would be similar to the scaling factor we apply under § 425.658(c)(1)(i) when calculating the prior savings adjustment, applicable to agreement periods beginning on or after January 1, 2024, as finalized in the CY 2023 final rule (refer to 87 FR 69899 through 69915). As with the prior savings adjustment calculation, it is important to consider a measure of the sharing rate used in determining the shared savings payment the ACO earned in the applicable performance years under the agreement period immediately before it would receive prepaid shared savings. Consistent with the prior savings adjustment scaling factor, 50 percent represents an appropriate multiplier in this context because it represents a middle ground between the maximum sharing rate of 75 percent under the ENHANCED track and the lower sharing rates available under the BASIC track.

Second, under new § 425.640(f)(2)(v)(A), we would apply a financial risk scaling factor equal to ⅔. The purpose of the financial risk scaling factor would be to mitigate financial risk to the Medicare Trust Funds and to ACOs by reducing the possibility that an ACO's prepaid shared savings payments exceed the ACO's actual earned shared savings. The rationale for a financial risk scaling factor of this magnitude is that it enables us to account for a scenario in which an ACO earned zero per capita savings in the performance year that constitutes BY3 of the current agreement period, which is necessarily excluded from the calculation of an ACO's average per capita savings or losses for purposes of the prepaid shared savings multiplier because, as mentioned previously, the performance year that constitutes BY3 of the ACO's current agreement period would not have been financially reconciled at the time of the ACO's application disposition. Thus, by multiplying an ACO's average per capita savings or losses across BY1 and BY2 by a financial risk scaling factor equal to ⅔, we are imposing a downward reduction on the prepaid shared savings multiplier by assuming that it would have been possible, in principle, for an ACO to have not earned any per capita savings in the performance year that constitutes BY3 of the current agreement period. By doing so, we are reducing the probability of distributing excessive prepaid shared savings. As discussed previously, it is important to avoid distribution of excessive prepaid shared savings because doing so could result in several undesirable outcomes, such as ACOs accruing debt to CMS that they are unable to repay, which could disruption the ACOs' operations and participation in the Shared Savings Program.

Consistent with calculations of the prior savings adjustment (refer to

§ 425.658), the positive regional adjustment (refer to § 425.656), and the proposed health equity benchmark adjustment (refer to section III.G.7.b of this proposed rule), we propose under new § 425.640(f)(2)(v)(B), to cap the pro-rated, adjusted prepaid shared savings multiplier at 5 percent of national per capita FFS expenditures for Parts A and B services in order to ensure that the amount of prepaid shared savings that an ACO receives does not exceed an amount that the ACO is able to repay through earned shared savings. Specifically, we propose to calculate the cap as 5 percent of national per capita FFS expenditures for Parts A and B services in BY2 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY2. Consequently, under new § 425.640(f)(2)(v), the pro-rated, adjusted, and capped prepaid shared savings multiplier that would ultimately be used to calculate a given maximum quarterly prepaid shared savings payment would be equal to the lesser of (A) the pro-rated, adjusted prepaid shared savings multiplier or (B) 5 percent of national per capita FFS expenditures for Parts A and B services in BY2 for assignable beneficiaries.

To calculate a given maximum quarterly prepaid shared savings payment, we propose under new § 425.640(f)(4), to multiply one-fourth of the pro-rated, adjusted, and capped prepaid shared savings multiplier (to account for four quarterly payments) by the ACO's assigned beneficiary person years for the latest available assignment list for a given performance year within the current agreement period. Varying the maximum quarterly payment to reflect the latest available assigned beneficiary person years is similar to how we calculate the AIP quarterly payment calculation (refer to § 425.630(f), CY 2023 PFS final rule (87 FR 69797)), for which we use the latest available assignment list to calculate the quarterly advance investment payment amount. We propose to use the latest available beneficiary assigned person years for the maximum quarterly prepaid shared savings payment because an ACO's assigned beneficiary person years change over the course of a performance year and over the course of an agreement period. Because later assignment lists more closely reflect the final assignment list that would be used for calculating shared savings and losses for a given performance year within the current agreement period, later assignment lists are more likely than earlier assignment lists to facilitate calculation of quarterly prepaid shared savings payment amounts that closely align with the earned shared savings or losses that an ACO actually generates in the contemporaneous performance year. Using the latest available assigned beneficiary person years mitigates a financial risk that an ACO experiencing declining person years over the course of a performance year could receive excessive prepaid shared savings. As mentioned previously, overpaying prepaid shared savings could result in ACOs accruing a level of debt to CMS that they are unable to repay through earned shared savings which could, in turn, disrupt ACOs' operations and participation in the Shared Savings Program.

We propose to use assigned beneficiary person year values that CMS provides to ACOs in annual and quarterly informational reports. For ACOs under preliminary prospective assignment with retrospective reconciliation, Medicare assigns beneficiaries in a preliminary manner at the beginning of a performance year based on the most recent data available (§ 425.400(a)(2)(i)). Assignment is updated quarterly based on the most recent 12 or 24 months of data, as applicable, under the methodology described in §§ 425.402 and 425.404 (§ 425.400(a)(2)(ii)). ACOs under preliminary prospective assignment with retrospective reconciliation receive an assigned beneficiary person years value based on the most recent 12 or 24 months of data, as applicable, in annual and quarterly informational reports. For ACOs under prospective assignment, Medicare FFS beneficiaries are prospectively assigned to an ACO at the beginning of each benchmark or performance year based on the beneficiary's use of primary care services in the most recent 12 or 24 months, as applicable, for which data are available, using the assignment methodology described in §§ 425.402 and 425.404 (§ 425.400(a)(3)(i)). Each quarter, CMS excludes any prospectively assigned beneficiaries that meet the exclusion criteria under § 425.401(b). ACOs under prospective assignment receive a year-to-date assigned beneficiary person years value with each quarterly report package. For ACOs under prospective assignment, we would annualize the quarterly year-to-date assigned beneficiary person years values for use in the maximum quarterly prepaid shared savings payment calculation. For example, a year-to-date person years value of 1,500 with quarter 1 informational reports would be annualized by multiplying 1,500 by 4. A year-to-date person years value of 3,000 with quarter 2 information reports would be annualized by multiplying 3,000 by 2.

We further propose to account for circumstances when an ACO was not reconciled for the performance year that constitutes BY1 in the calculation of average per capita prior savings and the proration factor. For instance, ACOs that renew their agreement periods early or are re-entering may not be reconciled for one or more of the years preceding the start of their current agreement period depending upon the timing of the expiration or termination of their prior agreement period and the start of their current agreement period. We propose under new § 425.640(f)(2)(i), that if an ACO was not reconciled during one of the 2 performance years that constitute BY1 or BY2 of its current agreement period, the ACO would receive zero savings or losses for the BY corresponding to the performance year that was not financially reconciled in the calculation of the prepaid shared savings multiplier. CMS has no way to determine whether the ACO would have generated savings or losses during a performance year for which it was not reconciled. We believe this is appropriate because it enables us to obtain a more conservative prediction of the ACO's financial performance for a given performance year within the current agreement period than we would be able to obtain if we were to exclude the BY corresponding to the performance year that was not financially reconciled from the calculation of the prepaid shared savings multiplier. Excluding this year entirely from the calculation of average per capita prior savings would unduly increase the weight on the other year included in the prepaid shared savings multiplier calculation. This would be problematic in a case where the ACO's financial performance in the BY corresponding to the performance year that was financially reconciled is atypically high because it would upwardly bias the prediction of the ACO's financial performance for a given performance year within the current agreement period. Thus, by imputing zero savings or losses for a BY corresponding to a performance year that was not financially reconciled in the calculation of the prepaid shared savings multiplier, we are reducing the probability of overpredicting the financial performance of the ACO for a given performance year within the current agreement period and, in turn, the probability of distributing excessive prepaid shared savings. As mentioned previously, excessive distribution of

prepaid shared savings could result in several undesirable outcomes, such as ACOs accruing debt to CMS that they are unable to repay, which could disrupt the ACOs' operations and participation in the Shared Savings Program.

In contrast, we determined that it would also be appropriate to exclude a year for which the ACO was not reconciled when calculating the proration factor. The purpose of the proration factor is to account for situations where an ACO's assigned beneficiary population calculated at financial reconciliation for the 2 performance years that constitute BY1 and BY2 of the ACO's current agreement period (numerator) is smaller than the ACO's assigned beneficiary population identified for those same years using the ACO's certified ACO participant list and assignment methodology for a given performance year within the current agreement period (denominator). If an ACO was not reconciled for one of the 2 performance years that constitute BY1 and BY2 of the current agreement period, it would naturally have zero assigned beneficiary person years determined at financial reconciliation for such year, which would factor into the numerator of the proration factor if such year was considered. However, the ACO would have positive beneficiary counts in the 2 performance years that constitute BY1 and BY2 of the current agreement period generated using the ACO's certified ACO participant list and assignment methodology for a given performance year within the current agreement period, which would factor into the denominator of the proration factor if such year was considered. Thus, if the numerator and the denominator were both calculated as averages over 2 years, incorporating a year for which the ACO was not reconciled in the calculation of the proration factor would artificially decrease the proration factor and lead to a smaller pro-rated average per capita prior savings for the ACO. Alternatively, if the numerator were calculated in a manner that excludes a performance year for which the ACO was not reconciled (that is, calculated in a manner that includes only the year for which the ACO was reconciled from among the 2 performance years that constitute BY1 and BY2 of the current agreement period) and the denominator was calculated as an average that included both of the 2 performance years that constitute BY1 and BY2 of the current agreement period, then the direction of the impact on the proration factor would depend on whether the number of assigned beneficiaries calculated using an ACO's current certified ACO participant list and assignment methodology in the benchmark year for which the ACO was not reconciled exceeds the number of assigned beneficiaries in the other benchmark year, and by how much. Therefore, we see no compelling reason to include a performance year immediately preceding the start of an ACO's current agreement period for which the ACO was not reconciled in the numerator or the denominator of the proration factor. Excluding such a year would ensure that the proration factor compares average person years determined for prior performance years at financial reconciliation (numerator) to average person years for those performance years determined using the ACO's current certified ACO participant list and assignment methodology (denominator) across a consistent set of years preceding the start of the ACO's current agreement period.

We also propose to account for certain circumstances where there could be changes to the values used in calculating the prepaid shared savings multiplier as a result of issuance of a revised initial determination of financial performance under § 425.315.

To account for these situations and for the need to recalculate the proration factor as described elsewhere in this section, we propose to specify in new § 425.640(f)(3) when CMS would recalculate the prepaid shared savings multiplier during the current agreement period. For the first performance year in the current agreement period, the ACO's prepaid shared savings multiplier would be recalculated for changes in per capita shared savings or losses for the performance years that constitute BY1 or BY2 and that are used in the calculation of the prepaid shared savings multiplier as a result of issuance of a revised initial determination under § 425.315. For the second and each subsequent performance year during the term of the current agreement period, the ACO's prepaid shared savings multiplier would be recalculated due to redetermining the proration factor for the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), for a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), for a change to the beneficiary assignment methodology specified in subpart E of this part, and for changes in per capita shared savings or losses for the performance years that constitute BY1 or BY2 and that are used in the calculation of the prepaid shared savings multiplier as a result of issuance of a revised initial determination under § 425.315.

The specific computations involved in arriving at the maximum prepaid shared savings payment amount for a given ACO in a given quarter are described below.

- *Step 1:* Calculate a prepaid shared savings multiplier as the average per capita savings across the performance years that constitute BY1 and BY2 of the ACO's current agreement period. First, calculate the total per capita savings amount for each applicable performance year by subtracting assigned beneficiary expenditures from total benchmark expenditures and divide the difference by assigned beneficiary person years. Then, sum the resulting quotients and divide by 2. The per capita savings or losses would be set to zero for a performance year if the ACO was not reconciled for the performance year.
- *Step 2:* Apply a proration factor to the prepaid shared savings multiplier calculated in Step 1. The proration factor is equal to the ratio of the ACO's average assigned beneficiary person years for the 2 performance years that constitute BY1 and BY2 for the ACO's current agreement period (regardless of whether these performance years occurred over one or multiple prior agreement periods) and the ACO's average assigned beneficiary person years in BY1 and BY2 for the ACO's current agreement period calculated using the ACO's certified ACO participant list and assignment methodology for a given performance year within the current agreement period, capped at one. If the ACO was not reconciled for the performance year that constitutes BY1, the person years from that year (or years) would be excluded from the averages in the numerator and the denominator of this ratio. This ratio would be redetermined for each performance year during the agreement period in the event of any changes to the number of average person years in the benchmark years as a result of changes to the ACO's certified ACO participant list, a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), or changes to the beneficiary assignment methodology specified in 42 CFR part 425, subpart E.
- *Step 3:* Adjust the pro-rated prepaid shared savings multiplier calculated in Step 2. First, apply a shared savings scaling factor by multiplying the pro-rated prepaid shared savings multiplier by 0.50. Then, multiply the resulting value by ⅔ to apply a financial risk scaling factor.
- *Step 4:* Cap the pro-rated, adjusted prepaid shared savings multiplier at 5

percent of national per capita FFS expenditures for Parts A and B services in BY2 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY2.

- *Step 5:* Multiply one-fourth of the pro-rated, adjusted, and capped prepaid shared savings multiplier by the assigned beneficiary person years derived from the ACO's latest available assignment list. The resulting product would serve as the ACO's total maximum prepaid shared savings payment for the applicable quarter. As discussed previously, an ACO's latest available assignment list is updated quarterly. For ACOs under preliminary prospective assignment with retrospective reconciliation, assignment is updated quarterly based on the most recent 12 or 24 months of data, as applicable, under the methodology described in §§ 425.402 and 425.404 (§ 425.400(a)(2)(ii)). For ACOs under prospective assignment, assignment is updated quarterly to exclude any prospectively assigned beneficiaries that meet the exclusion criteria under § 425.401(b) (§ 425.401(b)). Thus, consistent with the methodology that we apply in the case of advance investment payments, quarterly variations in an ACO's assignment list would translate to variations in the maximum quarterly total prepaid shared savings payments that an ACO may receive in any given quarter, in order to help ensure that the payments accurately reflect the attributes of the ACO's assigned beneficiary population throughout the current agreement period.

Table 37 presents a hypothetical example to demonstrate how the prepaid shared savings calculation would work in practice.

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TABLE 37: Calculation of Maximum Quarterly Prepaid Shared Savings Payment

Step 1: Calculate prepaid shared savings multiplier	Per capita savings generated in the two performance years that constitute BY1 and BY2 for the ACO's current agreement period beginning January 1, 2022 PY 2019: $350 PY 2020: $400 Multiplier: Simple average of the per capita savings across BY1 and BY2 ($350 + $400) / 2 = $375
Step 2: Pro-rate the prepaid shared savings multiplier	Assigned person years from the performance years that constitute BY1 and BY2 for the ACO's current agreement period beginning January 1, 2022: PY 2019: 6,000 PY 2020: 7,000 Assigned person years for BY1 and BY2 of current agreement period (determined using certified ACO participant list for the current performance year of PY 2022): BY 2019: 8,000 BY 2020: 7,500 Proration factor: Ratio between the ACO's average person years in the performance years that constitute BY1 and BY2 and the average person years in BY1 and BY2, excluding years for which the ACO was not reconciled, capped at 1. Apply the proration factor to the prepaid shared savings multiplier: [(6,000 + 7,000)/2] / [(8,000 + 7,500)/2] x $375 = $314.52
Step 3: Adjust the pro-rated prepaid shared savings multiplier for financial risk and sharing rate	Shared savings scaling factor: (0.5) Financial risk scaling factor: (2/3) Apply the shared savings scaling factor and the financial risk scaling factor to the pro-rated prepaid shared savings multiplier: $314.52 x (0.5) x (2/3) = $104.84
Step 4: Cap the pro-rated, adjusted prepaid shared savings multiplier	National assignable per capita FFS expenditures for assignable beneficiaries in BY2: $10,000 Cap: 5 percent of national assignable per capita FFS expenditures for assignable beneficiaries in BY2 0.05 * $10,000 = $500
Step 5: Determine the maximum prepaid shared savings payments for the applicable quarter	Assigned beneficiary person years derived from the ACO's latest available assignment list: 8,500. Total prepaid shared savings payments for the applicable quarter: Product of one-fourth of the pro-rated, adjusted, capped prepaid shared savings multiplier and the assigned beneficiary person years derived from the ACO's latest available assignment list. ($104.84/4) x 8,500 = $222,785

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The ACO's maximum quarterly prepaid shared savings payments would set a ceiling on the amount of quarterly prepaid shared savings that an ACO could receive from CMS for each quarter. ACOs will be able to request to receive an amount of funding under this maximum amount. Prior to each performance year, ACOs would notify CMS of the amount of prepaid shared savings they want to receive in the first quarter under the maximum quarterly prepaid shared savings amount and the first quarterly payment will be used to determine the total amount of prepaid shared savings the ACO will use to budget for that performance year. We are proposing in new § 425.640(f)(5) that for the purposes of determining the amount of prepaid shared savings permitted to be allocated to the uses specified in § 425.640(e), the estimated annual prepaid shared savings amount can be calculated by multiplying the first quarterly payment amount the ACO would receive in each performance year by four. This allows the ACO to calculate the total amount of funding they are permitted to spend on each allowable use at the start of each performance year. If an ACO's maximum quarterly payments decrease over the performance year and result in the ACO receiving less than the estimated annual prepaid shared savings amount, the ACO would not be subject to compliance actions solely because it spent more than 50 percent of the actual annual amount of prepaid shared savings it received during that PY on staffing and healthcare infrastructure, as long as it did not spend more than 50 percent of the originally estimated annual prepaid

shared savings amount on staffing and healthcare infrastructure. For example, if an ACO is eligible for a maximum quarterly prepaid shared savings payment of $300,000 for quarter 1 of a performance year, but only wishes to receive $250,000 for quarter 1 of a performance year, their estimated annual prepaid shared savings amount would be $1,000,000. This allows the ACO to spend up to $500,000 on staffing and healthcare infrastructure, or up to the full amount of $1,000,000 on direct beneficiary services. If an ACO has a reduction in assigned beneficiaries and is only eligible for a maximum quarterly prepaid shared savings payment of $200,000 for quarters 2, 3 and 4, this results in an actual total of $850,000 in received prepaid shared savings for the performance year. However, the ACO would still be permitted to spend up to $500,000 on staffing and healthcare infrastructure in that performance year, as that is 50 percent of the original estimated amount and we do not want to change budget maximums retroactively for an ACO.

f. Duration, Frequency and Withholding or Termination of Prepaid Shared Savings Payments

(1) Duration and Frequency

CMS anticipates that the vast majority of ACOs receiving prepaid shared savings would fully repay the amount they receive of prepaid shared savings from their earned shared savings on an annual basis. This would allow CMS to distribute prepaid shared savings to ACOs continually, throughout an agreement period in which the ACO is deemed eligible to participate, without withholding prepaid shared savings pursuant to § 425.640(h). We are proposing at § 425.640(f)(1) that ACOs would receive quarterly prepaid shared savings payments for the entirety of the ACO's agreement period unless withheld or terminated pursuant to § 425.640(h). However, we are also proposing at § 425.640(h)(3) that if CMS withholds or terminates a quarterly payment pursuant to paragraph (h), the ACO would not receive additional or catch-up payments if quarterly prepaid shared savings payments are later resumed. As discussed later in this section, prepaid shared savings payments would generally be withheld from ACOs when CMS has information that the ACO may not generate sufficient earned shared savings to repay the prepaid shared savings in current or future performance years or has other Shared Savings Program compliance issues. Once prepaid shared savings payments are withheld, if an ACO earns shared savings in a future year, then prepaid shared savings can resume at the time of the next scheduled quarterly payment, but catch-up payments would not be provided. This protects CMS from distributing payments that the ACOs may not be able to repay and the ACOs from accumulating more debt than they can repay through earned shared savings. An ACO would be notified if CMS is willing to resume prepaid shared savings payments, and would have the ability to elect to resume payments as well as select the payment amount they would like to receive under the maximum quarterly payment, if desired.

(2) Withholding and Termination

In order to ensure orderly administration of the Shared Savings Program, including protection of the Medicare Trust Funds, we intend to monitor the performance of ACOs receiving prepaid shared savings and propose that we may withhold or terminate quarterly prepaid shared savings payments under a variety of specified circumstances. Many of the circumstances under which we propose that CMS may withhold to terminate the payments directly relate to circumstances under which CMS would be concerned that the ACO has not or will not meet the standards for the use prepaid shared savings, such as an ACO's failure to comply with the requirements of proposed § 425.640. Other circumstances would address situations where it becomes apparent that the ACO's is likely to lack the ability to repay prepaid shared savings to CMS. For example, we propose that CMS may withhold or terminate the payments if CMS predicts that the ACO will not generate sufficient earned shared savings to repay the prepaid shared savings in future performance years or has other Shared Savings Program compliance issues. These predictions would be based on a rolling 12-month window of beneficiary claims data or year-to-date beneficiary claims data, depending on whether an ACO selects prospective Assignment or preliminary prospective assignment with retrospective reconciliation. We propose that CMS may also withhold quarterly payments if an ACO fails to earn enough shared savings in a performance year to fully repay the prepaid shared savings the ACO received during that performance year, in order to avoid the ACO accruing debt they would be unable to repay. As noted earlier in this section, an ACO would be notified if CMS determines the ACO is sufficiently likely to earn additional shared savings such that CMS could resume prepaid shared savings payments, in which case the ACO would have the ability to elect to resume payments and select the payment amount they would like to receive. Additionally, while unspent funds received for a performance year must be reallocated in the spend plan for the ACO's next performance year as noted in § 425.640(e)(3), if an ACO fails to spend a majority of the prepaid shared savings they receive in a performance year, CMS may withhold future quarterly payments until the ACO spends the funding they have already received and reports this spending to CMS through an updated spend plan. An ACO may also request that CMS withhold their future quarterly payments until the ACO is ready for payments to resume. ACOs that elect to have CMS withhold their prepaid shared savings payments would have the ability to later elect to resume payments as well as select the payment amount they would like to receive. If an ACO has unspent funding at the end of their agreement period, that funding must be repaid to CMS pursuant to proposed § 425.640(e)(3).

Accordingly, we propose at § 425.640(h)(1) that CMS may withhold or terminate prepaid shared savings during an agreement period if:

- The ACO fails to comply with any of the prepaid shared savings requirements of § 425.640;
- The ACO meets any of the grounds for ACO termination set forth in § 425.218(b); [498]
- The ACO fails to earn sufficient shared savings from a performance year to repay the prepaid shared savings they received during that performance year;
- CMS determines that the ACO is not expected to earn shared savings in a performance year during the agreement period in which the ACO received prepaid shared savings, based on a rolling 12-month window of beneficiary claims data or year-to-date beneficiary claims data;
- The ACO falls below 5,000 assigned beneficiaries;
- The ACO fails to spend the majority of prepaid shared savings they receive in a performance year; or
- The ACO requests that CMS withhold a future quarterly payment

Additionally, we propose at § 425.640(h)(2) that CMS must terminate an ACO's prepaid shared savings during an agreement period if:

[498] Under §§ 425.216 and 425.218, CMS can terminate an ACO's participation agreement or take pre-termination actions (such as requesting a corrective action plan) if CMS determines that an ACO is not in compliance with the requirements of Part 425 of our regulations.

- The ACO fails to maintain an adequate repayment mechanism in accordance with § 425.204(f); or
- The ACO fails to meet the quality performance standard as specified under § 425.512 or is subject to a pre-termination action after CMS determined the ACO avoided at-risk beneficiaries as specified under § 425.316(b)(2).

We further propose under § 425.640(h)(4) that CMS may immediately terminate an ACO's prepaid shared savings under § 425.640(h)(1) and (2) without taking any of the pre-termination actions set forth in § 425.216.

In general, if an ACO is complying with the Shared Savings Program and prepaid shared savings requirements but is not achieving, or is not predicted to achieve, success in earning shared savings, CMS may withhold payments while the ACO works to improve their financial performance. For example, if an ACO is eligible to receive quarterly prepaid shared savings payments in an agreement period beginning in 2026 but does not earn shared savings during 2025 reconciliation that occurs in mid-2026, the ACO's quarterly payments would be withheld until the ACO earns shared savings in a future performance year reconciliation. Similar to our rationale for the eligibility requirement described at § 425.640(b)(2), we believe that recent past performance in earning shared savings provides information on the ACO's potential to earn future shared savings, and we would not distribute prepaid shared savings to ACOs that have not earned sufficient shared savings in their most recent reconciled performance year to repay the prepaid shared savings they received during that performance year.

Additionally, if CMS, through its financial monitoring of ACOs, predicts that an ACO would not earn shared savings in its current performance year, quarterly prepaid shared savings may be withheld until the ACO generates earned shared savings in the future. We expect that immediate termination of prepaid shared savings during an agreement period, without a possibility of resumption of payments during that agreement period, would be invoked only in cases of serious noncompliance with the requirements of § 425.640, including deliberately spending prepaid shared savings on a prohibited use, or when the ACO's actions or inaction poses a risk of harm to beneficiaries or negatively affects their access to care. We seek comment on these proposals.

g. Monitoring ACO Eligibility for and Use of Prepaid Shared Savings

To provide CMS with a clear indication of how ACOs intend to spend prepaid shared savings, help provide adequate protection to the Medicare Trust Funds, and prevent funds from being misdirected or appropriated for activities that do not fall within the parameters set forth within proposed § 425.640(e), we propose in § 425.316(f)(1) to monitor ACOs receiving prepaid shared savings for compliance with § 425.640(e) and to determine whether it would be appropriate to withhold or terminate an ACO's prepaid shared savings under § 425.640(h)(1) and (h)(2). For the first performance year of the current agreement period, we would monitor the ACO's use of prepaid shared savings by comparing the anticipated spending as set forth in the spend plan submitted with an ACO's application against the actual spending as reported by the ACO, including any expenditures not identified in the spend plan. ACOs would be required to submit a revised spend plan with updated anticipated spending annually, as well as annually report their actual expenditures to CMS and on their public reporting web page as noted in §§ 425.308(b)(10) and 425.640(i), and we would similarly monitor the ACO's use of prepaid shared savings during the current agreement period using the updated spend plan and those reports. The reported annual spending must include any expenditures of prepaid shared savings on items not identified in the spend plan. In the event that an ACO uses prepaid shared savings for uses not permitted by § 425.640(e), CMS would require them to reallocate the funding to a permitted use and may take compliance action as specified in §§ 425.216, 425.218 or withhold or terminate payments as specified in proposed § 425.640(h)(1).

Similar to the policy for advance investment payments (§ 425.630), we additionally believe that transparency of information in the healthcare sector facilitates more informed patient choice and offers incentives and feedback that help improve the quality and lower the cost of care and improve oversight with respect to program integrity. As CMS has discussed in previous final rules, improved transparency supports a number of program requirements. In particular, increased transparency is consistent with and supports the requirement under section 1899(b)(2)(A) of the Act for an ACO to be willing to ''become accountable for the quality, cost, and overall care'' of the Medicare beneficiaries assigned to it. Therefore, we believe it is desirable and consistent with section 1899(b)(2)(A) of the Act for several aspects of an ACO's use of prepaid shared savings to be available to the public. Making this information available would provide both Medicare beneficiaries and the general public with insight into the use of prepaid shared savings by an ACO.

Accordingly, we are proposing to modify § 425.308 to require that an ACO publicly report information annually regarding prepaid shared savings on its public reporting web page. Specifically, under proposed new § 425.308(b)(10), we are proposing that, for each performance year, an ACO would be required to report (in a standardized format specified by CMS) its spend plan for each performance year, the total amount of prepaid shared savings received, and an itemization of how any prepaid shared savings were actually spent during each year, including expenditure categories, the dollar amounts spent on the various categories, information about which beneficiaries received direct beneficiary services that were purchased with prepaid shared savings and investments that were made in the ACO with prepaid shared savings, any changes to the spend plan as submitted under § 425.640(d)(1), and such other information as may be specified by CMS. We propose that this itemization would include expenditures not identified or anticipated in the ACO's submitted spend plan, and any amounts remaining unspent. We are also proposing at § 425.640(i) that ACOs also be required to report this information directly to CMS.

Under this proposal, if CMS determined that an ACO used prepaid shared savings for a prohibited use under proposed § 425.640(e)(2), allocated over 50 percent of their annual maximum prepaid shared savings on staffing and healthcare infrastructure as proposed at § 425.640(e)(1)(i), or failed to spend at least 50 percent of the annual maximum prepaid shared savings on direct beneficiary services, CMS would require the ACO to reallocate the funding in compliance with § 425.640(e) and submit an updated spend plan demonstrating the reallocation by a deadline specified by CMS and may withhold or terminate the ACO's receipt of prepaid shared savings under proposed § 425.640(h)(1). CMS could also take compliance action as specified in §§ 425.216 and 425.218. If an ACO fails to reallocate prepaid shared savings it received by a deadline specified by CMS, the ACO must repay all prepaid shared savings it received and may be subject to compliance action

as specified in §§ 425.216 and 425.218. CMS would provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

Additionally, we note that under existing § 425.314, ACOs would be required to retain and provide CMS with access to adequate books, contracts, records, and other evidence to ensure that CMS has the information necessary to conduct appropriate monitoring and oversight of ACOs' use of prepaid shared savings (for example, invoices, receipts, and other supporting documentation of prepaid shared savings disbursements). To protect the Shared Savings Program and the Medicare Trust Funds, we would reserve the right under §§ 425.314 and 425.316(a) to audit and monitor ACO compliance with Shared Savings Program requirements, including with respect to prepaid shared savings. We would conduct audits as necessary to monitor and assess an ACO's use of prepaid shared savings and compliance with program requirements related to such payments. We seek comment on these proposals.

h. Recoupment of Prepaid Shared Savings

CMS anticipates that a vast majority of ACOs receiving prepaid shared savings would fully repay the amount they receive prepaid shared savings from their earned shared savings on an annual basis. However, as prepaid shared savings are an advance of the shared savings payments an ACO is expected to earn, we propose to recoup prepaid shared savings from ACOs that are unable to fully repay prepaid shared savings through their earned shared savings. This approach will also help ensure that prepaid shared savings would not result in additional expenditures for the Shared Savings Program, as required by section 1899(i)(3)(B) of the Act.

We are proposing to add a new § 425.640(g)(1) to recoup prepaid shared savings from earned shared savings, as defined in § 425.20, in each performance year. If there are insufficient shared savings to recoup the prepaid shared savings made to an ACO for a performance year, we would hold paying future prepaid shared savings payments and carry forward the remaining balance owed to subsequent performance year(s) in which the ACO achieves shared savings.

Under new § 425.640(g)(2), we propose that in circumstances where the amount of shared savings earned by the ACO is revised upward by CMS for any reason, we would reduce the redetermined amount of shared savings by the amount of prepaid shared savings made to the ACO as of the date of the redetermination. If the amount of shared savings earned by the ACO is revised downward by CMS for any reason, we propose that the ACO would not receive a refund of any portion of the prepaid shared savings previously recouped or otherwise repaid, and any prepaid shared savings that are now outstanding due to the revision in earned shared savings must be repaid to CMS upon request.

We propose under § 425.640(g)(3) that if an ACO has an outstanding balance of prepaid shared savings after the calculation of shared savings or losses for the final performance year of an agreement period in which an ACO receives prepaid shared savings, the ACO must repay any outstanding amount of prepaid shared savings it received in full upon request from CMS. CMS would provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of notification. If an ACO fails to repay any outstanding amount of prepaid shared savings within 90 days of the notification, CMS would recoup that amount from the ACO's repayment mechanism established under § 425.204(f).

For example, if an ACO received $300,000 in prepaid shared savings payments and earned shared savings of $500,000 for the first performance year, we would recoup $300,000 in prepaid shared savings payments and make $200,000 in reconciliation shared savings payments to the ACO. Alternatively, if an ACO received $300,000 in prepaid shared savings and earned shared savings of $200,000 for the first performance year, we would recoup only $200,000 in prepaid shared savings payment and not make a reconciliation shared savings payment to the ACO. The ACO would have future prepaid shared savings payments placed on hold, and the outstanding balance of $100,000 would be carried forward, to be recouped in a future performance year in which the ACO achieves shared savings. Under a third scenario, if the ACO does not earn sufficient shared savings in all 5 performance years of its agreement period, CMS would recoup the outstanding balance directly from the ACO under new § 425.640(g)(3). If the ACO fails to repay the funding to CMS, we would recoup the outstanding balance from the ACO's repayment mechanism.

Under the new § 425.640(g)(4), we propose that if an ACO or CMS terminates its participation agreement during the agreement period in which it received prepaid shared savings, the ACO must repay all outstanding prepaid shared savings received in full. In such a case, CMS would provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of notification. If an ACO fails to repay any outstanding amount of prepaid shared savings within 90 days of the notification, CMS would recoup that amount from the ACO's repayment mechanism established under § 425.204(f). We also propose edits to § 425.204(f) replacing the phrase ''shared losses'' with ''shared losses and any prepaid shared savings'' in several paragraphs to clarify that CMS would be able to recoup outstanding prepaid shared savings from an ACO's repayment mechanism. If the ACO terminates its participation agreement early in order to renew under a new participation agreement, CMS may also recover the amount owed by reducing the amount of any future shared savings the ACO may be eligible to receive.

In the event the ACO enters into proceedings relating to bankruptcy, whether voluntary or involuntary, we are proposing under § 425.630(g)(5) that the ACO must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment for the agreement period has been made by either CMS or the administrative or judicial review proceedings relating to any payments under the Shared Savings Program have been fully and finally resolved. The notice of bankruptcy must be sent by certified mail no later than 5 days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number). The notice to CMS must be addressed to the CMS Office of Financial Management at 7500 Security Boulevard, Mailstop C3–01–24, Baltimore, MD 21244, or such other address as may be specified on the CMS website for purposes of receiving such notices.

i. OIG Safe Harbor Authority

CMS expects to make a determination, if this rulemaking is finalized, that the anti-kickback statute safe harbor for CMS-sponsored model patient incentives (§ 1001.952(ii)(2)) is available to protect patient incentives that may be permitted under the final rule, if issued. Specifically, we expect to determine that the CMS-sponsored models safe harbor would be available to protect direct beneficiary services provided to

beneficiaries through the prepaid shared savings payment option.

We propose to add a new paragraph (d) to § 425.304 that notes that CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) is available to protect remuneration furnished in the prepaid shared savings program option of the Shared Savings Program in the form of direct beneficiary services that meets all safe harbor requirements set forth in § 1001.952(ii)(2).

We are seeking comment on all aspects of our proposals.

6. Advance Investment Payment Policies

a. Proposal To Allow ACOs Receiving Advance Investment Payments to Voluntarily Terminate Payments While Continuing Participation in the Shared Savings Program

Beginning January 1, 2024, CMS implemented a new payment option in the Shared Savings Program, advance investment payments (AIP), and codified AIP requirements at § 425.630. In the CY 2023 PFS final rule (87 FR 69803 through FR 69805), we discussed policies for termination of advance investment payments from ACOs whose participation agreements are terminated for noncompliance with certain requirements and finalized a recoupment policy in which all advance investment payments must be repaid to CMS within 90 days from the date CMS provided the ACO whose participation agreement was terminated with written notice of the amount due. These regulations are codified at § 425.630(g) and (h).

Currently, there are no regulations that account for an ACO that seeks to voluntarily terminate receipt of advance investment payments from CMS, but that wishes to remain in the Shared Savings Program for the rest of their agreement period. While we expect advance investment payment terminations to be an uncommon occurrence, since advance investment payments are a voluntary payment option, ACOs should be able to decline further participation. To accommodate voluntary terminations of advance investment payments for ACOs that wish to continue participating in the Shared Savings Program, CMS proposes to modify program regulations at § 425.630(g) and (h). CMS proposes to allow ACOs who wish to voluntarily terminate receipt of advance investment payments to do so and remain in the Shared Savings Program. An ACO may have justified business reasons for terminating receipt of advance investment payments (such as an ACO's desire to enter a CMS Innovation Center model whose eligibility criteria exclude ACOs that receive AIP). CMS wishes to amend its termination policies to account for such a scenario. It is the best interest of the Medicare Trust Funds and the Shared Savings Program to allow continued program participation by ACOs that terminate receipt of advance investment payments, especially among ACOs and ACO participants in, or that serve, underserved communities. Therefore, CMS proposes new regulations effective January 1, 2025, to allow ACOs to voluntarily terminate receipt of advance investment payments while remaining in the Shared Savings Program. Under this proposal, CMS would develop an advance investment payment voluntary termination notification process to allow ACOs to voluntarily terminate receipt of these payments. If this proposal is finalized, CMS would issue guidance regarding this process to participating Shared Savings Program ACOs shortly after publication of the CY 2025 PFS final rule.

We propose to update § 425.630(g) to state that if an ACO opts to voluntarily terminate from the advance investment payment option, they would be required to return any outstanding advance investment payments to CMS. Upon an ACO notifying CMS that it wants to terminate from the advance investment payment option, CMS would then provide a written notification to the ACO of the total amount of recoupment due. CMS would then require the ACO to repay the amount due no later than 90 days after the receipt of such notification. This aligns with how CMS recoups advance investment payments from ACOs whose advance investment payments are involuntarily terminated due to failure to comply with advance investment payment eligibility requirements under § 425.316(e)(3) and with the repayment requirements under § 425.630(g)(4), if an ACO chooses to terminate from the Shared Savings Program.

ACOs that terminate from the advance investment payment option would no longer be monitored for their appropriate use of advance investment payments once the payments are repaid to CMS. As such, ACOs that terminate would no longer be subject to annual reporting requirements for their spend plans once the payments are repaid to CMS. This proposal would allow an ACO additional flexibility to determine its best payment and participation options, making it easier for an ACO receiving advance investment payments to continue their participation in the Shared Savings Program long-term. As noted in the CY 2023 PFS final rule (87 FR 69784), advance investment payments were designed to assist ACOs that face difficulty funding the start-up costs for forming ACOs, caring for beneficiaries in underserved communities, and achieving long term success in the Shared Savings Program. Allowing these ACOs more flexibility would have the effect of supporting continued Shared Savings Program participation among these ACOs, including those serving rural and underserved populations.

CMS proposes to update § 425.630(g)(5) to state that if an ACO notifies CMS that it no longer wants to participate in the advance investment payment option but does want to continue its participation in the Shared Savings Program, the ACO must repay all outstanding advance investment payments it received. CMS would provide written notice to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

Additionally, CMS proposes conforming revisions to § 425.630(h) to clarify that ACOs can voluntarily terminate from the advance investment payment option. Specifically, CMS proposes to add a paragraph (h)(1)(iv) to read ''Voluntarily terminates payments of advance investment payments but continues its participation in the Shared Savings Program.'' CMS also proposed conforming revisions to § 425.630(h)(1)(ii) and (iii). We seek comment on these proposals. If finalized, the proposed changes would be effective beginning January 1, 2025.

b. Proposal To Recoup Advance Investment Payments When CMS Terminates the Participation Agreement of an ACO

Under current advance investment payment recoupment regulations, there is no clear pathway for CMS to recoup outstanding advance investment payments if CMS terminates an ACO's participation agreement in accordance with § 425.218(b). To address this and reduce the risk to the Trust Fund, CMS proposes to add new § 425.630(g)(6) to require ACOs to repay any outstanding advance investment payments in the event that CMS terminates the ACO's Shared Savings Program participation agreement.

Upon the termination of their Shared Savings Program participation agreement, the ACO's advance investment payments would cease immediately under § 425.630(h)(1)(ii). CMS would provide the ACO with

written notification of the total amount due for the full recoupment of advance investment payments, and the ACO must pay such amount within 90 days after the receipt of such notification. This approach aligns with how CMS recoups advance investment payments for ACOs under § 425.630(g)(4) if an ACO receiving advance investment payments chooses to voluntarily terminate from the Shared Savings Program. This proposal protects CMS from not being able to recoup outstanding advance investment payments in the event CMS terminates an ACO's participation agreement in accordance with § 425.218(b).

Specifically, CMS proposes to add § 425.630(g)(6) to state that if CMS terminates the participation agreement of an ACO that has an outstanding balance of advance investment payments owed to CMS, the ACO must repay any outstanding advance investment payments it received. CMS would provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification. If an ACO fails to fully repay the advance investment payments they received, CMS would carry forward any remaining balance owed to subsequent performance year(s) in which the ACO achieves shared savings, including in any performance year(s) in a subsequent agreement period.

We also propose conforming edits to § 425.630(g)(3) to remove the phrase ''paragraph (g)(4) of this section'' and adding in its place the phrase ''paragraphs (g)(4) through (g)(6) of this section.'' This would allow CMS to recoup more than the amount of shared savings earned by an ACO in a particular performance year in the event that an ACO or CMS terminates an ACO from the advance investment payment option or the Shared Savings Program as a whole. This proposal also would require CMS to renumber regulations at § 425.630(g). Therefore, we propose a conforming change to redesignate § 425.630(g)(5) as § 425.630(g)(7). We seek comment on these proposals. If finalized, these proposals would be effective beginning January 1, 2025.

7. Financial Methodology

a. Overview

In this section of this proposed rule, we are proposing modifications to the financial methodologies used under the Shared Savings Program. The modifications we propose would encourage participation in the program by removing barriers for ACOs serving underserved communities [499] as well as provide greater specificity and clarity on how CMS would perform certain financial calculations in the Shared Savings Program. Specifically, we are proposing to create a health equity benchmark adjustment, to potentially provide an upward adjustment to an ACO's historical benchmark based on the proportion of beneficiaries they serve who are dually eligible or enrolled in the Medicare Part D low-income subsidy (LIS). We are also proposing to establish a calculation methodology to account for the impact of improper payments in recalculating expenditures and payment amounts used in Shared Savings Program financial calculations, upon reopening a payment determination pursuant to § 425.315(a). We are proposing to establish an approach to identify significant, anomalous, and highly suspect (''SAHS'') billing activity in CY 2024 or subsequent calendar years. We are proposing to specify how we would exclude payment amounts from expenditure and revenue calculations for the relevant calendar year for which the SAHS billing activity is identified as well as from historical benchmarks used to reconcile the ACO for a performance year corresponding to the calendar year for which the SAHS billing activity was identified to mitigate the impact of SAHS billing activity. We seek comment on a financial model that would allow for higher risk and potential reward than currently available under the ENHANCED track while still meeting the requirements for use of our authority under section 1899(i)(3) of the Act, among other considerations for the financial model design. We are also proposing certain modifications for clarity and consistency in provisions of the Shared Savings Program regulations on calculation of the ACO risk score growth cap in risk adjusting the benchmark each performance year and the regional risk score growth cap in calculating the regional component of the three-way blended benchmark update factor.

[499] As described in the *CMS Framework for Health Equity* and consistent with Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (86 FR 7009), the term ''underserved communities'' refers to populations sharing a particular characteristic, including geographic communities that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life, as exemplified in the definition of ''equity.''

b. Health Equity Benchmark Adjustment

(1) Background

(a) Summary of Statutory and Regulatory Background on Adjusting the Historical Benchmark

Section 1899(d)(1)(B)(ii) of the Act addresses how ACO benchmarks are to be established, updated, and reset at the start of each agreement period under the Shared Savings Program. This provision specifies that the Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per beneficiary expenditures for Parts A and B services for Medicare FFS beneficiaries assigned to the ACO. The benchmark shall be reset at the start of each agreement period. Section 1899(d)(1)(B)(ii) of the Act also provides the Secretary with discretion to adjust the historical benchmark by ''such other factors as the Secretary determines appropriate.'' Pursuant to this authority, over time we have adopted a variety of methods to adjust the historical benchmark to meet certain policy goals.

Benchmarking policies applicable to all ACOs in agreement periods beginning on January 1, 2024, and in subsequent years, are specified in § 425.652. We refer readers to discussions of the benchmark calculations in earlier rulemaking for details on the development of the current policies (see November 2011 final rule, 76 FR 67909 through 67927; June 2015 final rule, 80 FR 32785 through 32796; June 2016 final rule, 81 FR 37953 through 37991; December 2018 final rule, 83 FR 68005 through 68030; CY 2023 PFS final rule, 87 FR 69875 through 69928; and CY 2024 PFS final rule, 88 FR 79174 through 79208).

In the CY 2023 PFS final rule, we adopted policies to modify the regional adjustment under § 425.656 (refer to 87 FR 69915 through 69923) and to reinstate a prior savings adjustment under § 425.658 (refer to 87 FR 69898 through 69915). The modifications to the regional adjustment are designed to limit the impact of negative regional adjustments on ACO historical benchmarks and further incentivize program participation among ACOs serving high-cost beneficiaries. In the CY 2024 PFS final rule (refer to 88 FR 79185 through 79196), we modified the regional adjustment policy further to prevent any ACO from receiving an adjustment that would cause its benchmark to be lower than it would have been in the absence of a regional adjustment. The prior savings adjustment policy was developed such that a renewing or re-entering ACO may

be eligible to receive an adjustment to its benchmark to account for savings generated in performance years that correspond to the benchmark years of its new agreement period. In the CY 2024 PFS final rule (refer to 88 FR 79196 through 79200), we modified the prior savings adjustment policy further to account for the following: a change in savings earned by the ACO in a benchmark year due to compliance action taken to address avoidance of at-risk beneficiaries or a change in the amount of savings or losses for a benchmark year as a result of a reopening of a prior determination of ACO shared savings or shared losses and the issuance of a revised initial determination under § 425.315.

(b) Methodology for Determining the Applicability of a Regional Adjustment or Prior Savings Adjustment to the ACO's Historical Benchmark, for Agreement Periods Beginning on or After January 1, 2024

Under the benchmarking methodology for agreement periods beginning on January 1, 2024, and in subsequent years, CMS calculates two adjustments to the historical benchmark, a regional adjustment (refer to § 425.656) and a prior savings adjustment (refer to § 425.658). We determine which adjustment is applied to the benchmark, either the regional adjustment, prior savings adjustment, or no adjustment (refer to § 425.652(a)(8) and (c)).

Under the current methodology, the adjustment that will apply in the establishment of benchmarks for ACOs entering an agreement period beginning on January 1, 2024, and in subsequent years, is calculated as follows:

- *Step 1:* Calculate capped regional adjustment expressed as a single dollar value as specified in § 425.656. CMS calculates the regional adjustment to the historical benchmark based on the ACO's regional service area expenditures, making separate calculations for the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

++ Under § 425.656(c)(3), CMS caps the per capita dollar amount for each Medicare enrollment type at a dollar amount equal to a percentage of national per capita expenditures for Parts A and B services under the original Medicare fee-for-service (FFS) program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary.

-- Under § 425.656(c)(3)(i), for positive adjustments, the per capita dollar amount for a Medicare enrollment type is capped at 5 percent of the national per capita expenditure amount for the enrollment type for BY3.

-- Under § 425.656(c)(3)(ii), for negative adjustments, the per capita dollar amount for a Medicare enrollment type is capped at negative 1.5 percent of the national per capita expenditure amount for the enrollment type for BY3.

++ Under § 425.656(d)(1), CMS expresses the regional adjustment as a single value by taking a person year [500] weighted average of the Medicare enrollment type-specific regional adjustment values.

- *Step 2:* For eligible ACOs, calculate the capped prior savings adjustment as specified in § 425.658. Under § 425.658(c)(1), CMS calculates an adjustment to the historical benchmark to account for savings generated in the 3 years prior to the start of the ACO's current agreement period for renewing or re-entering ACOs that were reconciled for one or more performance years in the Shared Savings Program during this period.
- *Step 3:* Determine the final adjustment to the benchmark, as specified in § 425.652(a)(8). Compare the regional adjustment in accordance with § 425.656 and the prior savings adjustment in accordance with § 425.658.

++ Under § 425.652(a)(8)(ii), if an ACO is not eligible to receive a prior savings adjustment under § 425.658(b)(3)(i), and the regional adjustment, expressed as a single value as described in § 425.656(d), is positive, the ACO will receive an adjustment to its benchmark equal to the positive regional adjustment amount. The adjustment will be calculated as described in § 425.656(c) and applied separately to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. Under § 425.652(a)(8)(iii), if an ACO is not eligible to receive a prior savings adjustment under § 425.658(b)(3)(i), and the regional adjustment, expressed as a single value as described in § 425.656(d), is negative or zero, the ACO will not receive an adjustment to its benchmark.

++ Under § 425.652(a)(8)(iv), if an ACO is eligible to receive a prior savings adjustment and the regional adjustment, expressed as a single value as described in § 425.656(d), is positive, the ACO will receive an adjustment to its benchmark equal to the higher of the following:

-- Under § 425.652(a)(8)(iv)(A), the positive regional adjustment amount. The adjustment will be calculated as described in § 425.656(c) and applied separately to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

-- Under § 425.652(a)(8)(iv)(B), the prior savings adjustment. The adjustment will be calculated as described in § 425.658(c) and applied as a flat dollar amount to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

++ Under § 425.652(a)(8)(v), if an ACO is eligible to receive a prior savings adjustment and the regional adjustment, expressed as a single value as described in § 425.656(d), is negative or zero, the ACO will receive an adjustment to its benchmark equal to the prior savings adjustment. The adjustment will be calculated as described in § 425.658(c) and applied as a flat dollar amount to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(c) Background on Incorporating Health Equity Data Within the Shared Savings Program

Development of a health equity benchmark adjustment builds upon Shared Savings Program policies finalized in the CY 2023 and CY 2024 PFS final rules to advance health equity, including the establishment of the health equity adjustment to an ACO's MIPS quality performance category score (applicable to all ACOs beginning with performance year 2023) (87 FR

[500] To calculate person years: We sum the number of Shared Savings Program-eligible months (beneficiaries are only assigned a monthly enrollment status for months in which they are alive on 1st of the month, enrolled in both Parts A and B, and not enrolled in a Medicare Group Health Plan for the month) for each assigned beneficiary for each Medicare enrollment type; we then divide this number by 12 (the number of months in a calendar year). Refer to the Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (version #11, January 2023), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2* (Section 3.1 Calculating ACO-Assigned Beneficiary Expenditures).

69838 through 69857 and 88 FR 79114 through 79117); the availability of advance investment payments to eligible new, low revenue ACOs entering a new agreement period beginning on January 1, 2024, and in subsequent years (87 FR 69782 through 69805 and 88 FR 79208 through 79216); as well as changes to the benchmarking methodology aimed to facilitate participation by ACOs serving medically complex or underserved beneficiaries (87 FR 69915 through 69924 and 88 FR 79185 through 79195).

Further, in a Request for Information in the CY 2023 PFS final rule (87 FR 69977 through 69979), we discussed addressing health equity through benchmarking and summarized related comments. In the CY 2023 PFS final rule (87 FR 69978), we explained our interest in considering how direct modification of benchmarks to account for existing inequities in care can be used to advance health equity. The vast majority of commenters expressed support for exploring methodologies to address health equity via benchmarking changes. Specifically, many of these commenters noted that benchmark adjustments could be an effective tool to redirect resources to ACOs serving underserved communities. Multiple commenters commented specifically on the health equity benchmark adjustment approach utilized by the ACO Realizing Equity, Access, and Community Health (REACH) Model. Several of these commenters expressed support for using a similar methodology in implementing a health equity benchmark adjustment in the Shared Savings Program. In response, we stated that we will consider these comments in the development of policies for future rulemaking. Based on our experience with adjustments under the current benchmarking methodology, our experience establishing policies to advance health equity in the Shared Savings Program, and the support received for addressing health equity through benchmarking in response to the Request for Information, we have determined that it would be timely to implement a health equity benchmark adjustment (HEBA) into the Shared Savings Program's benchmarking methodology. Implementing a HEBA would ensure benchmarks continue to serve as a reasonable baseline when ACOs serve high proportions of beneficiaries who are members of underserved communities and incentivize ACOs to provide coordinated care to beneficiaries who are members of underserved communities.

A health equity benchmark adjustment is likely to encourage more participation in the Shared Savings Program by ACOs that serve beneficiaries who are members of rural and underserved communities by allowing them to participate with potentially higher benchmarks. That, in turn, would increase the likelihood that they could earn shared savings and increase the amount of those shared savings payments and reduce the financial barriers to forming ACOs that providers who serve underserved communities face. Benchmarks based on historically observed spending could be set too low if they are based on the spending of a population of underserved communities. An ACO serving such communities could be harmed financially if they are successful at improving access to high-value care during the performance period. Additionally, the Congressional Budget Office (CBO) recently reported high start-up costs for providers in rural and underserved communities as a barrier to forming ACOs.[501] These providers may want to participate in ACOs but are disincentivized due to steep start-up costs.

A health equity benchmark adjustment would also encourage currently participating ACOs to attract more beneficiaries who are members of underserved communities and remain in the Shared Savings Program. Direct increases to benchmarks for ACOs serving higher proportions of beneficiaries who are members of underserved communities would grant additional financial resources to health care providers accountable for the care of these populations and may work to offset historical patterns of underspending that influence benchmark calculations.

The ACO REACH Model incorporates a HEBA to test a way to address historical health inequities within CMS ACO initiatives, with the intent of incentivizing ACOs to seek out and form relationships with beneficiaries who are members of underserved communities. The adjustment is intended to mitigate the disincentive for ACOs to serve underserved communities by accounting for historically suppressed spending levels for these populations. It is a critical step towards enabling ACOs to serve underserved communities in a manner that reflects their health needs.[502] Likewise, the Shared Savings Program aims to design a health equity benchmark adjustment that achieves those same goals while aligning the program's benchmarking policies and health equity initiatives. The HEBA proposal is informed by CMS' initial experience with the ACO REACH Model, which includes a HEBA, that has been associated with increased participation in ACOs by safety net providers.[503] Increasing access to providers participating in ACOs in rural and other underserved areas remains a priority for CMS to help address inequities in ACO participation and grow accountable care.

(2) Proposed Revisions

Relying on our authority under section 1899(d)(1)(B)(ii) of the Act, we are proposing a HEBA applicable to ACOs in agreement periods beginning on January 1, 2025, and in subsequent years. The proposed HEBA would offer a third method of upwardly adjusting an ACO's historical benchmark, in addition to the existing regional adjustment and prior savings adjustment. This upward adjustment to the historical benchmark is designed to benefit ACOs serving larger proportions of beneficiaries from underserved communities and receiving lower regional adjustments (§ 425.656) or lower prior savings adjustments (§ 425.658) or receiving neither adjustment. Under proposed § 425.652(a)(8)(ii), an ACO would receive the highest of the positive adjustments for which it is eligible, either the regional adjustment, prior savings adjustment, or health equity benchmark adjustment. If an ACO is not eligible to receive a prior savings adjustment or a HEBA, and the regional adjustment, expressed as a single value, is negative or zero, then the ACO would not receive an adjustment to its benchmark.

By increasing the likelihood that an ACO would earn shared savings and by potentially increasing the amount of shared savings earned, the HEBA is meant to provide a greater financial incentive for ACOs to serve more beneficiaries from underserved

[501] Congressional Budget Office (CBO), ''Medicare Accountable Care Organizations: Past Performance and Future Directions,'' April 2024, available at *https://www.cbo.gov/system/files/2024-04/59879-Medicare-ACOs.pdf.*

[502] Centers for Medicare & Medicaid Services, ''ACO Realizing Equity, Access, and Community Health (REACH) Model Finance-Focused Frequently Asked Questions'' (Version 1, April 2022), available at *https://www.cms.gov/priorities/innovation/media/document/aco-reach-finfaqs.*

[503] See Rawal P, Seyoum S, Fowler E. ''Advancing Health Equity Through Value-Based Care: CMS Innovation Center Update'', *Health Affairs Forefront,* June 4, 2024. DOI: 10.1377/forefront.20240603.385559. Available at *https://www.healthaffairs.org/content/forefront/advancing-health-equity-through-value-based-care-cms-innovation-center-update.*

communities and to encourage ACOs already serving higher proportions of beneficiaries from underserved communities to enter and remain in the Shared Savings Program. Practices that serve large proportions of beneficiaries who are members of underserved communities that may otherwise see financial risk in joining the program may be incentivized to form an ACO and join the program with a health equity benchmark adjustment policy in place. In addition, currently participating ACOs that may otherwise see risk in attracting additional beneficiaries from underserved communities to their ACOs may be incentivized to do so with a health equity benchmark adjustment policy in place. We note that, if finalized, the proposed prepaid shared savings option (see section III.G.5 of this proposed rule) would operate synergistically with the proposed HEBA, in that ACOs that have been successful in earning shared savings while serving larger proportions of beneficiaries from underserved communities would in subsequent years have additional capabilities through prepaid shared savings to address the unmet health-related social needs of the beneficiaries they serve and may have higher benchmarks due to the HEBA.

We propose to calculate the HEBA as the multiplicative product of the HEBA scaler and the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid. We propose to calculate the HEBA scaler as a measure of the difference between the following two per-capita dollar values:

- 5 percent of national per capita expenditures for Parts A and B services under the original Medicare FFS program in BY3 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary, expressed as a single value by taking a person year weighted average of the Medicare enrollment type-specific values: ESRD, disabled, aged/dually eligible for Medicare and Medicaid, and aged/non-dually eligible for Medicare and Medicaid, and
- the higher of the regional adjustment expressed as a single value, the prior savings adjustment, or no adjustment, in the case where the regional adjustment is negative and the ACO is not eligible for the prior savings adjustment.

This approach would ensure that the value of the HEBA itself cannot exceed 5 percent of national assignable per capita expenditures expressed as a single value using the ACO's BY3 enrollment proportions, similar to the cap applied to the regional adjustment under § 425.656(c)(3) and the cap applied to the prior savings adjustment under § 425.658(c)(1)(ii).

For this proposed health equity benchmark adjustment, we propose to identify beneficiaries from underserved communities as those who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid. Furthermore, we propose to determine the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid using the ACO's performance year assigned population. Because a higher proportion of assigned beneficiaries who are enrolled in Medicare Part D LIS or dually eligible would result in a higher HEBA, using the performance year assigned population is expected to incentivize ACOs to provide coordinated care to beneficiaries who are members of underserved communities while accounting for changes in the ACO's population over the agreement period.

We propose to provide ACOs with a preliminary calculation of the HEBA near the start of their agreement period when final historical benchmarks are determined, using the ACO's BY3 assigned population in this preliminary calculation of the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid. We would then update the calculation when the ACO's historical benchmark is updated at the time of financial reconciliation for the performance year to reflect the ACO's performance year-assigned population in the calculation of the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid.

We propose that ACOs with a proportion of assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid of less than 20 percent would be ineligible for a HEBA.[504] We believe that imposing this threshold of 20 percent would reinforce that the HEBA is intended for ACOs serving higher proportions of beneficiaries who are members of underserved communities. Based on data from 2022, the average proportion of ACO-assigned beneficiaries enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid was roughly 15 percent. Thus, ACOs meeting the threshold of 20 percent are serving a larger-than-average proportion of beneficiaries from underserved communities. Absent such a threshold, an ACO with a lower than average regional adjustment or prior savings adjustment (and therefore a larger HEBA scaler) that is providing care for relatively few beneficiaries from underserved communities may receive a sizable HEBA, which would reward the ACO despite it not serving a significant proportion of beneficiaries from underserved communities. This would not support the purpose of the HEBA, which is to provide a greater financial incentive for ACOs to serve more beneficiaries from communities and encourage practices already serving higher proportions of beneficiaries from underserved communities to enter and/or remain in the Shared Savings Program.

Under this proposed approach, simulation analysis based on 456 ACOs using historical benchmark data from 2023 indicates that 20 ACOs would receive a HEBA greater than either the prior savings adjustment or regional adjustment. With the HEBA applied, the average increase to historical benchmarks among these 20 ACOs would be $230 per capita, which corresponds to an increase of 1.57 percent to their historical benchmarks on average.

Tables 38 through 40 present hypothetical examples to demonstrate how the HEBA would work in practice.

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[504] The health equity adjustment to an ACO's MIPS quality performance category score (87 FR 69838 through 69857 and 88 FR 79114 through 79117) has established a similar 20 percent threshold. ACOs with an underserved multiplier of less than 20 percent are not eligible to receive a health equity adjustment (§ 425.512(b)).

TABLE 38: ACO with a HEBA Greater Than the Regional Adjustment and Prior Savings Adjustment

Calculation Step	Description of Calculation and Example
Step 1: Calculate Proportion of Assigned Beneficiaries Who Are Enrolled in Medicare Part D LIS or Dually Eligible for Medicare and Medicaid	Proportion of PY-assigned beneficiaries enrolled in Medicare Part D LIS or dually eligible for Medicare and Medicaid: 0.60
Step 2: Calculate HEBA Scaler	5 percent of the national per capita expenditures for assignable beneficiaries in BY3 expressed as a single value: $600 Prior savings adjustment: $200 Regional adjustment expressed as single value: $100 Difference between 5 percent of the national per capita expenditures for assignable beneficiaries in BY3 expressed as a single value and the higher of prior savings adjustment and regional adjustment expressed as a single value: $600 – higher of $200 or $100 = $400
Step 3: Calculate HEBA	Product of the proportion of assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid and the HEBA Scaler: 0.60 x $400 = $240
Step 4: Determine Final Adjustment to Benchmark	Highest of regional adjustment expressed as a single value, prior savings adjustment, or HEBA: Highest of $200, $100, or $240 = $240 Per capita historical benchmark expenditures by enrollment type after adjustment: ESRD: $92,000 + $240 = $92,240 Disabled: $13,000 + $240 = $13,240 Aged/dual: $19,000 + $240 = $19,240 Aged/non-dual: $10,000 + $240 = $10,240

TABLE 39: ACO with a HEBA Less Than the Regional Adjustment and Prior Savings Adjustment

Calculation Step	Description of Calculation and Example
Step 1: Calculate Proportion of Assigned Beneficiaries Who Are Enrolled in Medicare Part D LIS or Dually Eligible for Medicare and Medicaid	Proportion of PY-assigned beneficiaries enrolled in Medicare Part D LIS or dually eligible for Medicare and Medicaid: 0.25
Step 2: Calculate HEBA Scaler	5 percent of the national per capita expenditures for assignable beneficiaries in BY3 expressed as a single value: $600 Prior savings adjustment: $200 Regional adjustment expressed as single value: $300 Difference between 5 percent of the national per capita expenditures for assignable beneficiaries in BY3 expressed as a single value and the higher of prior savings adjustment and regional adjustment expressed as a single value: $600 – higher of $200 or $300 = $300
Step 3: Calculate HEBA	Product of the proportion of assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid and the HEBA Scaler: 0.25 x $300 = $75
Step 4: Determine Final Adjustment to Benchmark	Highest of regional adjustment expressed as a single value, prior savings adjustment, or HEBA: Highest of $200, $300, or $75 = $300 Per capita historical benchmark expenditures by enrollment type after adjustment: ESRD: $92,000 + $300 = $92,300 Disabled: $13,000 + $300 = $13,300 Aged/dual: $19,000 + $300 = $19,300 Aged/non-dual: $10,000 + $300 = $10,300

TABLE 40: ACO Ineligible for the HEBA

Calculation Step	Description of Calculation and Example
Step 1: Calculate Proportion of Assigned Beneficiaries Who Are Enrolled in the Medicare Part D LIS or Dually Eligible for Medicare and Medicaid	Proportion of PY-assigned beneficiaries enrolled in Medicare Part D LIS or dually eligible for Medicare and Medicaid: 0.10
Step 2: Calculate HEBA Scaler	5 percent of the national per capita expenditures for assignable beneficiaries in BY3 expressed as a single value: $600 Prior savings adjustment: $200 Regional adjustment expressed as single value: $300 Difference between 5 percent of the national per capita expenditures for assignable beneficiaries in BY3 expressed as a single value and the higher of prior savings adjustment and regional adjustment expressed as a single value: $600 – higher of $200 or $300 = $300
Step 3: Calculate HEBA	Step not applicable as ACO has a proportion of assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid less than 0.20 and is ineligible for a HEBA as a result.
Step 4: Determine Final Adjustment to Benchmark	Higher of regional adjustment expressed as a single value or prior savings adjustment: Higher of $200 or $300 = $300 Per capita historical benchmark expenditures by enrollment type after adjustment: ESRD: $92,000 + $300 = $92,300 Disabled: $13,000 + $300 = $13,300 Aged/dual: $19,000 + $300 = $19,300 Aged/non-dual: $10,000 + $300 = $10,300

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We propose to implement the changes described in this section through revisions to § 425.652 and the addition of § 425.662. Specifically, within § 425.652, which sets forth the methodology for establishing, adjusting, and updating the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years, we propose revisions to § 25.652(a)(8). As proposed, this revised provision would describe how we would determine and apply the adjustment to an ACO's benchmark, if any, based on a comparison of the ACO's regional adjustment expressed as a single value, prior savings adjustment, and the proposed health equity benchmark adjustment. Furthermore, we propose to amend § 425.652 by redesignating paragraphs (a)(9)(v) and (vi) as paragraphs (a)(9)(vi) and (vii), respectively, and to specify in a new paragraph (a)(9)(v) the adjustments made to the health equity benchmark adjustment for the first performance year during the term of the agreement period and in the second and each subsequent performance year during the term of the ACO's agreement period, if applicable. We also propose conforming changes in newly redesignated § 425.652(a)(9)(vi), specifying that CMS redetermines the adjustment to benchmark in accordance with § 425.652(a)(8), to list the HEBA along with the regional adjustment and prior savings adjustment. In the proposed new section of the regulation at § 425.662 we describe the calculation of the HEBA. We also propose to make conforming changes to § 425.658(d), which describes the applicability of the prior savings adjustment, to include consideration of the HEBA in addition to the regional adjustment, in determining the adjustment (if any) that would be applied to the ACO's benchmark. We seek comment on these proposals.

In combination with the proportion of ACO-assigned beneficiaries who are enrolled in the Medicare Part D LIS or are dually eligible for Medicare and Medicaid, we are seeking comment on the use of the Area Deprivation Index (ADI) to identify beneficiaries from underserved communities for purposes of determining eligibility for and the amount of any health equity benchmark adjustment. For example, similar to how the ADI is used in the underserved multiplier as part of the calculation of the health equity adjustment to an ACO's MIPS Quality performance category score (87 FR 69838 through 69857 and 88 FR 79114 through 79117), we are considering taking the higher of either the proportion of the ACO's assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85 or the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid to determine eligibility for and the amount of any health equity benchmark adjustment. CMS will explore how best to incorporate geographic parameters into Shared Savings Program benchmark adjustments, informed by the current use of the ADI in other health equity

provisions of the Shared Savings Program. CMS will also consider learnings from the Innovation Center's ACO REACH Model, which is testing the use of the ADI as a component of the model's HEBA. By considering the ADI in addition to the proportion of ACO-assigned beneficiaries who are enrolled in the Medicare Part D LIS or are dually eligible for Medicare and Medicaid, the HEBA would more closely align with existing Shared Savings Program policies to advance health equity, such as the health equity adjustment to an ACO's MIPS Quality performance category score (87 FR 69838 through 69857 and 88 FR 79114 through 79117) and the calculation of the amount of quarterly advance investment payments made available to eligible new, low revenue ACOs (87 FR 69782 through 69805 and 88 FR 79208 through 79216).

Additionally, recent analyses have found that the ADI weights 2 variables (median home value and median income) higher relative to the weights associated with the other 15 variables in the index, which may have limited contributions in determining the ADI. In many indexes, variables are standardized to the same range for ease of comparison, prior to incorporation into the index. The ADI does not standardize its variables; median home value and median income are measured on their local area dollar-value scales, which are larger than the scales on which the other variables are measured. Some researchers have reported that, without standardization, the ADI overemphasizes the 2 variables (median home value and median income), a finding that may underscore the importance of using standardized values.[505] [506] [507] We seek comment on considering the ADI for purposes of determining eligibility for and the amount of any health equity benchmark adjustment, and related factors including the calculation of the ADI.

c. Reopening ACO Payment Determinations

(1) Background

(a) Statutory Background on Shared Savings Program Financial Calculations

Section 1899(d)(1)(B)(ii) of the Act provides for the calculation and update of ACO benchmarks under the Shared Savings Program. This provision specifies that the Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per beneficiary expenditures for Parts A and B services for Medicare FFS beneficiaries assigned to the ACO. Such benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate and updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program, as estimated by the Secretary. Further, an ACO's benchmark must be reset at the start of each agreement period. Section 1899(d)(1)(B)(i) of the Act specifies that, in each year of the agreement period, an ACO is eligible to receive payment for shared savings only if the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark under section 1899(d)(1)(B)(ii) of the Act.

Section 1899(i)(3) of the Act authorizes the Secretary to use other payment models, if the Secretary determines it is appropriate, and if the Secretary determines that doing so would improve the quality and efficiency of items and services furnished under Title XVIII and the alternative methodology would result in program expenditures equal to or lower than those that would result under the statutory payment model. As discussed in earlier rulemaking, we have used the authority under section 1899(i)(3) of the Act to adopt alternative policies to the provisions of section 1899(d)(1)(B) of the Act for updating the historical benchmark [508] and calculating performance year expenditures,[509] among other factors.[510] We have also used our authority under section 1899(i)(3) of the Act to establish the Shared Savings Program's two-sided payment models,[511] and to mitigate shared losses owed by ACOs affected by extreme and uncontrollable circumstances during PY 2017 and subsequent performance years.[512]

(b) Background on Shared Savings Program Reopening Policy and Financial Calculation Methodology

Under § 425.315(a)(1), if CMS determines that the amount of shared savings due to the ACO or the amount of shared losses owed by the ACO has been calculated in error CMS may reopen the initial determination or a final agency determination under subpart I and issue a revised initial determination: (i) at any time in the case of fraud or similar fault as defined in § 405.902; [513] or (ii) not later than 4 years after the date of the notification to

[505] *See* Hannan, EL, et al. The Neighborhood Atlas Area Deprivation Index For Measuring Socioeconomic Status: An Overemphasis On Home Value. *Health Affairs,* vol. 42, no. 5 (May 2023): 702–709. Available at *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.01406.*

[506] *See* Rehkopf, DH, and Phillips, RL, Jr. The Neighborhood Atlas Area Deprivation Index And Recommendations For Area-Based Deprivation Measures. *Health Affairs,* vol. 42, no. 5 (May 2023): 710–711. Available at *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2023.00282.*

[507] *See* Petterson, S. Deciphering the Neighborhood Atlas Area Deprivation Index: the consequences of not standardizing. *Health Affairs Scholar,* volume 1, issue no. 5 (November 2023), qxad063; Available at *https://academic.oup.com/healthaffairsscholar/article/1/5/qxad063/7342005.*

[508] Such as using only assignable beneficiaries instead of all Medicare FFS beneficiaries in calculating the benchmark update based on national FFS expenditures (81 FR 37985 through 37989), calculating the benchmark update using factors based on regional FFS expenditures (81 FR 37977 through 37981), calculating the benchmark update using a blend of national and regional expenditure growth rates (83 FR 68027 through 68030), removing payment amounts for episodes of care for treatment of COVID–19 from expenditures used to calculate the benchmark update (85 FR 27577 through 27582), and calculating the benchmark update using an Accountable Care Prospective Trend/national-regional three-way blended update factor (87 FR 69881 through 69898).

[509] Such as excluding indirect medical education and disproportionate share hospital payments from ACO performance year expenditures (76 FR 67920 through 67922), determining shared savings and shared losses for the 6-month performance years (or performance period) in 2019 using expenditures for the entire CY 2019 and then pro-rating these amounts to reflect the shorter performance year or performance period (83 FR 59949 through 59951, 83 FR 67950 through 67956), removing payment amounts for episodes of care for treatment of COVID–19 from performance year expenditures (85 FR 27577 through 27582), and the exclusion of the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals from performance year expenditures (87 FR 69954 through 69956).

[510] Such as allowing for advance investment payments (87 FR 69782 through 69805), and expansion of the criteria for certain low revenue ACOs participating in the BASIC track to qualify for shared savings in the event the ACO does not meet the MSR as required under section 1899(d)(1)(B)(i) of the Act (87 FR 69946 through 69952).

[511] See earlier rulemaking establishing two-sided models: Track 2 (76 FR 67904 through 67909), Track 3 (subsequently renamed the ENHANCED track) (80 FR 32771 and 32772), and the BASIC track (83 FR 67834 through 67841). We also used our authority under section 1899(i)(3) of the Act to remove payment amounts for episodes of care for treatment of COVID–19 from ACO participants' Medicare FFS revenue used to determine the loss sharing limit in the two-sided models of the BASIC track (85 FR 27577 through 27582).

[512] See earlier rulemaking establishing policies for mitigating shared losses owed by ACOs affected by extreme and uncontrollable circumstances (82 FR 60916 and 60917, 83 FR 59974 through 59977).

[513] As defined in § 405.902, ''similar fault'' means to obtain, retain, convert, seek, or receive Medicare funds to which a person knows or should reasonably be expected to know that he or she or another for whose benefit Medicare funds are obtained, retained, converted, sought, or received is not legally entitled. This includes, but is not limited to, a failure to demonstrate that he or she filed a proper claim as defined in 42 CFR part 411.

the ACO of the initial determination of savings or losses for the relevant performance year, for good cause.

In accordance with § 425.315(a)(2), good cause may be established when (i) there is new and material evidence that was not available or known at the time of the payment determination and may result in a different conclusion, or (ii) the evidence that was considered in making the payment determination clearly shows on its face that an obvious error was made at the time of the payment determination. Section 425.315(a)(3) specifies that a change of legal interpretation or policy by CMS in a regulation, CMS ruling or CMS general instruction, whether made in response to judicial precedent or otherwise, is not a basis for reopening a payment determination under the Shared Savings Program regulations. CMS has sole discretion to determine whether good cause exists for reopening a payment determination (§ 425.315(a)(4)).

We first adopted a reopening policy in the November 2011 final rule, where we finalized at § 425.314(a)(4) a provision reserving the right for CMS to reopen the initial determination and issue a revised initial determination, if as a result of any inspection, evaluation, or audit, it is determined that the amount of shared savings due to the ACO or amount of shared losses owed by the ACO has been calculated in error (see 76 FR 67957 through 67958, and 67982). In the June 2016 final rule, we revised the Shared Savings Program regulations, including to remove the provision in § 425.314(a)(4), and further specify the reopening policy in a new section of the regulation at § 425.315 (81 FR 37997 through 38002, and 38013 through 38014). We subsequently revised § 425.315 to apply the policies on reopening determinations to payment determinations for a 6-month performance year or 6-month performance period during CY 2019 (refer to the November 2018 final rule, 83 FR 59958 and 60092, and the December 2018 final rule, 83 FR 67955 through 67967), and to ACOs participating in the BASIC track (refer to the December 2018 final rule, 83 FR 67842 and 68068). In the CY 2023 PFS final rule, we clarified the circumstances in which CMS would exercise discretion to reopen the initial determination of an ACO's financial performance for good cause to correct errors in the determination of MIPS Quality performance category scores that affect the determination of whether an ACO is eligible for shared savings, the amount of shared savings due to the ACO, or the amount of shared losses owed by the ACO (see 87 FR 69868 through 69869).

Most recently, in the CY 2024 PFS final rule, we finalized an approach to recalculating the prior savings adjustment for changes in values used in benchmark calculations due to compliance action taken to address avoidance of at-risk beneficiaries, or as a result of the issuance of a revised initial determination of financial performance for a previous performance year following a reopening of ACO shared savings and shared losses calculations (88 FR 79195 through 79200). In the CY 2024 PFS final rule, we also discussed a proposed timing cutoff such that changes to savings or losses for a benchmark year that were finalized after notification to the ACO of the initial determination of shared savings or shared losses for a given performance year would be reflected in the adjusted benchmark applied to any subsequent performance year during the relevant agreement period but would not be retroactively applied to completed performance years in the agreement period (88 FR 79198 through 79200). We stated that we believed it would be appropriate to consider new information that could impact the prior savings adjustment up to the point at which an ACO receives its initial determination. However, we also noted that we would continue to consider the complexities surrounding reopening initial determinations for multiple prior performance years throughout the program's benchmarking and financial reconciliation methodologies and may address this issue in future rulemaking (88 FR 79199). We refer readers to these discussions in past rulemaking for additional details.

In our earlier rulemaking, we did not discuss the specific methodology that would be employed for recalculating an ACO's shared savings or shared losses in the event of a reopening in order to issue a revised initial determination. As additional background, in the following discussion, we summarize the general approach to identification and use of payment amounts from Medicare FFS Parts A and B FFS claims and certain other payment amounts in Shared Savings Program calculations.

Under the Shared Savings Program, providers and suppliers continue to bill for services furnished to Medicare beneficiaries and receive FFS payments under traditional Medicare. CMS uses payment amounts for Parts A and B FFS claims for calculating benchmark and performance year expenditures and determining benchmark update factors as specified in the Shared Savings Program regulations in subpart G. These operations typically require the determination of expenditures for Parts A and B services under the original Medicare FFS program for a specified population of Medicare FFS beneficiaries or the Medicare Parts A and B FFS revenue of ACO participants. The Medicare FFS beneficiary population for which expenditures are determined may differ depending on the specific program operation being performed and may reflect expenditures for the ACO's assigned beneficiaries, assignable beneficiaries, or all Medicare FFS beneficiaries. The applicable Medicare FFS beneficiary population is specified in the regulations governing each program operation.

In calculating expenditures for Medicare FFS beneficiaries used in Shared Savings Program calculations, CMS uses payment amounts included on Parts A and B FFS claims with dates of service in the relevant benchmark or performance year, allowing for a 3-month claims run out, as follows: claim payment amounts identified for inpatient, Skilled Nursing Facility (SNF), outpatient, Home Health Agency (HHA), and hospice claims at any provider; and line item payment amounts identified for carrier (including physician/supplier Part B) and Durable Medical Equipment, Prosthetics, Orthotics & Supplies (DMEPOS) claims. For both Parts A and B claims, CMS excludes payments on denied claims or line items from the calculation, for claims or line items with dates of service within the relevant benchmark year or performance year, processed before the end of the 3-month claims run out period. In calculating expenditure amounts for Medicare FFS beneficiaries under the Shared Savings Program, CMS makes certain adjustments,[514] which if applicable, exclude indirect medical education (IME) and disproportionate share hospital (DSH) payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals, and take into consideration individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program. We also account for certain population-based payments or other similarly structured payments made under other Medicare shared savings initiatives, specifically the Pioneer ACO Model, Next Generation ACO Model, Vermont All-Payer ACO Model, and ACO REACH Model (as

[514] The Shared Savings Program's financial models and benchmarking policies, among other program policies, have changed over time as described in earlier rulemaking (refer to section III.G.1.b. of this proposed rule), and as outlined in the provisions of subpart G.

applicable). Population-based payments are a per-beneficiary per month payment amount intended to replace some or all of the FFS payments with prospective monthly payment.[515]

The Shared Savings Program's existing financial methodology does not fully account for actions taken to protect the integrity of the Medicare program, or address the impact of improper payments, including improper payments resulting from fraud or similar fault on program calculations. For instance, demanded overpayment determinations resulting in adjusted claim or line item payment amounts after the 3-month claims run out period, or aggregate amounts that are not linked to specific claims or line items, are not accounted for in Shared Savings Program expenditure calculations. Additionally, under the existing financial methodology for the Shared Savings Program, we lack a means to account for improper payment amounts identified in a settlement agreement between a provider or supplier and the Government or a court's judgment, including pursuant to conduct by individuals or entities performing functions or services related to an ACO's activities. Under the proposed approach described in section III.G.7.c.(2).(c) of this proposed rule, the term ''improper payment'' for purposes of the Shared Savings Program would include an amount associated with a demanded overpayment determination and certain amounts identified in a settlement agreement or judgment that have the potential to impact program financial calculations. Since January 2023, we have evaluated several cases where such improper payments may have impacted one or more reconciled performance years for an ACO under the Shared Savings Program, including cases where ACOs reported concerns about alleged fraud or similar fault to CMS. It is thus timely and appropriate to undertake notice and comment rulemaking to establish a calculation methodology to account for the impact of improper payments in recalculating expenditures and payment amounts used in Shared Savings Program financial calculations, upon reopening a payment determination pursuant to § 425.315(a); to describe factors that we may consider in exercising our discretion to reopen an ACO's payment determination under which we apply the proposed methodology to recalculate the ACO's financial performance; and to propose to establish a process by which an ACO could request a reopening of an initial determination of shared savings or shared losses. Our experience reviewing several cases supported the development of our proposed revisions to Shared Savings Program policies.

(2) Proposed Revisions

This section of this proposed rule includes a proposed change to the provision specifying CMS' discretion to reopen payment determinations under § 425.315(a)(4) (as described in section III.G.7.c.(2).(a) of this proposed rule). We discuss and seek comment on the circumstances in which we would exercise our discretion to reopen a payment determination and issue a revised initial determination to account for the impact of identified improper payments on Shared Savings Program calculations (as described in section III.G.7.c.(2).(b) of this proposed rule). We propose modifications to the Shared Savings Program regulations to specify a calculation methodology to account for the impact of identified improper payments in recalculating expenditures and payment amounts used in Shared Savings Program financial calculations, upon reopening a payment determination pursuant to § 425.315(a) (as described in section III.G.7.c.(2).(c) of this proposed rule). We also propose certain adjustments to Shared Savings Program benchmark calculations to account for the impact of identified improper payments, in the event a performance year for which we issue a revised initial determination becomes a benchmark year of an ACO's current agreement period, and when CMS has not yet issued an initial determination for a performance year of the ACO's current agreement period (as described in section III.G.7.c.(2).(d) of this proposed rule). Lastly, we propose a process for ACOs to request that CMS reopen a payment determination (as described in section III.G.7.c.(2).(e) of this proposed rule), and briefly discuss the role of ACOs in preventing and reporting Medicare fraud (as described in section III.G.7.c.(2).(f) of this proposed rule). Our specific proposals are discussed in detail in the following sections.

We propose that the policy changes discussed in this section of this proposed rule would be effective January 1, 2025, unless specified otherwise. Should the proposed policies be finalized, the policies would apply to reopening requests made on or after January 1, 2025. As described in section III.G.7.c.(2).(e) of this proposed rule, we propose to establish a process by which an ACO may request a reopening review. If finalized, we anticipate continuing to evaluate previously received reopening requests for performance years for which initial determinations were issued prior to January 1, 2025, consistent with the timeframes specified under § 425.315(a)(1). We anticipate consistently applying the recalculation methodology to account for the impact of improper payments, described in section III.G.7.c.(2).(c) of this proposed rule, if finalized, in recalculating expenditures and payment amounts used in Shared Savings Program financial calculations, upon reopening a payment determination pursuant to § 425.315(a).

(a) Proposed Change to Provision Specifying CMS' Discretion To Reopen Payment Determinations

In earlier rulemaking we explained that CMS would have discretion to reopen a payment determination for fraud or similar fault, or good cause, as reflected in the provisions in § 425.315(a)(1) and (4). The latter provision expressly provides that CMS has sole discretion to determine whether good cause exists for reopening a payment determination. In the June 2016 final rule, in restating the discussion of the proposal from the February 2016 proposed rule, we explained that CMS would have discretion to reopen a payment determination at any time in the case of fraud or ''similar fault,'' as defined in § 405.902 (81 FR 37998).

We continue to believe that it is important to maintain CMS' sole discretion in determining whether to reopen a payment determination. We also believe it is important to preserve CMS' flexibility in determining whether reopening is warranted to address the impact of fraud or similar fault on Shared Savings Program calculations, in particular given the potential for various actions to be taken by CMS, law enforcement agencies and courts in response to fraud or similar fault. Thus, we are proposing revisions to § 425.315(a)(4) to make clear CMS' discretion to determine whether to reopen a payment determination applies in the case of fraud or similar fault, as well as to determining whether good cause exists to reopen a payment determination.

[515] See for example, Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (Version 11, January 2023), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2* (refer to Section 3.1 Calculating ACO-Assigned Beneficiary Expenditures).

(b) Considerations for Reopening a Payment Determination To Account for Improper Payments

In the discussion that follows we describe factors CMS may consider to inform our decision of whether to reopen an initial determination of an ACO's financial performance pursuant to § 425.315(a)(1)(i) or (ii) to account for the impact of improper payments that affect the determination of whether an ACO is eligible for shared savings or liable for shared losses, and the amount of shared savings due to the ACO or the amount of shared losses owed by the ACO. We welcome comments on these considerations. We also anticipate revisiting these considerations as we gain experience with processing ACO reopening requests as described in section III.G.7.c.(2).(e) of this proposed rule, reopening payment determinations and applying the calculation methodology described in section III.G.7.c.(2).(c) of this proposed rule and applying the benchmark adjustment described in section III.G.7.c.(2).(d) of this proposed rule. If appropriate, we may revisit these considerations for exercising our discretion to reopen payment determinations in future notice and comment rulemaking.

As an initial matter, the Shared Savings Program would need to identify improper payments that have the potential to impact program financial calculations. The Shared Savings Program depends on input from the CMS Center for Program Integrity (CPI) and law enforcement agencies (including the Department of Justice) to identify and quantify improper payments potentially impacting expenditures used in program calculations that are not otherwise accounted for in Shared Savings Program expenditure calculations as described in this section of this proposed rule. This could include: (1) certain demanded overpayment determinations, such as demanded overpayment amounts that result in adjusted claim or line item payment amounts associated with dates of service during a performance year or benchmark year, where the adjustment occurs after the 3-month claims run out period, and demanded extrapolated overpayment amounts which are aggregate amounts that are not linked to specific claims or line items and are not currently accounted for in Shared Savings Program expenditures;[516] and (2) improper payments resulting from conduct by individuals or entities performing functions or services related to an ACO's activities as identified in certain settlement agreements or judgments. Refer to section III.G.7.c.(2).(c) of this proposed rule for discussion of considerations for identifying these amounts. Further, as discussed in greater detail in section III.G.7.c.(2).(e) of this proposed rule, ACOs can play an important role in identifying for CMS improper payments that may impact Shared Savings Program calculations. ACO reopening requests submitted to CMS may be another means by which the Shared Savings Program becomes aware of improper payments impacting ACO financial calculations; however, CMS would retain discretion over whether to reopen payment determinations after reviewing information provided in such requests.

Second, we anticipate needing to perform an initial analysis of whether the improper payments would warrant reopening the ACO's payment determination. This analysis may include a number of factors, such as whether the improper payments meet the requirements for reopening for fraud or similar fault in accordance with § 425.315(a)(1)(i), or for good cause in accordance with § 425.315(a)(1)(ii) and (a)(2). A variety of circumstances could lead CMS, law enforcement agencies or courts to determine whether good cause exists or whether fraud or similar fault has occurred. The timelines associated with the related investigations, and the potential for various actions to be taken in response, can make it challenging to identify a one-size-fits-all approach to addressing the impact of improper payments on Shared Savings Program calculations. We note that once we are notified of potential improper payments impacting Shared Savings Program calculations, it may take months or years to determine the actual amount of any improper payments impacting an ACO's payment determination, particularly if we are awaiting the conclusion of program integrity and law enforcement investigations, among other possible determinations about the related conduct of providers or suppliers. Additionally, administrative action and judicial action leading to the identification of improper payments may be subject to appeal, and ultimately the amount of the improper payments may be redetermined or otherwise amended.[517] It would further protract the timeline for considering use of improper payments in recalculating ACO financial performance results to await the outcome of any appeal of an improper payment.

Since there could be a variety of reasons for which CMS seeks to recoup an overpayment amount from a provider or supplier, there are many possible circumstances that could warrant reopening under § 425.315. As an example, we may consider a combination of factors in evaluating whether demanded overpayment determinations would be the basis for reopening for fraud or similar fault under § 425.315(a)(1)(i).[518] For instance, we may consider whether there is ''reliable evidence'' (as defined according to § 405.902, which means evidence that is relevant, credible, and material) of similar fault to warrant reopening a Shared Savings Program payment determination.[519] For purposes of the Shared Savings Program's reopening policy, we may find there is reliable evidence of similar fault when a demanded overpayment determination was issued to a provider or supplier for which CMS has revoked or deactivated their Medicare billing privileges, or for which there is a closed law enforcement investigation, among other possible factors. Although demanded overpayment determinations are subject to appeal, we believe use of these amounts in reopening and recalculating an ACO's financial performance under

[516] For additional information on overpayment procedures and overpayment estimation, see, for example, Medicare Program Integrity Manual, Chapter 8—Administrative Actions and Sanctions and Statistical Sampling for Overpayment Estimation, available at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/pim83c08.pdf*.

[517] For instance, a provider receiving an initial demand letter for an overpayment may appeal the overpayment by requesting a redetermination, among other actions. See for example, CMS, MLN Fact Sheet, ''Medicare Overpayments'' (MLN006379 October 2023), available at *https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/overpaymentbrochure508-09.pdf*. The Medicare Parts A and B appeals process includes multiple levels of appeal. See for example, CMS, MLN Booklet, ''Medicare Parts A & B Appeals Process'' (MLN006562 November 2023), available at *https://www.cms.gov/files/document/mln006562-medicare-parts-b-appeals-process.pdf*.

[518] While this example presumes reopening for fraud or similar fault, there may be additional considerations and complexities around reopening for good cause.

[519] This approach may continue to maintain a degree of alignment between reopening policies under the Shared Savings Program and other Medicare policies. In the February 2016 proposed rule, in which we proposed amending the Shared Savings Program's reopening policy, we referred to the longstanding policy in the Medicare program that a determination may be reopened at any time if it was procured by fraud or similar fault, and as an example referred to 42 CFR 405.980(b)(3) (see 81 FR 5855). In accordance with § 405.980(b)(3), a contractor may reopen an initial determination or redetermination on its own motion at any time if there exists reliable evidence as defined in § 405.902 that the initial determination was procured by fraud or similar fault as defined in § 405.902.

the Shared Savings Program would allow us to more timely address the impact of improper payments on Shared Savings Program calculations, rather than waiting to consider the outcome of any possible appeal of the amounts (as discussed in section III.G.7.c.(2).(c) of this proposed rule).

As part of our initial analysis to evaluate whether to reopen an ACO's initial determination, we may also consider the significance of the improper payments to an ACO's financial calculations by estimating the financial impact of improper payments on an ACO's payment determination. If we estimate that the improper payments have impacted the dollar amount of earned shared savings, or the amount of shared losses that the ACO owes or has paid to CMS, we anticipate reopening an ACO's payment determination. When determining whether to reopen an ACO's payment determination, we anticipate considering a combination of factors including:

- The dollar value of improper payments and the number of claims or line items impacted (if applicable).
- How any related impact on performance year expenditures may compare to the impact on the ACO's updated historical benchmark (which could include considering the impact on benchmark year expenditures and factors used to establish, adjust and update the benchmark). In particular, we may consider whether comparing performance year expenditures to the updated benchmark expenditures used in financial reconciliation, once adjusted to account for the estimated impact of the improper payments, would result in a significant change in the amount of shared savings paid to or shared losses owed by the ACO. For purposes of this analysis we may consider the following:

++ The MSR/MLR applicable to the ACO for the relevant performance year.

++ Whether the ACO met or exceeded the applicable MSR/MLR with the initial determination.

++ Whether accounting for improper payments would cause a change in the ACO's financial performance compared to its performance under the initial determination, including:

-- Causing an ACO to meet or exceed its MSR/MLR when it did not do so under its initial determination, or no longer meet or exceed the relevant threshold when it did so under its initial determination.

-- Causing an ACO that shared savings or owed losses under the initial determination to share in either a higher or lower amount of savings or losses (respectively).

-- Causing an ACO to continue to generate savings or losses less than the MSR/MLR threshold, as it did under its initial determination, and therefore the ACO would remain ineligible for shared savings, except in cases where certain low revenue ACOs participating in the BASIC track may qualify for a shared savings payment in accordance with § 425.605(h), and would not be held liable for shared losses.

We note that the existing reopening authority at § 425.315 and the proposed financial methodology to address improper payments in such a reopening are not intended to address particular instances of low-value improper payments which, in an individual case may be to the benefit of either the ACO or CMS and in the aggregate are likely have a de minimis net effect on program expenditures in the long run.[520] CMS would be highly unlikely to reopen in such cases under § 425.315. We believe that considering the significance of the potential impact of the improper payments on the ACO's payment determination, in deciding whether to reopen the payment determination, is a key component of striking a balance between improving the accuracy of the calculations and ACOs' and CMS' interest in administrative finality of payment determinations. We discuss related concerns and considerations elsewhere in this section of this proposed rule. Therefore, we would seek to reopen an ACO's payment determination only in cases where the impact of improper payments warrants disrupting the initial determination.

Consider, for example, that in our initial determination we found that an ACO generated savings below its minimum savings rate (MSR) and, therefore, did not qualify for a shared savings payment according to the policies for determining the ACO's eligibility for shared savings applicable to its agreement period under the Shared Savings Program.[521] If, based on an initial analysis, we estimate that the ACO's savings, though higher once adjusted to remove improper payments from performance year expenditure calculations, would still fall below the minimum savings rate, it would not be necessary to reopen an ACO's payment determination because the ACO would still not qualify for a shared savings payment. Under such circumstances, we would not reopen the initial determination or proceed with the recalculations described in section III.G.7.c.(2).(c) of this proposed rule. We anticipate that this particular type of situation could occur in cases where the improper payments at issue are relatively small and the differential between an ACO's generated shared savings and minimum savings rate as calculated in the initial determination is relatively large such that recalculating the amounts would not produce a different outcome to the payment determination.

It is also possible that improper payments would have no impact on Shared Savings Program financial calculations as they may consist of claims or payment amounts that were not used in reaching the initial determination of the ACO's financial performance. For instance, if a demanded overpayment determination was for a payment amount on a claim with a HCPCS or CPT code identified as having significant, anomalous, and highly suspect billing activity, and therefore the payment amount was excluded from certain financial calculations used in determining the ACO's financial performance under the proposed adjustment discussed in section III.G.7.d of this proposed rule, we would not include this amount as part of a reopening for the same performance year. As another example, if the demanded overpayment determination was for a claim or line item that was initially paid after the end of the 3-month claims run out period, we would not take into account through the reopening process a payment amount that was not included in Shared Savings Program calculations to begin with. We anticipate improper payments identified in these circumstances would not merit reopening the ACO's initial determination.

A number of steps would follow after CMS has decided to reopen the initial determination. We would recalculate the ACO's financial performance for a performance year by applying the methodology as described in section III.G.7.c.(2).(c) of this proposed rule. With this recalculation we would determine the amount of shared savings payment the ACO may be eligible to receive or the amount of shared losses the ACO may owe for the performance year after accounting for the impact of the improper payments. We would issue a revised initial determination to the ACO with the recalculated payment determination for the performance year. We would notify the ACO of savings and losses in accordance with § 425.604(f), § 425.605(e), § 425.606(h), § 425.609(e), or § 425.610(h) (as applicable). Depending on the outcome

[520] *See, for example,* 81 FR 38000 and 38001.

[521] This example assumes a one-sided model ACO with an MSR based on the number of beneficiaries assigned to the ACO, or a two-sided model ACO with an MSR/MLR greater than zero.

of the recalculation as specified in the revised initial determination, we would engage in payment activities and recoupment activities, as needed. As explained in earlier rulemaking, we anticipate considering ways to minimize program disruptions for ACOs that could result from one or more reopenings (see for example, 81 FR 38001 through 38002; see also, 87 FR 69868 through 69872). CMS may require considerable time after deciding to reopen an initial determination before it can complete the process described above for a variety of reasons. For example, additional time may be necessary for CMS or other agencies to ascertain the precise amount of improper payments that affected the initial determination.

In reopening a payment determination, we note that improper payments may impact either performance year expenditures, the ACO's updated historical benchmark used in determining the ACO's financial performance (including calculation of benchmark expenditures and factors used to establish, adjust and update the ACO's historical benchmark), or both. The recalculation of the ACO's financial performance may have varying effects on the ACO's payment determination for the performance year. In some scenarios, the recalculation may change the determination of whether the ACO earned shared savings or owes shared losses, or may change the amount of any shared savings earned or shared losses owed. It is also possible that we may observe there is no impact on the amount of shared savings earned or amount of shared losses owed by the ACO, once we have performed the recalculation of the ACO's financial performance.

Under the Shared Savings Program's benchmarking methodology, there are potential interactions between performance of an ACO under the program for a performance year during an agreement period and resetting the ACO's benchmark for a subsequent agreement period. Specifically, an ACO's performance year may correspond to a benchmark year of its subsequent agreement period, such that improper payments impacting expenditures for Medicare FFS beneficiaries used to determine performance year expenditures may similarly impact expenditures for the same period used to establish the ACO's historical benchmark. For instance, for ACOs that have participated in the Shared Savings Program over multiple agreement periods, improper payments may impact the amount of a prior savings adjustment to the historical benchmark (if applicable).[522] We discussed the complexity around some related interactions in CY 2024 PFS rulemaking, in regard to recalculating the prior savings adjustment, as described in section III.G.7.c.(1).(b) of this proposed rule (see 88 FR 79198 through 79200). We note that reopenings at any time for fraud or similar fault could extend to any prior performance year of the Shared Savings Program. Since Shared Savings Program policies have changed over time, in performing the recalculation we would apply the relevant financial model and benchmarking policy for the ACO for that performance year, in accordance with the applicable provisions of subpart G.

Third, we are considering limiting the instances in which we reopen an initial determination to account for improper payments, pursuant to § 425.315(a), to strike a balance between improving the accuracy of the calculations and ACOs' and CMS' interest in administrative finality of payment determinations. In rulemaking for the Shared Savings Program during 2016, we considered factors for balancing the need to reopen and correct Shared Savings Program payment determinations with the need for administrative finality, which has implications for both ACOs and CMS (81 FR 5853 through 5858, and 81 FR 37997 through 38002). Some of these factors were discussed more generally, in the February 2016 proposed rule, with respect to our consideration of options for further developing our reopening policy (see, for example, 81 FR 5854 and 5855). We explained that an approach of correcting even very minor errors might result in significant operational burdens for ACOs and CMS, including multiple financial reconciliation re-runs and off-cycle payment/recoupment activities that could have the potential for significant and unintended operational consequences, and could jeopardize the certainty of performance results for both ACOs and CMS. We explained our concern that a relatively broad scope and extended timeframe for reopening could introduce financial uncertainty that could limit an ACO's ability to invest in additional improvements to increase quality and efficiency of care. This uncertainty could also limit an ACO's ability to get a clean opinion from its financial auditors and/or to obtain funds from lenders or investors.

We remain especially concerned about the potential for financial uncertainty resulting from a broad scope and extended timeframe for reopening for ACOs and CMS, particularly if correcting minor errors resulting from improper payments. We are concerned that reopening payment determinations for minor issues impacting calculations for one or several performance years of an ACO's earlier agreement period could in turn disrupt the administrative finality of calculations for multiple performances years, in one or more subsequent agreement period, if the impacted year(s) become benchmark year(s) used in resetting the ACO's historical benchmark. We also note that since an ACO's performance can vary from year to year (in terms of whether the ACO generates savings or losses and is eligible for shared savings or owes shared losses), it is possible for there to be a mixed effect across reopening payment determinations for multiple performance years. If the recalculation of financial performance identifies relatively small changes in the amount of shared savings or shared losses, it could be possible for these changes to balance out over a span of multiple performance years. This raises further questions about the utility of reopening payment determinations versus maintaining administrative finality of initial determinations.

A relatively straight-forward case would be to reopen a single performance year that we identify as having been impacted by improper payments. When a performance year for which we issue a revised initial determination becomes a benchmark year of an ACO's subsequent agreement period, whether we reopen an ACO's payment determination to account for the impact of improper payments in Shared Savings Program calculations would differ depending on whether or not we have issued an initial determination for a performance year of the ACO's subsequent agreement period. If the subsequent agreement period is the ACO's current agreement period, and CMS has not yet issued an initial determination for a performance year within the current agreement period, we would account for the impact of improper payments on future financial calculations pursuant to the proposed

[522] Refer to § 425.658 specifying calculation of the prior savings adjustment applicable to ACOs in agreement periods beginning on January 1, 2024, and in subsequent years. Refer to § 425.603(b)(2) specifying an additional adjustment is made to the historical benchmark to account for the average per capita amount of savings generated during the ACO's previous agreement period, implemented for renewing ACOs entering a second agreement period in 2016. See the discussion in the CY 2023 PFS final rule, in which we finalized the prior savings adjustment applicable for agreement periods beginning on January 1, 2024, and in subsequent years, and provided background on, and a description of, the prior savings adjustment that applied to certain ACOs in an earlier agreement period (87 FR 69898 through 69915).

benchmark adjustment specified in modifications to §§ 425.601(a)(9) and 425.652(a)(9). See section III.G.7.c.(2).(d) of this proposed rule for a discussion of our proposals related to modifying these provisions.

CMS' decision to reopen an initial determination for a performance year is independent of a determination by CMS to reopen an initial determination for any other performance year, including in cases where multiple performance years are impacted by the same improper payments, whether within the ACO's current agreement period, or a past agreement period. In these circumstances, we would need to potentially consider reopening initial determinations for multiple performance years, which may span multiple agreement periods, in cases where an ACO has continued its participation in the Shared Savings Program over time. Therefore, we are considering applying a combination of the following factors in determining whether to reopen an initial determination: (1) consideration of the timing of reopening and recalculating the payment determination for a performance year, and the timing of financial reconciliation for one or more performance year of a subsequent agreement period that includes the affected period as a benchmark year, and (2) consideration of whether the improper payments result from conduct of individuals or entities performing functions or services related to the ACO's activities.

Regarding the timing for reopening, we may consider whether a performance year that is being reopened corresponds to a benchmark year of an ACO's subsequent agreement period. We may consider whether we have completed financial reconciliation for a subsequent performance year, using a benchmark that is impacted by the same improper payments that were accounted for in reopening a payment determination for a performance year corresponding to a benchmark year.

We expect ACOs continuing their participation over multiple agreement periods in the Shared Savings Program have a heightened interest in administrative finality of payment determinations, which would provide greater financial certainty to the continued operation of ACOs and progress towards meeting the program's goals. In such cases, we believe (1) reopening payment determinations for a performance year to account for the impact of improper payments remains important to improving the accuracy of the Shared Savings Program's calculations, and (2) maintaining the administrative finality of subsequent payment determinations, if the same improper payments impact a benchmark year of an ACO's subsequent agreement period, could provide ACOs greater financial certainty with respect to their participation which may outweigh the benefits of reopening the calculations. Maintaining administrative finality of the payment determinations for these subsequent performance years may be warranted in cases where the improper payments are not a result of the conduct of individuals or entities within the ACO. On the other hand, in cases where improper payments impacting Shared Savings Program calculations results from conduct by individuals or entities within the ACO, CMS' interest in addressing program integrity concerns would warrant reopening all affected payment determinations. In these cases, if left unaddressed, ACOs, ACO participants and ACO providers/suppliers, among others, may have incentives to continue to engage in conduct, which could include fraud or similar fault, in a way that could improve the ACO's performance under the Shared Savings Program.

Although not expressly stated in § 425.315, we note that improper payments that are the basis of a reopening may result from the conduct of individuals or entities including but not limited to: (1) conduct of an ACO, ACO participant, ACO provider/supplier, ACO professional, or other individuals or entities performing functions or services related to the ACO's activities; or (2) conduct of a provider or supplier, or other individuals or entities outside the ACO. For purposes of the discussion within this section of this proposed rule, we refer to the former as improper payments originating ''inside the ACO'', and the latter as improper payments originating ''outside the ACO''.

To follow is a brief summary of the approach we are considering for differentiating between cases where improper payments originate inside the ACO versus outside the ACO. If we identify a single performance year for which we have issued an initial determination that has been impacted by improper payments, we would seek to reopen the payment determination if the improper payments originated either inside the ACO or outside the ACO.

When a performance year for which we issue a revised initial determination becomes a benchmark year of an ACO's subsequent agreement period, we would consider whether to reopen each initial determination for a subsequent performance year that is impacted. We are considering taking the following approach as one means to operate reopenings in an equitable and manageable manner:

- *In cases where improper payments originated outside the ACO:* Generally, we would not seek to reopen payment determinations for any performance year of the ACO's subsequent agreement period in order to mitigate the extent to which we disrupt the administrative finality of payment determinations for ACOs when the improper payments impacting Shared Savings Program calculations originate outside the ACO. However, we may consider reopening the initial determination for the performance year upon the ACO's request for a reopening if the improper payments are anticipated to result in significant adjustment to the ACO's initial determination upon recalculation.
- *In cases where improper payments originated inside the ACO:* As a means to address our program integrity concerns, we would reopen the payment determination for any performance year of the ACO's subsequent agreement period issued prior to the revised initial determination for the performance year corresponding to the benchmark year impacted by improper payments originating inside the ACO, if the improper payments are anticipated to result in significant adjustment to the ACO's initial determination upon recalculation. We believe this approach would guard against circumstances where an ACO may benefit from improper payments remaining in its benchmark calculations that result from conduct by individuals or entities performing functions or services related to the ACO's activities.

We seek comment on the factors we have described in this section of this proposed rule, that may inform our decision of whether to reopen an initial determination of an ACO's financial performance to account for the impact of improper payments. In particular, we seek comment on the approach we outlined for conducting initial analysis of whether the improper payments would warrant reopening the ACO's payment determination. We also seek comment on approaches to, and considerations in connection with, balancing the need for accuracy in payment calculations with the need for administrative finality in payment determinations.

(c) Methodology for Recalculating Expenditures To Account for Improper Payments

We propose to establish a financial calculation methodology that may be used to account for the impact of

improper payments on Shared Savings Program financial calculations, upon reopening a payment determination pursuant to § 425.315(a). We propose to add to subpart G a new section of the Shared Savings Program regulation at § 425.674 specifying provisions on accounting for the impact of improper payments on Shared Savings Program financial calculations.

As a general rule, we propose to specify in paragraph (a) of § 425.674, that upon the reopening of an initial determination pursuant to § 425.315(a)(4), CMS will use the methodology set forth in § 425.674 to account for the impact of improper payments when: (1) determining savings or losses for the relevant performance year in accordance with § 425.315 in order to issue a revised initial determination, and (2) adjusting the benchmark by recalculating benchmark year expenditures in the event that we recalculate a payment determination and issue a revised initial determination for the corresponding performance year in a prior agreement period (as discussed in section III.G.7.c.(2).(d) of this proposed rule).

We propose to specify in paragraph (b) of § 425.674 that for the purpose of the Shared Savings Program, ''improper payment'' includes: (1) an amount associated with a demanded overpayment determination, and (2) an amount identified in a settlement agreement or judgment, pursuant to conduct of individuals or entities performing functions or services related to an ACO's activities, less any penalties or damages.

We propose to establish a methodology under § 425.674 under which we would adjust Medicare Parts A and B FFS expenditure values used in certain Shared Savings Program financial calculations to account for a per capita amount of improper payments for an identified population used in calculating performance year or benchmark year expenditures, and in calculating county-level FFS expenditures used in factors based on regional expenditures.

We propose to specify under § 425.674 a generalized approach to calculating the per capita amounts of improper payments that accounts for the fact that improper payments may be associated with specific claims or line items, or may be aggregate amounts. A number of factors informed our consideration of this approach. For one, we considered the need to establish a calculation methodology to account for demanded overpayment determinations that result in adjustments to payment amounts associated with claims and line items used in Shared Savings Program calculations, such as the denial of claims or line items that occur after the 3-month claims run out period, or in an aggregate amount, such as based on extrapolated overpayment demands that do not result in adjustments to claim or line item payment amounts. Medicare Parts A and B FFS claim adjustments for overpayments would be reflected in current Shared Savings Program expenditure calculations if processed before the end of the 3-month claims run out period but are not included in calculations if processed after the 3-month claims run out period. Regarding the latter, the amounts of the claims adjusted overpayments can be identified for Medicare FFS beneficiaries, and can be aggregated across a population of Medicare FFS beneficiaries that is the basis for certain Shared Savings Program calculations. Additionally, aggregate amounts of demanded overpayment determinations, such as extrapolated overpayment demands, may be used to identify the amount of improper payments for a large set of claims for a particular provider or supplier and a certain time period, since error rates are extrapolated and applied to a universe of claims rather than individual claims. In these cases, an aggregate amount of a demanded overpayment determination is attributable to a provider or supplier and would have to be further prorated to determine its relevance to a particular population of Medicare FFS beneficiaries that is the basis for certain Shared Savings Program calculations.

Second, we considered the need for the calculation methodology to account for improper payments resulting from conduct by an ACO, ACO participant, ACO provider/supplier, ACO professional, or other individuals or entities performing functions or services related to the ACO's activities identified in certain settlements, or judgments. With respect to the Shared Savings Program calculations, we anticipate that a key focus would be on improper payments pursuant to conduct of individuals or entities performing functions or services related to an ACO's activities as identified in certain False Claims Act (31 U.S.C. 3729 *et seq.*) settlement agreements, or judgments. In considering the amount of improper payments that are relevant to Shared Savings Program calculations, we would exclude the amount of any penalties or damages included in the settlement or judgment. In addition, we may seek to attribute an aggregate improper payment amount to a provider or supplier that is specified within a settlement agreement, or judgment, across a population of Medicare FFS beneficiaries that is the basis for the applicable Shared Savings Program calculation.

Further, we anticipate there may be circumstances that warrant adjustment to payment amounts used in Shared Savings Program calculations, at the claims level, instead of or in addition to accounting for the amount of demanded overpayment determinations or an aggregate amount in a settlement agreement or judgment. For instance, in analyzing improper payments impacting Shared Savings Program calculations, we may conclude that a provider's or supplier's billings for a particular HCPCS or CPT code for a population of Medicare FFS beneficiaries resulted in inaccuracies in payment amounts used in Shared Savings Program calculations. We propose that we may address these circumstances by decreasing or entirely removing the value of HCPCS or CPT code payment amounts for certain claims or line items used in Shared Savings Program calculations, in reopening and recalculating the ACO's payment determination. We anticipate using all information available to us from an investigation, settlement agreement, or judgment to determine the correct payment amount or level of billing. This could include considering the nature of the remedy in the case and how any related amount would be applied in the proposed methodology to account for improper payments impacting Shared Savings Program financial calculations. In particular, we would consider if it would be a more precise adjustment to Shared Savings Program financial calculations to adjust the claim or line item payment amounts, instead of or in addition to accounting for the amount of demanded overpayment determinations or an aggregate amount in a settlement agreement or judgment (if applicable). For instance, in cases where an investigation, settlement agreement, or judgement has determined inaccurate use of a higher paying code [523] that is reflected in payment amounts used in Shared Savings Program calculations, we may identify use of a code with lower reimbursement within a HCPCS or CPT code category that would result

[523] See, for example, CMS, Medicare Claims Processing Manual Chapter 23—Fee Schedule Administration and Coding Requirements, section 20.9.5 ''Adjustments'', available at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c23.pdf* (explaining that if the wrong, higher paying code is paid on the first of multiple claims submitted, A/B MACs processing Medicare Part B claims pay the subsequent claim(s) and initiate recovery action on the previously paid claim(s)).

in a more precise adjustment to the ACO's payment determination.

We propose to specify in paragraphs (c) and (d) of § 425.674 the general approach for adjusting Medicare Parts A and B FFS expenditures for improper payments, according to the following steps:

• *Step 1—Identify calculation for adjustment:* Identify each Shared Savings Program expenditure calculation for a performance year or benchmark year, as calculated according to the standard methodology described in subpart G and expressed as a per capita dollar amount, that would be adjusted for the impact of improper payments (as proposed in § 425.674(c)(1)).

• *Step 2—Determine the relevant population for adjustment:* Determine each specific population of Medicare FFS beneficiaries used to calculate the expenditure amount identified in Step 1, expressed as person years (as proposed in § 425.674(c)(2)). The populations relevant for a specific expenditure calculation may include:

++ The population of beneficiaries assigned to the ACO for calculating the ACO's performance year or benchmark year expenditures.

++ The population of assignable beneficiaries in each county in the ACO's regional service area for calculating county-level expenditures.

++ The national population of assignable beneficiaries for calculating national assignable expenditures.

++ The national population of Medicare FFS beneficiaries for calculating national expenditures.

• *Step 3—Determine per capita amount of improper payments attributable to the relevant population:* Determine the per capita amount of improper payments for the performance year or benchmark year included in the per capita Medicare Parts A and B FFS expenditure amount for a population identified in Step 2 (as proposed in § 425.674(c)(3)). We may use one or more of the following approaches to determine the per capita amount of improper payments, for all providers or suppliers with improper payments, that would be used to adjust the expenditure calculations identified in Step 1 (as proposed in § 425.674(d)):

++ *Step 3(i):* Calculate aggregate improper payments attributable to a population identified in Step 2 for each provider or supplier that had improper payments.

--For improper payments associated with specific claims, we would do the following:

(A) For improper payments to a provider or supplier that correspond to payment amounts on claims or line items that were used in a Shared Savings Program calculation identified in Step 1, and subsequently adjusted after the 3-month claims run out period, we would sum the improper payment amounts across all such claims or line items with dates of service during the period used to calculate performance year or benchmark year expenditures, for a population identified in Step 2.

To allow for this approach, we propose to adjust Shared Savings Program expenditure calculations to reflect adjustments occurring after the original 3-month claims run out period for claim or line item payment amounts associated with improper payments. We would not capture payments or payment adjustments occurring outside the original 3-month claims run out period for claims or line items unrelated to improper payments.

(B) In the event that CMS determines it is necessary to account for the impact of improper payments on Shared Savings Program financial calculations by adjusting the payment amounts for a specific HCPCS or CPT code billed by the provider or supplier for the population identified in Step 2, we would do the following: identify the applicable claims or line items with dates of service during the period used to calculate performance year or benchmark year expenditures processed before the end of the applicable 3-month claims run out period, and sum the claim or line item payment amounts on the claims or line items identified; and if applicable, multiply the resulting sum by a scaling factor to compute the payment differential between the HCPCS or CPT code that was improperly billed and a CMS-identified alternate code. We would apply a scaling factor in cases where it is determined that the provider or supplier did not bill the correct code for a particular service. In cases where we determine it is appropriate to remove payments for the billed HCPCS or CPT code in their entirety, we would not apply a scaling factor.

--For aggregate improper payment amounts that are not linked to specific claims or line items, we would calculate the amount attributable to the population identified in Step 2 by applying a proration factor to the aggregate improper payment amount identified for that provider or supplier. We would calculate the proration factor as follows:

(A) The denominator of the proration factor would be total Medicare Parts A and B claim or line item payment amounts to the provider or supplier for all FFS beneficiaries on claims of specified claim types for the time period associated with the aggregate improper payment amount identified for the provider or supplier that were made before the end of the applicable 3-month claims run out period.

(B) The numerator of the proration factor would be the portion of the total from the denominator that CMS determines is attributable to the population identified in Step 2 with dates of service during the period used to calculate expenditures for the applicable performance year or benchmark year.

Under this proposed approach, if an aggregate amount of improper payment is associated with claims activity that spans multiple calendar years, we would account for this in the proration factor by expanding the time period used to compute payments for the denominator to include the relevant years. For example, if the aggregate amount of improper payments was associated with claims activity in 2021 and 2022, we would include in the denominator payments on claims or line items with dates of service in 2021 (made before the end of March 2022) and on claims or line items with dates of service in 2022 (made before the end of March 2023). If we were adjusting PY 2022 expenditures for an ACO's assigned population, the numerator of the proration factor would be the portion of the denominator that is attributable to the ACO's assigned population during CY 2022.

++ *Step 3(ii):* Sum the amounts calculated under Step 3(i) attributable to the population identified in Step 2 across providers or suppliers that had identified improper payments.

++ *Step 3(iii):* Take the lesser of the following two values:

--The sum from Step 3(ii); or

--Total Medicare Parts A and B claim or line item payment amounts to all providers or suppliers that had improper payments for the population identified in Step 2 on claims of specified claim types with dates of service within the performance year or benchmark year made before the end of the applicable 3-month claims run out period.

The purpose of taking the lesser of two values in this step is to ensure that the improper payment amount that we attribute to a given population cannot be greater than the total amount of payments for the providers or suppliers at issue that was included in the original expenditure calculation for that population.

++ *Step 3(iv):* Express the lesser-of-amount from Step 3(iii) as a per capita value by dividing by the total

beneficiary person years in the population identified in Step 2 for the applicable performance year or the benchmark year.

- *Step 4—Subtract per capita improper payment amount from original expenditures:* From the expenditure calculation identified in Step 1 for the population identified in Step 2, subtract the per capita amount calculated in Step 3(iv) for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries (as proposed in § 425.674(c)(4)).
- *Step 5—Determine adjusted regional expenditures:* If applicable, we would do the following to adjust regional expenditures for improper payments (as proposed in § 425.674(c)(5)):

++ *Step 5(i):* Adjust county-level FFS expenditures determined in Step 4, for each county in the ACO's regional service area, for severity and case mix of assignable beneficiaries in the county using prospective HCC risk scores. This calculation would be for each of the following populations of beneficiaries based on Medicare enrollment type: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. We note that under this approach CMS would not adjust the risk scores used to calculate risk adjusted county-level FFS expenditures.

++ *Step 5(ii):* Weight the risk-adjusted county-level FFS expenditures determined in Step 5(i) according to the ACO's proportion of assigned beneficiaries in the county, determined in accordance with § 425.601(d)(1), § 425.603(f)(1), or § 425.654(b)(1), as applicable, for each of the populations of beneficiaries by Medicare enrollment type.

++ *Step 5(iii):* Aggregate the values determined in Step 5(ii) for each of the populations of beneficiaries (by Medicare enrollment type) across all counties within the ACO's regional service area.

To illustrate how the proposed calculation methodology would be applied, we can consider the following hypothetical example in which CMS confirmed that two suppliers, NPI 1 and NPI 2, received improper payments from Medicare during calendar year 2022. Specifically, CMS identified $8 million in demanded overpayment determinations for NPI 1 which resulted in CMS adjusting payment amounts after the 3-month claims run out period for PY 2022 on claims or line items with dates of service during the performance year, and CMS identified an aggregate extrapolated overpayment demand amount of $30 million for NPI 2. Assume that in this example, CMS determines that reopening the ACO's PY 2022 initial determination is warranted, and CMS recalculates that ACO's financial performance using the proposed methodology to account for improper payments. To recalculate the ACO's financial performance for PY 2022, we would identify three separate expenditure calculations that need to be recalculated to determine the impact on an ACO's earned performance payment or owed shared losses: (1) PY 2022 expenditures for the ACO's assigned beneficiaries; (2) PY 2022 expenditures for assignable beneficiaries in the ACO's regional service area; and (3) PY 2022 expenditures for national assignable beneficiaries. For this example, in Table 41 we outline the steps and calculations for recalculating expenditures for beneficiaries assigned to the ACO for PY 2022. In Table 42 we outline how PY 2022 expenditures for assignable beneficiaries in the ACO's regional service area and PY 2022 expenditures for national assignable beneficiaries, recalculated to account for improper payments, would be incorporated into the blended national-regional benchmark update factor. In Table 43 we outline how an ACO's financial performance may be recalculated after accounting for improper payments in PY 2022 expenditures for the ACO's assigned beneficiaries, and using the recalculated blended national-regional benchmark update factor.

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TABLE 41: Hypothetical Example of Steps for Recalculating ACO Assigned Beneficiary Expenditures Using Proposed Methodology to Account for Improper Payments

	Amount
Steps 1 and 2: Identify calculation and relevant population for adjustment	
ACO PY assigned beneficiary expenditures by enrollment type (per capita) [A]	
ESRD	$80,000
Disabled	$11,000
Aged/dual	$15,000
Aged/non-dual	$12,000
ACO PY total assigned beneficiary person years [B]	20,000
Step 3: Determine per capita amount of improper payments attributable to the relevant population	
Aggregate improper payments attributable to the ACO's assigned beneficiaries for NPI 1 (identified at the claim or line item level)	
Total aggregate improper payments for NPI 1 [C]	$8,000,000
Aggregate improper payments for NPI 1 attributable to the ACO's assigned beneficiaries [D]	$200,000
Aggregate improper payments attributable to the ACO's assigned beneficiaries for NPI 2 (identified at the NPI level)	
Total aggregate improper payments for NPI 2 [E]	$30,000,000
Total Medicare Parts A and B claim or line item payment amounts to NPI 2 for the ACO's assigned beneficiaries for PY (a portion of row [G]) [F]	$4,800,000
Total Medicare Parts A and B claim or line item payment amounts to NPI 2 for all Medicare FFS beneficiaries, on claims of specified claim types for the time period associated with improper payment amount, made before the end of the 3-month claims run out period for PY [G]	$80,000,000
Proration factor [H] = [F] / [G]	0.06
Aggregate improper payments attributable to the ACO's assigned beneficiaries [I] = [E] x [H]	$1,800,000
Sum of improper payments attributable to the ACO's assigned beneficiaries for NPI 1 and NPI 2 [J] = [D] + [I]	$2,000,000
Total Medicare Parts A and B claim or line item payment amounts to NPI 1 and NPI 2 for the ACO's assigned beneficiaries made before the end of the 3-month claims run out period for PY [K]	$5,200,000
Total aggregate improper payments attributable to the ACO's assigned beneficiaries [L] = Lesser of [J] and [K]	$2,000,000
Per capita improper payments attributable to the ACO's assigned beneficiaries [M] = [L] / [B]	$100
Step 4: Subtract per capita improper payment amount from original expenditures	
Adjusted ACO PY assigned beneficiary expenditures by enrollment type (per capita) [N] = [A] – [M]	
ESRD	$79,900
Disabled	$10,900
Aged/dual	$14,900
Aged/non-dual	$11,900

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In Step 1, we identify expenditures for the ACO's assigned beneficiaries in PY 2022 as the calculation to be recalculated. In Step 2, we identify the ACO's assigned beneficiaries in PY 2022 as the population relevant for this expenditure calculation. In Step 3, we determine the per capita amount of improper payments that is attributable to the ACO's assigned beneficiaries. For NPI 1, we identify that $200,000 of the NPI's total aggregate improper payments were on claims for the ACO's assigned beneficiaries (row [D]). Because improper payments for NPI 2 were identified at the NPI level and thus are not tied to individual claims, we need to apply a proration factor to calculate the share of the total aggregate improper payments, $30 million (row [E]), that is attributable to the ACO's assigned beneficiaries. We calculate this proration factor as the total Medicare Parts A and B claim or line item payment amounts made to NPI 2 for the ACO's assigned beneficiaries for PY 2022 ($4.8 million, row [F]), divided by the total Medicare Parts A and B claim or line item payment amounts made to NPI 2 for all Medicare FFS beneficiaries ($80 million, row [G]); this results in a proration factor of 0.06 (row [H]), which when applied to NPI 2's total aggregate improper payments results in $1.8 million in aggregate improper payments attributable to the ACO's assigned beneficiaries (row [I]). Summing across NPI 1 and NPI 2, we calculate $2 million in total aggregate improper payments attributable to the ACO's assigned beneficiaries for PY 2022 (row

[J]). We then compare this sum (row [J]) with total Medicare Parts A and B claim or line item payment amounts to the two suppliers for the ACO's assigned beneficiaries for PY 2022 (row [K]) and take the lesser of the two values (row [L]). We then express this lesser-of value in per capita terms by dividing by the ACO's total assigned beneficiary person years for PY 2022, 20,000, arriving at a $100 per capita improper payment amount attributable to the ACO's assigned beneficiaries (row [M]). Finally, in Step 4, we subtract the $100 per capita improper payment amount from the original PY 2022 per capita expenditure amount for the ACO's assigned beneficiaries used to make the initial payment determination, conducting this adjustment by enrollment type (row [N]).

We note that subtracting the same per capita improper payment amount ($100 in this example) from the expenditure calculation for each enrollment type population implicitly assumes that improper payments attributable to the overall population are distributed in proportion to the four enrollment types (ESRD, disabled, aged/dual eligible, aged/non-dual eligible). For example, if the aged/non-dual eligible population represents 82 percent of an ACO's overall assigned population for the performance year, we are assuming that 82 percent of improper payments attributable to the ACO's entire assigned population are associated with aged/non-dual eligible beneficiaries. We believe that this is a reasonable assumption as we expect that, in most cases, improper payments are unlikely to be associated with a particular enrollment type as defined by the Shared Savings Program and used in program financial calculations.[524] This also allows for a standard approach across the potential variety of reopening scenarios, lending greater transparency and simplicity to the proposed methodology.

We would follow the same overall methodology to account for the impact of improper payments in recalculating PY 2022 expenditures for assignable beneficiaries in the ACO's regional service area and for national assignable beneficiaries. These amounts are calculated for the following populations of beneficiaries, by Medicare enrollment type: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. We would then use these adjusted expenditure calculations as new inputs along with other original calculations that were not adjusted for the impact of improper payments (such as the ACO's historical benchmark for PY 2022) to recalculate the ACO's financial performance for PY 2022, following the standard financial methodology described in § 425.605 (for ACOs participating in the BASIC track) or § 425.610 (for ACOs participating in the ENHANCED track), as applicable.

In Table 42, we expand upon the hypothetical example described in Table 41 and summarize how we would calculate national and regional update factors following the methodology specified in § 425.652(b)(2) but using the adjusted regional and national expenditures for the performance year for each enrollment type in place of the original values. Because benchmark update factors are calculated by enrollment type under the standard financial methodology, they would also be recalculated by enrollment type when using the adjusted national and regional expenditures. However, for brevity, we describe only the recalculation of the update factors for the aged/non-dual eligible population in Table 42.

In this continued hypothetical example, we used the proposed methodology to account for the impact of improper payments in recalculating national and regional per capita expenditures in the performance year, resulting in adjusted expenditures of $11,609 (row [A]) and $11,210 (row [C]), respectively. Dividing these PY values by the original BY3 national and regional per capita expenditures ($10,977, row [A], and $10,900, row [C], respectively), we recalculate the national update factor (1.058, row [B]) and regional update factor (1.028, row [D]). In this example, there is a $1 difference between the original and recalculated national per capita expenditure amount. The resulting value for the recalculated national update factor, shown rounded to the third decimal place, remains the same as the original value, but there would be a difference in the values if additional precision was shown. We then blend these adjusted update factors using the original national and regional weights (0.250, row [E], and 0.750, row [F], respectively). As shown in row [G], accounting for improper payments in PY 2022 causes the blended benchmark update factor to decrease from 1.042 to 1.036.

TABLE 42: Hypothetical Example of How the Blended National-Regional Benchmark Update Factor for the Aged/Non-Dual Eligible Enrollment Type May Be Recalculated After Accounting for Improper Payments

	BY3	PY (Original)	PY (Adjusted)
National per capita expenditures [A]	$10,977	$11,610	$11,609
National update factor [B] = $[A]_{PY}$ / $[A]_{BY3}$		1.058	1.058
Regional per capita expenditures [C]	$10,900	$11,300	$11,210
Regional update factor [D] = $[C]_{PY}$ / $[C]_{BY3}$		1.037	1.028
National weight [E]		0.250	0.250
Regional weight [F]		0.750	0.750
National-regional blended update factor [G] = [B] x [E] + [D] x [F]		1.042	1.036

Table 43 summarizes how recalculated blended update factor to account for improper payments, based on adjusted national and regional expenditures for PY 2022, would be used with other original calculations

[524] For criteria used to identify the four Medicare enrollment types, refer to the Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (version #11, January 2023), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2* (Appendix E: Identifying Medicare Enrollment Type).

and adjusted PY expenditures for ACO assigned beneficiaries to recalculate the ACO's financial performance for PY 2022. Applying the blended update factor (row [B]) to the original historical benchmark values by enrollment type (row [A]), we recalculate the updated benchmark values by enrollment type (row [C]) that account for improper payments occurring in PY 2022. The adjusted updated benchmark values (row [C]) and adjusted PY expenditures for ACO assigned beneficiaries by enrollment type (row [D]), also described in Table 41, are multiplied by original PY assigned beneficiary proportions by enrollment type (row [E]), and summed across enrollment types to recalculate the per capita updated benchmark (row [F]) and per capita ACO PY assigned beneficiary expenditures (row [G]). We then express these per capita quantities as the total updated benchmark amount (row [I]) and the total ACO PY assigned beneficiary expenditures amount (row [J]) by multiplying the per capita dollar amount by the ACO's total assigned beneficiary person years for PY 2022 (row [H]). The recalculated total updated benchmark (row [I]) can then be used to recalculate the minimum savings rate/minimum loss rate dollar threshold (row [L]). We subtract the recalculated total ACO PY assigned beneficiary expenditures (row [J]) from the recalculated total updated benchmark (row [I]) to determine if the ACO has gross savings or gross losses. Under this example, the recalculation indicates the ACO has total gross savings (row [K]). Finally, because the recalculated total gross savings (row [K]) is greater than the recalculated minimum savings rate dollar threshold, we recalculate the ACO's shared savings (row [N]) by multiplying the total gross savings (row [K]) by the original sharing rate (row [M]).

The result of these calculations is an adjusted shared savings amount of $17,355,000 (before accounting for sequestration), compared to an original amount of $16,950,000. Thus, while adjustments for improper payments reduced the ACO's PY assigned beneficiary expenditures by $2 million, the impact on the ACO's recalculated shared savings is only $405,000 due to the impact of improper payments on the expenditures for assignable beneficiaries that factor into the ACO's recalculated updated benchmark for PY 2022.

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TABLE 43: Hypothetical Example of How an ACO's Financial Performance May Be Recalculated After Accounting for Improper Payments

	Original	Adjusted	Adjusted Minus Original
Historical benchmark by enrollment type (risk adjusted, per capita) [A]			
ESRD	$89,200		
Disabled	$12,700		
Aged/dual	$17,700		
Aged/non-dual	$12,200		
National-regional blended update factor by enrollment type [B]			
ESRD	1.007	1.006	-0.001
Disabled	1.028	1.022	-0.006
Aged/dual	1.043	1.039	-0.004
Aged/non-dual	1.042	1.036	-0.006
Updated benchmark by enrollment type (per capita) [C] = [A] x [B]			
ESRD	$89,824	$89,735	-$89
Disabled	$13,056	$12,979	-$77
Aged/dual	$18,461	$18,390	-$71
Aged/non-dual	$12,712	$12,639	-$73
ACO PY assigned beneficiary expenditures by enrollment type (per capita) [D]			
ESRD	$80,000	$79,900	-$100
Disabled	$11,000	$10,900	-$100
Aged/dual	$15,000	$14,900	-$100
Aged/non-dual	$12,000	$11,900	-$100
ACO PY assigned beneficiary proportions by enrollment type [E]			
ESRD	0.010		
Disabled	0.100		
Aged/dual	0.070		
Aged/non-dual	0.820		
Updated benchmark (per capita) [F] = Sum of [C] x [E]	$13,920	$13,847	-$73
ACO PY assigned beneficiary expenditures (per capita) [G] = Sum of [D] x [E]	$12,790	$12,690	-$100
ACO PY total assigned beneficiary person years [H]	20,000		
Total updated benchmark [I] = [F] x [H]	$278,400,000	$276,940,000	-$1,460,000
Total ACO PY assigned beneficiary expenditures [J] = [G] x [H]	$255,800,000	$253,800,000	-$2,000,000
Total updated benchmark expenditures minus Total ACO PY assigned beneficiary expenditures [K] = [I] – [J] (example showing gross savings)	$22,600,000	$23,140,000	$540,000
Minimum savings rate / Minimum loss rate in dollars [L] = 0.02 x [I]	$5,568,000	$5,538,800	-$29,200
Sharing rate [M]	75%		
Shared savings [N] = [K] x [M]	$16,950,000	$17,355,000	$405,000

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Under the proposed financial methodology, accounting for the impact of improper payments on expenditures could increase or decrease an ACO's amount of shared savings or shared losses. As demonstrated in the hypothetical example, the direction of changes to an ACO's shared savings or shared losses would depend on the differential impact of improper payments on the ACO's assigned beneficiary expenditures compared to the impact on expenditures for assignable beneficiaries used to determine the national and regional updates to the ACO's benchmark. In this example, the reduction in ACO PY assigned beneficiary expenditures due to the adjustment for improper payments was larger than the reduction to the updated benchmark stemming from adjustments to PY national and regional expenditures, ultimately

causing the ACO to see an increase in both gross savings and shared savings. Other ACOs for which the reduction in ACO PY assigned beneficiary expenditures is greater than the reduction to the updated benchmark, may switch from earning no shared savings to earning shared savings or may see a reduction in shared losses owed. However, if accounting for improper payments results in relatively larger reductions to the expenditures for assignable beneficiaries in the ACO's regional service area or in the national assignable population, and relatively smaller reductions to the ACO's PY assigned beneficiary expenditures, the ACO might observe a reduction in shared savings or increase in shared losses, or potentially cause the ACO to switch from earning shared savings to not earning any shared savings or to owing shared losses.

As we propose in section III.G.7.c.(2).(d) of this proposed rule, if the reopened PY becomes a BY for a subsequent agreement period, CMS would adjust the historical benchmark to be used for any PY in that subsequent agreement period that has not yet been reconciled. Accounting for improper payments as it affects the ACO's benchmark could then result in changes to the ACO's shared savings or shared losses for a future performance year that differ in direction compared to the change in shared savings or shared losses observed with the initial reopening that affected PY expenditures. That is, following the example from Table 43, accounting for improper payments occurring in calendar year 2022 might result in the ACO earning greater shared savings (or smaller shared losses) for PY 2022 (because the reduction in ACO PY assigned beneficiary expenditures outweighs the reduction in national and regional expenditures used to update the benchmark), but may result in smaller shared savings (or greater shared losses) for future performance years for which CY 2022 becomes a benchmark year (because the adjustment for improper payments in BY 2022 causes a reduction in the overall benchmark with no corresponding reduction to ACO PY expenditures).

As we described in section III.G.7.c.(2).(b) of this proposed rule, administrative action and judicial action leading to the identification of improper payments may be subject to appeal, and ultimately the amount of the improper payments may be redetermined or otherwise amended. We acknowledge the potential inaccuracy in using amounts of improper payments that may be reversed, in whole or in part, in recalculating an ACO's financial performance. However, waiting for each possible appeal to be raised and resolved with respect to improper payments could delay our ability to reach a determination of whether to reopen an ACO's payment determination, identify the amounts of improper payments to be used in the recalculation, or both. We considered whether to account for the possibility that the improper payment amounts would be appealed, and the amount redetermined, as part the proposed methodology, but are not proposing a related approach at this time. For instance, we considered whether to apply an adjustment factor as part of the methodology, that would reduce the amount of improper payments by a percentage, to account for the rate at which the amounts could change, and to base this rate on statistics gathered on the outcomes of Medicare Parts A and B administrative appeals processes. Given that the proposed approach, if finalized, would be the initial use of improper payment amounts in Shared Savings Program calculation, we note our intent to monitor for the impact of appeals on the amounts of improper payments that may be used in reopenings under the Shared Savings Program. We may revisit our approach in future notice and comment rulemaking, after we gain additional experience with using improper payment amounts in Shared Savings Program calculations.

We propose to use our authority under section 1899(d)(1)(B)(ii) of the Act to calculate benchmark year expenditures using the proposed methodology to account for the impact of improper payments. This provision authorizes the Secretary to adjust the benchmark for beneficiary characteristics and ''such other factors as the Secretary determines appropriate''. When reopening an initial determination for a performance year pursuant to § 425.315, we consider it appropriate to account for the impact of improper payments on expenditures used to establish the ACO's historical benchmark, consistent with our proposal.

We propose to use our authority under section 1899(i)(3) of the Act to use the proposed methodology to account for the impact of improper payments in calculating performance year expenditures and calculating the historical benchmark update factors. CMS may only adopt an alternative payment methodology pursuant to section 1899(i)(3) of the Act if we determine that the alternative payment methodology will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without resulting in additional program expenditures.

The proposed adjustments would remove improper payments from the performance year expenditures and factors used to calculate updated historical benchmarks, among other financial calculations, that resulted in inaccuracies in an ACO's payment determination, including the amount of shared savings CMS paid an ACO or the amount of shared losses owed to CMS by an ACO participating under a two-sided model. These policies improve the accuracy of financial calculations by which ACOs are held accountable for the cost and quality of care for their assigned beneficiary populations.

Addressing the impact of improper payments on ACO payment determinations could serve as a mechanism to bolster program integrity. ACO accountability for the total cost of care can deter fraud, waste, and abuse that is otherwise under the control of ACO participants. Additionally, ACOs have unique insight into Medicare Part A, B, and D claims data for their assigned beneficiary populations from monthly claim and claim line level data ACOs receive from CMS for care coordination and quality improvement. This vantage point makes ACOs uniquely situated to observe trends in expenditures and utilization patterns, including by providers and suppliers that are not participating in the ACO. Further establishing policies to specify the approach to excluding improper payments from Shared Savings Program calculations could encourage ACOs to report to CMS and the Department of Health and Human Services Office of Inspector General (HHS–OIG) potential fraud and abuse within the Medicare program. Addressing improper payments in the Medicare program would protect the accuracy, fairness, and integrity of Shared Savings Program financial calculations, and lead to greater beneficiary protections, and protection of the Trust Funds.

Accounting for the impact of improper payments in financial calculations promotes continued integrity and fairness of Shared Savings Program payment determinations and may in turn bolster ACO participation in the Shared Savings Program. Policies that improve the accuracy of the payment calculations could provide greater certainty to organizations considering entering or continuing their participation in the Shared Savings Program and thereby lead to more robust and sustained participation by ACOs in the Shared Savings Program.

This, in turn, means that these organizations would continue working towards meeting the Shared Savings Program's goals of lowering growth in Medicare FFS expenditures and improving the quality of care furnished to Medicare beneficiaries.

As described in the Regulatory Impact Analysis (section VII. of this proposed rule), we believe accounting for the impact of improper payments on performance year expenditures and factors used to calculate updated historical benchmarks would not result in an increase in spending beyond the expenditures that would otherwise occur under the statutory payment methodology in section 1899(d) of the Act. As we also discuss elsewhere in this section of this proposed rule, across an ACO's reconciliations where improper payments impact performance year or BY expenditures, the overall net impact of using the proposed methodology on the ACO's aggregate shared savings or shared losses across those reconciliations could be positive or negative and would depend on the circumstances of a given reopening scenario.

We will continue to reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. In the event that we later determine that the payment model established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

(d) Adjusting Historical Benchmarks To Account for the Impact of Improper Payments

CMS adjusts an ACO's historical benchmark annually, during the term of the ACO's agreement period, to account for certain changes, as specified in the Shared Savings Program regulations. The related adjustment is specified under § 425.601(a)(9), for the benchmarking methodology applicable to agreement periods beginning on or after July 1, 2019, and before January 1, 2024, and under § 425.652(a)(9), for the benchmarking methodology applicable to agreement periods beginning on January 1, 2024, and in subsequent years. As finalized with the CY 2024 PFS final rule (88 FR 79195 through 79200), § 425.652(a)(9) introductory text was amended to specify, among other changes, that for each performance year during the term of the agreement period, the ACO's benchmark is adjusted for changes in values used in benchmark calculations as a result of issuance of a revised initial determination under § 425.315 (among other factors). Similar language is not currently included in § 425.601(a)(9) introductory text.

We propose to use our authority under section 1899(d)(1)(B)(ii) of the Act to adjust the benchmark to account for the impact of improper payments, in the event CMS recalculates a payment determination and issues a revised initial determination for a performance year in a prior agreement period that corresponds to a benchmark year of the ACO's current agreement period. We propose to adjust an ACO's historical benchmark for use in reaching an initial determination of financial performance for a performance year, in cases where an ACO has a benchmark year that corresponds to a performance year for which we issued a revised initial determination. In such a case, we would apply the same methodology to recalculate the ACO's BY expenditures as used in recalculating the expenditures for the corresponding performance year, as part of a reopening. Under this proposed approach, we would be able to improve the accuracy of the benchmark year calculations used in reaching an initial determination for a performance year, by addressing the impact of previously identified improper payments on the expenditure calculations. Such an adjustment to the benchmark expenditures would appropriately calculate the ACO's historical benchmark that might otherwise be under- or over-stated due to improper payments.

Expanding upon the example illustrated in Table 43, if we have issued a revised initial determination for PY 2022 in December 2025, for an ACO that renewed to continue its participation under a new agreement period beginning on January 1, 2025, our proposed policy would enable us to use the same methodology for calculating BY 2022 expenditures for PY 2025, in reaching the initial determination for PY 2025.

We propose to amend §§ 425.601(a)(9) and 425.652(a)(9) to specify this proposed adjustment to the historical benchmark. We propose to revise § 425.601(a)(9) introductory text to further specify that for the second and each subsequent performance year during the term of the agreement period, the ACO's benchmark would be adjusted for changes in values used in benchmark calculations as a result of issuance of a revised initial determination under § 425.315. We also propose to add a new paragraph (a)(9)(iii) to § 425.601 and to add a new paragraph (a)(9)(viii) to § 425.652, each specifying that we would recalculate benchmark year expenditures to account for the impact of improper payments, for the benchmark year corresponding to a performance year for which CMS issued a revised initial determination under § 425.315. In recalculating expenditures for the benchmark year, CMS would apply the same calculation methodology applied in recalculating expenditures for the corresponding performance year, in accordance with the proposed new section of the regulation at § 425.674.

(e) ACO Reopening Requests

The following discussion of requesting and conducting a reopening pertains to reopening a payment determination for good cause or for fraud or similar fault, unless specified otherwise.

We propose to establish a process at § 425.315(b) by which an ACO may request a reopening of an initial determination, or a final agency determination under subpart I, of shared savings or shared losses. Although an ACO's submission of a reopening request is optional, we propose to require that the ACO's request be in a form and manner specified by CMS. Further, we propose that the timing of the ACO's reopening request must be consistent with the timeframes specified in § 425.315(a)(1)(i) and (ii), respectively, either (i) at any time in the case of fraud or similar fault, or (ii) not later than 4 years after the date of the notification to the ACO of the initial determination of savings or losses for the relevant performance year for good cause. We anticipate providing additional information on the reopening request process for ACOs through guidance, including the form and manner in which CMS must receive a reopening request.

CMS will need to receive sufficient, detailed information from ACOs to evaluate an ACO's reopening request. For instance, in the case of a reopening request in connection with improper payments, or fraud or similar fault potentially impacting the ACO's financial calculations, receiving detailed information about the issue, including the following information, would aid in our analysis of the ACO's request:

- ACO identifier(s) (also referred to as ''ACO ID'') and Legal Business Name(s).
- Identity of the provider or supplier for which there may be improper payment(s), or that may be suspected of fraud or similar fault, including name,

NPI or Provider Transaction Access Number (PTAN), TIN, or other identifier.

- Time period during which potentially impacted claims were submitted or improper conduct occurred.
- Short description of the improper payment, alleged fraud or similar fault, and how it was identified, including information such as any specific claim type codes and HCPCS or CPT codes.
- Evidence of financial impact on the ACO's shared savings or shared losses calculation, such as any analysis supporting the calculation of financial impact to the ACO and a list of beneficiaries assigned to the ACO for whom claims were submitted by the provider or supplier suspected of fraud or similar fault, or for which expenditures may be impacted by improper payments.

As we describe elsewhere in this section of this proposed rule, a recalculation of shared savings and shared losses to account for improper payments could result in a variety of outcomes. An ACO should weigh these potential outcomes when considering whether to submit a reopening request.

We acknowledge that the proposed process for requesting a reopening, whether for good cause or for fraud or similar fault, would represent a new process. Therefore, we seek comments and suggestions on the form and manner in which CMS should receive these requests. We also seek comment on approaches to ensuring that ACOs submit reopening requests with sufficient information to allow CMS to identify and evaluate the impact on Shared Savings Program financial performance.

The following steps illustrate how we may conduct review of an ACO's request to reopen a payment determination to account for the impact of improper payments:

- Upon receiving an ACO's reopening request, CMS would evaluate this request, and ask the requesting ACO to provide supplemental information if needed.
- We would work with CPI and law enforcement agencies to identify, validate and quantify improper payments potentially impacting expenditures used in program calculations. We note that identification of improper payments may be contingent on the conclusion of an investigation that is underway.
- We may conduct initial analysis to consider the basis for reopening the ACO's payment determination under § 425.315(a), and the significance of the improper payments to an ACO's financial calculations under the Shared Savings Program (as described in section III.G.7.c.(2).(b) of this proposed rule):

++ If we find that the potential improper payment does not meet CMS' standards for reopening the payment determination, we anticipate notifying the ACO of our decision.

++ If we reach a determination to reopen the ACO's payment determination for a performance year:

—We would recalculate expenditures to account for improper payments using the methodology proposed in section III.G.7.c.(2).(c) of this proposed rule, recalculate the ACO's shared savings and shared losses, issue a revised initial determination, and engage in payment activities and recoupment activities, as needed.

—During the recalculation period CMS would also identify whether the relevant performance year is also serving as a benchmark year for the ACO's current agreement period and prepare to adjust the ACO's benchmark year expenditures to account for the revised initial determination (once issued), as discussed in section III.G.7.c.(2).(d) of this proposed rule.

In the event that improper payments identified in analyzing an ACO's reopening request have the potential to impact the payment determinations of one or more other ACOs, we anticipate only determining whether to reopen the payment determination for an ACO that submitted the reopening request. More generally, we may initiate analysis of the impact of improper payments on Shared Savings Program financial calculations, and potentially reopen the payment determination for one or more ACOs absent an ACO's request for reopening. For instance, in learning of improper payments that may potentially impact Shared Savings Program calculations for multiple ACOs, including through the reopening request process, we may seek to reopen payment determinations where improper payments are anticipated to result in significant adjustments to ACOs' initial determinations upon recalculation. We also anticipate initiating analysis of the impact of improper payments on an ACO's payment determination upon learning of improper payments originating inside the ACO that may potentially impact Shared Savings Program calculations, and may reopen the ACO's payment determination, as needed, to address program integrity concerns.

We anticipate that our review and analysis of reopening requests could occur over a protracted period of time during which we may be able to provide little additional information to the ACO until we have reached our decision. We would aim to conduct a reopening such that the timing of any issuance of a revised initial determination aligns with the timeframe for when CMS typically completes annual performance year financial reconciliation and payment and recoupment. However, because investigations into improper payments, including considering whether there is reliable evidence of fraud or similar fault, may involve varying degrees of complexity and scale, and because the application of our proposed methodology for calculating expenditures relies on information that may result from such investigations, among other sources of information, CMS may not always be able to conduct a reopening within a specific timeframe after an ACO submits a reopening request. As reflected in the discussions within this section of this proposed rule, the process for analyzing an ACO's reopening request, reaching a decision on whether to reopen the initial determination, recalculating the ACO's payment determination, and issuing a revised initial determination, may occur over a period of months or potentially years, and may have impacts on future agreement periods. In cases where CMS and law enforcement officials may have investigations underway, CMS must refrain from providing details to ACOs, and other individuals or entities, of pending actions to protect the integrity of those investigations. Therefore, we may be limited in the information we can communicate to an ACO about our consideration of the ACO's reopening request.

We seek comment on the aforementioned considerations for how we could conduct review of an ACO's request to reopen a payment determination to account for the impact of improper payments. More generally, as we gain additional experience with ACOs' submission of reopening requests, including the volume of the requests, and nature of the requests, we may revisit the reopening request process, as needed, in future notice and comment rulemaking.

(f) Preventing and Reporting Medicare Fraud

ACOs can help prevent fraud and abuse within the Medicare program or in other Federal health care programs. Program integrity requirements for the Shared Savings Program include the requirement under § 425.300 that the ACO must have a compliance plan. Among other required elements, an ACO's compliance plan must include a method for employees or contractors of

the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to anonymously report suspected problems related to the ACO to the compliance officer (§ 425.300(a)(3)). ACOs' compliance plans must also include a requirement for the ACO to report probable violations of law to an appropriate law enforcement agency (§ 425.300(a)(5)). (Refer to the November 2011 final rule, 76 FR 67951 and 67952.)

ACOs are encouraged to report potential fraud or abuse by submitting a complaint to the CMS Center for Program Integrity (CPI), Fraud Investigations Group (FIG), Division of Provider Investigations (DPI) at *dpi.intake@cms.hhs.gov*. ACOs can also report potential fraud or abuse by submitting a complaint to the HHS–OIG website, *https://oig.hhs.gov/fraud/report-fraud/*, HHS–OIG hotline at 1–800–HHS–TIPS (1–800–447–8477), TTY at 1–800–377–4950, by fax at 1–800–223–8164, or by mailing to: Office of Inspector General ATTN: OIG HOTLINE OPERATIONS P.O. Box 23489 Washington, DC 20026. ACOs suspecting healthcare fraud, waste, or abuse are encouraged to visit the CMS Center for Program Integrity's web page on Reporting Fraud, at *https://www.cms.gov/medicare/medicaid-coordination/center-program-integrity/reporting-fraud* for more information. More generally, anyone suspecting healthcare fraud, waste or abuse is encouraged to report it to CMS or HHS–OIG.

In the absence of a reopening request submitted by an ACO in the form and manner specified by CMS, as discussed in section III.G.7.c.(2).(e) of this proposed rule, the reporting of potential fraud or abuse to CPI or HHS–OIG does not itself constitute a reopening request under the Shared Savings Program.

We seek comment on the proposals, and considerations, described in this section of this proposed rule, including: considerations for reopening a payment determination to account for improper payments; the proposed changes to the regulations to specify (1) CMS' discretion to reopen payment determinations, (2) a calculation methodology to account for the impact of improper payments in recalculating expenditures and payment amounts used in Shared Savings Program financial calculations upon reopening a payment determination pursuant to § 425.315, (3) an adjustment to the historical benchmark to account for the impact of improper payments, and (4) a process for ACOs to request reopening of a payment determination. We also welcome comments on considerations in connection with ACOs' potential role in preventing and reporting Medicare fraud.

d. Mitigating the Impact of Significant, Anomalous, and Highly Suspect Billing Activity on Shared Savings Program Financial Calculations in Calendar Year 2024 or Subsequent Calendar Years

(1) Background

(a) Statutory Background on Shared Savings Program Financial Calculations

Section 1899 of the Social Security Act (the Act) (42 U.S.C. 1395jjj), as added by section 3022 of the Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted March 23, 2010), establishes the general requirements for payments to participating ACOs in the Shared Savings Program. Specifically, section 1899(d)(1)(A) of the Act provides that providers of services and suppliers participating in an ACO will continue to receive payment under the original Medicare fee-for-service program under Medicare Parts A and B in the same manner as they would otherwise be made. However, section 1899(d)(1)(A) of the Act also provides for an ACO to receive payment for shared savings provided that the ACO meets both the quality performance standards established by the Secretary and demonstrates that it has achieved savings against a benchmark of expected average per capita Medicare FFS expenditures. Additionally, section 1899(i) of the Act authorizes the Secretary to use other payment models in place of the one-sided model described in section 1899(d) of the Act. This provision authorizes the Secretary to select a partial capitation model or any other payment model that the Secretary determines will improve the quality and efficiency of items and services furnished to Medicare beneficiaries without additional program expenditures. We have used our authority under section 1899(i)(3) of the Act to establish the Shared Savings Program's two-sided payment model (see for example, 80 FR 32771 and 32772, and 83 FR 67834 through 67841) and to mitigate shared losses owed by ACOs affected by extreme and uncontrollable circumstances during PY 2017 and subsequent performance years (82 FR 60916 and 60917, 83 FR 59974 through 59977), among other uses of this authority described elsewhere in this proposed rule.

Section 1899(d)(1)(B)(i) of the Act specifies that, in each year of the agreement period, an ACO is eligible to receive payment for shared savings only if the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark under section 1899(d)(1)(B)(ii) of the Act. Section 1899(d)(1)(B)(ii) of the Act addresses how ACO benchmarks are to be established and updated under the Shared Savings Program. This provision specifies that the Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per beneficiary expenditures for Parts A and B services for Medicare FFS beneficiaries assigned to the ACO. This benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate and updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program, as estimated by the Secretary.

In past rulemaking, we have used our authority under sections 1899(d)(1)(B)(ii) and 1899(i)(3) of the Act to establish adjustments to the benchmark and program expenditure calculations, respectively, to exclude certain Medicare Parts A and B payments. In the November 2011 final rule (76 FR 67920 through 67922), we adopted an alternate payment methodology that excluded Indirect Medical Education (IME) and Disproportionate Share Hospital (DSH) payments from ACO benchmark and performance year expenditures due to concerns that the inclusion of these amounts would incentivize ACOs to avoid referring patients to the types of providers that receive these payments. In the CY 2023 PFS final rule (87 FR 69954 through 69956), we excluded new supplemental payments to Indian Health Service/Tribal hospitals and hospitals located in Puerto Rico consistent with our longstanding policy to exclude IME, DSH and uncompensated care payments from ACOs' assigned and assignable beneficiary expenditure calculations. In the May 8, 2020 COVID–19 IFC (85 FR 27577 through 27582), we established a methodology to adjust Shared Savings Program financial calculations to account for the COVID–19 Public Health Emergency. Specifically, we established a methodology that would exclude all Medicare Parts A and B FFS payment amounts for a beneficiary's episode of care for treatment of COVID–19 to

prevent distortion to, among other calculations, an ACO's benchmark and program expenditure calculations.

(b) Background on Significant, Anomalous, and Highly Suspect Billing Activity

Recently, ACOs and other interested parties have raised concerns about an increase in billing to Medicare for selected intermittent urinary catheter supplies on Durable Medical Equipment, Prosthetics, Orthotics & Supplies (DMEPOS) claims in CY 2023, alleging that the increase in payments represents fraudulent activity (the ''alleged conduct''). The observed DMEPOS billing volume for intermittent urinary catheters in CY 2023 represents significant, anomalous, and highly suspect (SAHS) billing activity.[525]

Generally, a level of billing for a given HCPCS or CPT code is considered SAHS billing activity when a given HCPCS or CPT code exhibits a level of billing that represents a significant claims increase either in the volume or dollars (for example, dollar volume significantly above prior year, or claims volume beyond expectations) with national or regional impact (for example, not only impacting one or few ACOs) and represents a deviation from historical utilization trends that is unexpected and is not clearly attributable to reasonably explained changes in policy or the supply or demand for covered items or services. The billing level is significant and represents billing activity that would cause significantly inaccurate and inequitable payments and repayment obligations in the Shared Savings Program if not addressed.

Current Shared Savings Program regulations, codified at 42 CFR part 425, do not provide a basis for CMS to adjust program expenditure or revenue calculations to remove the impact of SAHS billing activity such as that arising from the alleged conduct in advance of issuing an initial determination. As discussed in section III.G.7.c of this proposed rule, CMS may reopen an initial determination or a final agency determination and issue a revised initial determination at any time in the case of fraud or similar fault, and not later than 4 years after the date of the notification to the ACO of the initial determination of savings or losses for the relevant performance year for good cause (§ 425.315). This does not allow for CMS to address SAHS billing activity, which must be addressed prior to conducting financial reconciliation, which is an initial determination, to prevent significant inequity and inaccurate payment determinations.

We are concerned that such SAHS billing activity, should it occur in CY 2024 or later, would inflate Medicare Parts A and B payment amounts and affect Shared Savings Program calculations, including:

- Performance year reconciliation calculations, including expenditures for each ACO's assigned beneficiaries for the calendar year that has SAHS billing activity, the national-regional blended update factor used to update the benchmark for ACOs beginning an agreement period before January 1, 2024 (refer to § 425.601(b)), the three-way blended update factor used to update the benchmark for ACOs beginning an agreement period on January 1, 2024 and in subsequent years (refer to § 425.652(b)), and factors based on ACO participant revenue to determine the loss recoupment limits for ACOs participating under two-sided models of the BASIC track (Levels C, D, E) (refer to § 425.605(d)).
- Historical benchmark calculations for establishing the benchmark for ACOs beginning new agreement periods on January 1, 2025, or in subsequent years with a benchmark year that has SAHS billing activity (refer to § 425.652(a)).
- Factors used in the application cycle for ACOs applying to enter a new agreement period beginning two years after the SAHS billing activity occurred, and the change request cycle for ACOs continuing their participation in the program, including data used to determine an ACO's eligibility for Advance Investment Payments under § 425.630(b) or for the CMS Innovation Center's new ACO Primary Care Flex Model (ACO PC Flex Model) based on ACO revenue status (high revenue or low revenue), and to determine repayment mechanism amounts for ACOs entering, or continuing in, two-sided models (refer to § 425.204(f)).

The accuracy of the Shared Savings Program's determination of an ACO's financial performance (through a process referred to as financial reconciliation) in terms of the ACO's eligibility for and amount of a shared savings payment or liability for shared losses, depends on the accuracy of claims data. Absent CMS action, SAHS billing activity would affect performance year financial reconciliation program-wide rather than being limited to ACOs that have assigned beneficiaries directly impacted by the issue. For instance:

- An ACO with assigned beneficiaries impacted by the SAHS billing activity will see an increase in performance year expenditures, reducing the ACO's shared savings or increasing the amount of shared losses owed by the ACO. The impact on the ACO's performance may be partially mitigated if the SAHS billing activity also increases the ACO's regional service area expenditures and the national expenditures used to calculate the two-way national-regional blended benchmark update factor.
- An ACO with assigned beneficiary expenditures and regional service area expenditures with little or no impact from the SAHS billing activity will receive a relatively higher benchmark update under the national-regional blended update factors used in performance year reconciliation, and therefore, may appear to perform better as a result of the national impact of the SAHS billing activity, resulting in higher earned performance payments or lower or no losses for the ACO.

Unaddressed, SAHS billing activity in a given calendar year can distort the historical benchmarks for an ACO in an agreement period that have the calendar year as a benchmark year and the accuracy of any future financial reconciliation performed against those benchmarks. Similarly, inaccurate revenue and expenditure calculations based on data from a calendar year affected by SAHS billing activity may affect an ACO's revenue status and the amount of funds an ACO in a two-sided model must secure as a repayment mechanism, one of the program's important safeguards for protecting the Medicare Trust Funds. Absent CMS action, SAHS billing activity likely would significantly impact shared savings and losses calculations for the performance year affected by SAHS billing activity, and for future performance years that have benchmark years affected by SAHS billing activity. Under these circumstances, some ACOs would likely experience adverse impacts (for example, lower or no shared savings or higher shared losses) while other ACOs would experience windfall gains (for example, higher shared savings or lower or no shared losses).

Failing to address SAHS billing activity would jeopardize the integrity of the Shared Savings Program. There are 480 ACOs in the Shared Savings Program with over 608,000 health care providers who care for 10.8 million

[525] SAHS billing activity may appear in claims for items and services rendered to beneficiaries assigned to an ACO as well as for beneficiaries who are not assigned to an ACO. Such activity may be caused by providers and suppliers who participate in an ACO and who do not participate in an ACO. This discussion is primarily focused on SAHS billing activity performed by providers and suppliers that do not participate in ACOs billing items and services for beneficiaries who are assigned to ACOs or who are in the assignable population used in national and regional factors used in Shared Savings Program calculations.

assigned FFS beneficiaries.[526] In PY 2022, the most recent year for which data is available, savings achieved by ACOs relative to benchmarks amounted to $4.3 billion, of which ACOs received shared savings payments totaling $2.5 billion, and Medicare retained $1.8 billion in savings.[527] ACOs are held accountable for 100 percent of total Medicare Parts A and B expenditures for their assigned beneficiary populations (with limited exceptions). This incentivizes ACOs to generate savings for the Medicare program as they have the opportunity to share in those savings if certain requirements are met. It also discourages the ACO from generating unnecessary expenditures for Medicare as they may be required to repay those amounts to CMS. Accountable care arrangements such as this cannot function if the ACO may be held responsible for all SAHS billing activity that is outside of their control. Holding an ACO accountable for substantial losses due to SAHS billing activity is not only inequitable but will dramatically increase the level of risk associated with participation, making the Shared Savings Program unattractive.

In a separate proposed rule entitled ''Medicare Program: Mitigating the Impact of Significant, Anomalous, and Highly Suspect Billing Activity on Medicare Shared Savings Program Financial Calculations in Calendar Year 2023'' (89 FR 55168, July 3, 2024) (referred to herein as the SAHS billing activity proposed rule), we have proposed an approach to address the SAHS billing activity identified for CY 2023 to protect the accuracy, fairness, and integrity of Shared Savings Program financial calculations. Specifically, we have proposed to exclude payment amounts for two HCPCS codes (A4352 (*Intermittent urinary catheter; Coude (curved) tip, with or without coating (Teflon, silicone, silicone elastomeric, or hydrophilic, etc.),* each) and A4353 (*Intermittent urinary catheter, with insertion supplies*)) on DMEPOS claims submitted by any supplier from expenditure and revenue calculations used for: assessing performance year (PY) 2023 financial performance of Shared Savings Program ACOs, establishing benchmarks for ACOs starting agreement periods in 2024, 2025, and 2026, and calculating factors used to determine revenue status and repayment mechanism amounts in the application and change request cycle for ACOs applying to enter a new agreement period beginning on January 1, 2025, or continue their participation in the program in PY 2025, respectively. There will be a 30-day public comment period on the SAHS billing activity proposed rule so as to minimize the negative impact on ACOs of a delay in the issuance of PY 2023 initial financial determinations and disbursement of performance payments, as well as to other program milestones, necessitated by the calculation of amounts under the financial methodology proposed in the SAHS billing activity proposed rule.

(2) Proposed Revisions

It is important to establish a policy that would allow CMS to proactively make similar adjustments for future calendar years, should new SAHS billing activity be identified. In general, we anticipate that billing activity that meets the high bar to be considered significant, anomalous, and highly suspect billing activity will be a rare occurrence. This is evidenced by the program's history. The SAHS billing activity surrounding selected catheter codes in 2023 is the first occasion we have had in the program's 12-year history to consider this issue. We propose that we would notify ACOs and ACO applicants of our determinations to remove any codes and the aggregate per capita dollar amount of the codes removed as part of the annual financial reconciliation process. While we anticipate future occurrences of the scope and magnitude observed for urinary catheters in CY 2023 to be rare, having a permanent policy in place would:

- Allow CMS to move quickly to make adjustments to financial calculations without having to engage in additional rulemaking, ensuring timely issuance of initial determinations of savings and losses and disbursement of earned performance payments;
- Provide ACOs with greater certainty that they will not be held accountable for SAHS billing activity that is out of their control, promote integrity and fairness and ensure accuracy of program calculations;
- Limit requests to reopen initial determinations, thus reducing burden for ACOs and CMS.

In this proposed rule we are therefore proposing an approach by which we would adjust Shared Savings Program calculations to mitigate the impacts of SAHS billing activity occurring in CY 2024 or subsequent calendar years.

(a) Identifying Significant, Anomalous, and Highly Suspect Billing Activity

We propose that CMS would have the sole discretion to identify cases of SAHS billing activity for a particular calendar year that would warrant the adjustment of Shared Savings Program financial calculations. We anticipate routinely examining billing trends identified by CMS and other relevant information that had been raised through complaints by ACOs or other interested parties to the HHS–OIG or to the CMS CPI. We would seek to identify and monitor any codes that would potentially trigger the adjustment policy by meeting the high bar for removal under the criteria used to determine SAHS billing activity. Shortly after the start of a calendar year CMS would make a final determination as to which codes, if any, warrant adjustments for the previous calendar year. For example, in early CY 2026 CMS would make a final determination of whether any codes met the high bar for removal under the criteria used to determine SAHS billing activity in CY 2025, allowing time for the adjustments to be incorporated in forthcoming calculations.

CMS must retain sole discretion to identify cases of SAHS billing activity because we cannot anticipate what SAHS billing activity we may encounter in the future that may warrant adjustments to the program's financial calculations. We are also concerned about balancing adjustments for billing activity that rises to the level of SAHS versus removing payment amounts associated with billing activity due to inefficiencies that are within the ACO's control. Depending on the frequency of the use of this authority and the occurrence of SAHS billing activity, and thus the experience we develop in this area, we would consider proposing to codify criteria to identify SAHS billing activity in the future through additional rulemaking. Nonetheless, we believe that CMS should retain sole discretion to determine whether SAHS billing activity occurred on a case-by-case basis at this time.

We anticipate considering multiple criteria in determining whether SAHS billing activity warrants removal of the corresponding billing codes from Shared Savings Program financial calculations. These criteria include:

- The observed increase in claims for a HCPCS or CPT code year-to-year meets the definition of significant, anomalous, and highly suspect billing activity, as defined elsewhere in this section of this proposed rule;

[526] Refer to CMS, Shared Savings Program Fast Facts—As of January 1, 2024, available at *https://www.cms.gov/files/document/2024-shared-savings-program-fast-facts.pdf.*

[527] Refer to CMS, Shared Savings Program Performance Year Financial and Quality Results, 2022, available at *https://data.cms.gov/medicare-shared-savings-program/performance-year-financial-and-quality-results/data.*

- The observed billing activity has national or regional impact or significance, such as:
  - ++ Involves a Medicare provider or supplier, a beneficiary population and/or states with claims activity that that significantly impacts national or regional expenditure values or trends;
  - ++ Warrants adjustment (all or partial) to national Medicare expenditure trend calculations used in payment (for example, United States Per Capita Cost) and/or Federal budget forecast calculations;
  - ++ Warrants removal from national and regional growth rates used to update ACO historical benchmarks;
- If no action is taken there would be an imbalance between ACO performance year and historical benchmark year expenditures;
- Use of payment amounts associated with the SAHS billing activity could result in payment inaccuracies that produce significantly inaccurate and inequitable payment determinations in the Shared Savings Program (including the amount of shared savings or shared losses), due to factors beyond the control of ACOs; and
- The claims in question may be disproportionately represented by Medicare providers or suppliers whose Medicare enrollment status has been revoked.

We anticipate utilizing this authority only in rare and extreme cases where a number of the criteria are satisfied. We anticipate we would consider the extent to which the billing activity meets each criterion when developing a holistic assessment of the billing activity's impact on the Shared Savings Program.

The extent of the geographic impact of the SAHS billing activity in question is relevant given that the proposed policy would entail adjustments program-wide. One consideration for determining whether the billing activity has national or regional significance would be if the pattern warrants an adjustment to or special assumption for calculating official Medicare expenditure trends (such as the United States Per Capita Cost (USPCC) or Federal budget forecasts) due to the activity's significant, anomalous, and highly suspect nature. For example, the 2024 Medicare Trustees Report noted a significant increase in suspected fraudulent spending on certain intermittent catheters in 2023.[528] The DME projections in the report include the assumption that this suspected fraud will be addressed during 2024.[529] Billing activity in the Medicare FFS program at a scale warranting a special assumption for calculating the USPCC or Federal budget forecasts has *per se* national or regional significance, and thus would likely rise to the high bar of warranting adjustment to Shared Savings Program expenditure and revenue calculations.

We would seek to assess whether the billing activity creates an imbalance between ACO performance year and historical benchmark year expenditures. This assessment could involve considering whether the increase in billing activity was at such scale that it causes the difference between performance year and benchmark year expenditures for an ACO's assigned beneficiary population for the claim type affected by the billing activity (for example, DMEPOS) to be substantially larger than differences for other claim types.

We would also consider whether the billing activity, and any inaccurate or inequitable payment determinations that could result from using the related payment amounts, was outside of Shared Savings Program ACOs' ability to reasonably control. Most commonly, this would entail examining whether the Medicare providers or suppliers billing the codes in question are ACO providers or suppliers. Generally, we would be more likely to apply the proposed policy if the SAHS billing activity were outside of the ACO's control as the program may otherwise lack a means to control the growth of such amounts.

Finally, we would consider whether billing activity were disproportionately represented by Medicare providers or suppliers whose Medicare enrollment status has been revoked. Such a circumstance would provide further evidence that the billing activity surrounding these codes was highly suspect. We seek comment on the processes and criteria described.

(b) Adjustments to Shared Savings Program Calculations

In the event that CMS identifies one or more HCPCS or CPT codes with SAHS billing activity in CY 2024 or a subsequent calendar year that warrant adjustment, we propose to exclude all Medicare Parts A and B payment amounts associated with the identified codes on specified claim types submitted by any provider or supplier from expenditure and revenue calculations for the relevant calendar year for which the SAHS billing activity is identified. For example, if CMS identifies one or more codes with SAHS billing activity in CY 2025 that warrant adjustment, we would exclude payments for those codes for both calculations where CY 2025 is the performance year and in calculations where CY 2025 is a benchmark year for ACOs in agreement periods beginning in 2026, 2027, and 2028.

We propose that we would also adjust the 3 most recent years prior to the start of the ACO's agreement period used in establishing the historical benchmark that is used to reconcile the ACO for a performance year corresponding to the calendar year for which the SAHS billing activity was identified. In the example where CMS identified SAHS billing activity for 2025, we would adjust benchmark expenditures (ACO, national, and regional) for 2019, 2020, and 2021, for an ACO that began an agreement period in 2022 (for which PY 2025 is the fourth performance year in its agreement period) and would adjust benchmark expenditures (ACO, national, and regional) for 2022, 2023, and 2024 for an ACO that began its agreement period in 2025 (for which PY 2025 is the first performance year in its agreement period). Note that in computing benchmark expenditures for 2023 for this second ACO, because 2023 is a benchmark year, CMS would also exclude payments for the catheter claims with SAHS billing activity in 2023, as proposed in the SAHS billing activity proposed rule, if finalized.

Our proposal to adjust an ACO's historical benchmark to exclude Medicare Parts A and B FFS payment amounts associated with the HCPCS or CPT codes displaying SAHS billing activity during a performance year would achieve greater consistency between the benchmark period and the performance year, given that we are excluding all payments on specified claim types for the selected codes from performance year calculations, including payments that would have been made in the absence of any SAHS billing activity. This helps to ensure a balance between the benchmark and the performance year such that an ACO is not unfairly benefitting from a benchmark that includes certain expenditures that are excluded from the performance year. Under our proposal, we would identify any codes warranting adjustment at the start of the next calendar year and our operational schedule would accommodate the additional calculations required. Therefore, we anticipate we would be able to compute adjusted historical

[528] The Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, ''2024 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds'', p. 136, available at *https://www.cms.gov/oact/tr/2024*.

[529] Ibid.

benchmarks for the affected reconciliation with minimal, if any, delays to the typical timeline for issuing initial determinations.

We propose that we would provide the historical benchmark that has been adjusted to exclude payment amounts for HCPSC or CPT codes associated with SAHS billing activity occurring in the performance year being reconciled to ACOs as part of their financial reconciliation settlement package for the performance year, as opposed to providing a separate new historical benchmark report in advance of settlement. This approach is consistent with what we have done for rare past occasions where we computed revised benchmarks immediately prior to reconciliation to correct for late-breaking data issues. Consistent with existing operational practice, in calculating these adjusted benchmarks, we would recompute ACO expenditures using beneficiary assignment data that was generated during the performance year being reconciled for all ACOs. For example, if computing adjusted historical benchmarks for PY 2025 to exclude claim payments for codes with SAHS billing activity during the performance year, we would use beneficiary assignment data generated during CY 2025. Although the benchmark year assignment data generated during the performance year being reconciled would be based on the same ACO participant list, assignment methodology selection under § 425.226(a)(1), and assignment methodology under subpart E of Part 425 of the regulations as used in calculating the ACO's most recent prior benchmark, other factors, such as more recent Medicare beneficiary eligibility data along with the ACOs included in the claims-based assignment competition, could differ and impact an ACO's assigned population. We considered whether to provide ACOs with their adjusted benchmark at the time we announce our determination of SAHS billing activity for a given calendar year (anticipated to occur near the start of the next calendar year), however we concluded this would delay other important program milestones, such as the issuance of preliminary and adjusted historical benchmarks for the new performance year.

When the calendar year with SAHS billing activity becomes a benchmark year, we are proposing adjustments to calculations for the calendar year itself, and not for other years in the benchmark period, or the performance years that will be reconciled against those benchmarks. Thus, in the example where we identified codes with SAHS billing activity in CY 2025, in establishing or resetting the benchmark for an ACO entering an agreement period in 2026, we would exclude payments for the relevant codes identified for CY 2025 from BY 2025 calculations and, if our proposed policy in the SAHS billing activity proposed rule is finalized, would remove payments for the specified catheter codes from BY 2023 calculations. We would not exclude the catheter codes identified as having SAHS billing activity in BY 2023 or the codes identified for CY 2025 from either BY 2024 calculations or calculations for PY 2026 or any subsequent performance years in the same agreement period.[530]

Specifically, we are proposing to adjust the following Shared Savings Program calculations, as applicable, to exclude all Medicare Parts A and B payment amounts associated with a HCPCS or CPT code on claims for the specified claim types displaying SAHS billing activity:

- Calculation of Medicare Parts A and B FFS expenditures for an ACO's assigned beneficiaries for all purposes including the following: Establishing, adjusting, updating, and resetting the ACO's historical benchmark and determining performance year expenditures.
- Calculation of FFS expenditures for assignable beneficiaries as used in determining county-level FFS expenditures and national Medicare FFS expenditures, including the following calculations:

++ Determining average county FFS expenditures based on expenditures for the assignable population of beneficiaries in each county in the ACO's regional service area according to §§ 425.601(c) and 425.654(a) for purposes of calculating the ACO's regional FFS expenditures.

++ Determining the 99th percentile of national Medicare FFS expenditures for assignable beneficiaries for purposes of the following:

-- Truncating assigned beneficiary expenditures used in calculating benchmark expenditures under §§ 425.601(a)(4) and 425.652(a)(4), and performance year expenditures under §§ 425.605(a)(3) and 425.610(a)(4).

-- Truncating expenditures for assignable beneficiaries in each county for purposes of determining county FFS expenditures according to §§ 425.601(c)(3) and 425.654(a)(3).

-- Truncating expenditures for assignable beneficiaries for purposes of determining truncated national per capita FFS expenditures for purposes of calculating the Accountable Care Prospective Trend (ACPT) according to § 425.660(b)(3).

++ Determining truncated national per capita expenditures FFS per capita expenditures for assignable beneficiaries for purposes of calculating the ACPT according to § 425.660(b)(3).

++ Determining national per capita expenditures for Parts A and B services under the original Medicare FFS program for assignable beneficiaries for purposes of capping the regional adjustment to the ACO's historical benchmark according to §§ 425.601(a)(8)(ii)(C) and 425.656(c)(3), capping the prior savings adjustment according to § 425.658(c)(1)(ii), capping the prepaid shared savings multiplier according to § 425.640(f)(2)(v), and calculating the proposed HEBA scaler according to § 425.662(b)(2).

++ Determining national growth rates that are used as part of the blended growth rates used to trend forward BY1 and BY2 expenditures to BY3 according to §§ 425.601(a)(5)(ii) and 425.652(a)(5)(ii) and as part of the blended growth rates used to update the benchmark according to §§ 425.601(b)(2) and 425.652(b)(2)(i).

- Calculation of Medicare Parts A and B FFS revenue of ACO participants for purposes of calculating the ACO's loss recoupment limit under the BASIC track as specified in § 425.605(d).
- Calculation of total Medicare Parts A and B FFS revenue of ACO participants and total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries for purposes of identifying whether an ACO is a high revenue ACO or low revenue ACO, as defined under § 425.20, determining an ACO's eligibility to receive advance investment payments according to § 425.630, and determining whether an a ACO qualifies for a shared savings payment under § 425.605(h).
- Calculation or recalculation of the amount of the ACO's repayment mechanism arrangement according to § 425.204(f)(4).

This approach would recognize that SAHS billing activity has the potential to impact an ACO's savings and loss determination for both the performance year when the SAHS billing activity occurred and future performance years for which the affected year is a benchmark year. Making adjustments when the affected period represents a performance year or benchmark year is consistent with our approach for the exclusion of payment amounts for episodes of care for treatment of COVID–19 that we established in the

[530] This assumes these same codes were not identified as having SAHS billing activity in CY 2024 or CY 2026 or later years.

May 8, 2020 COVID–19 IFC (85 FR 27577 through 27581).

The listed calculations reflect the same set of calculations that CMS adjusts for a beneficiary's episode of care for treatment of COVID–19, specified at § 425.611(c), as amended by the CY 2021 PFS final rule (85 FR 85044), the CY 2023 PFS final rule (87 FR 70241), and the CY 2024 PFS final rule (88 FR 79548), with a few exceptions. First, § 425.611(c) includes certain provisions that are not relevant for the proposed policy.[531] Second, the proposed policy includes calculations related to truncated national per capita expenditures used in determining the ACPT as described in § 425.660(b)(3) that are not included in § 425.611(c),[532] as well as references to other new or proposed calculations that do not rely on expenditures from a period of time overlapping the Public Health Emergency for COVID–19 for the United States which was in effect from January 27, 2020, through May 11, 2023 (capping the proposed prepaid shared savings multiplier (§ 425.640(f)(2)(v)), calculating the proposed HEBA scaler (§ 425.662(b)(2)), and determining whether an ACO that does not meet its minimum savings requirement qualifies for a shared savings payment (§ 425.605(h)). We propose to adjust calculations used for the ACPT to mitigate the impact of any SAHS billing activity identified for CY 2024 or subsequent calendar years. Specifically, in projecting growth rates at the start of an agreement period according to § 425.660, we would make an adjustment to the growth rates to mitigate the impact that any known SAHS billing activity have on spending growth projections.

We believe it is unlikely that fixed growth rates projected at the start of agreement periods beginning in earlier years may also need mitigation from a code displaying SAHS billing activity. For example, if CMS identifies a HCPCS or CPT code displaying SAHS billing activity in CY 2025, the projected growth rate from 2023 to 2025—which will be used to update the historical benchmark for PY 2025 financial reconciliation for ACOs that began an agreement period on January 1, 2024—would likely have assumed typical billing patterns for the code in CY 2025. Additionally, the projected growth rate from BY 2024 to PY 2025—which will be used to update the historical benchmark for PY 2025 financial reconciliation for ACOs that began an agreement period on January 1, 2025—would likely also have assumed typical billing patterns for the code in CY 2025 given the projections were finalized early in CY 2025.

However, if we determine a bias exists due to differences between adjustments to the projected growth rates for the ACPT and other Shared Savings Program calculations, we could rely on our current policy under § 425.652(b)(4)(ii) to reduce the weight of the ACPT in the three-way blend. We propose that we would use our discretion to reduce the weight of the ACPT rather than recalculate the growth rates that had been projected at the start of agreement periods starting in earlier years, as we believe it is important to maintain the policy that the projected growth rates remain fixed for the ACO's agreement period. In the CY 2023 PFS final rule (refer to 87 FR 69886 through 69898) we finalized our proposal to establish the ACPT at the outset of an agreement period, based on one or more annualized growth rates. We explained that we will not adjust the ACPT due to external factors such as geographic price changes, efficiency discounts, or other retrospective updates occurring during the performance years throughout the agreement period. In response to commenters concern that CMS might adjust the ACPT downward during the agreement period, we stated that we will not adjust the ACPT projections over the course of the agreement period (87 FR 69897). However, we acknowledged that a variety of circumstances could cause actual expenditure trends to significantly deviate from projections. If unforeseen circumstances occur during an ACO's agreement period we retained flexibility to reduce the impact of the prospectively determined ACPT portion of the three-way blend when necessary to mitigate unforeseen circumstances. We explained that we anticipate determining, on an ad hoc basis, whether an unforeseen circumstance warrants adjustment of the weight placed on the ACPT component of the three-way blend by considering whether it has a material impact across the entire Shared Savings Program. If we determine that expenditure growth has differed significantly from projections made at the start of the agreement period due to unforeseen circumstances, such as an economic recession, pandemic, or other factors, a reduction in the weight placed on the ACPT may be considered.

To summarize, we propose that when projecting growth rates used for the ACPT at the beginning of an agreement period, we would make an adjustment to mitigate the impact of any known SAHS billing activity on spending growth projections. Additionally, in accordance with § 425.660(a), CMS would not adjust the ACPT projections over the course of the agreement period to account for SAHS billing activity later identified. Rather, CMS may use its discretion to reduce the weight of the ACPT in the three-way blend in accordance with § 425.652(b)(4)(ii) if CMS determines that the SAHS billing activity represents an unforeseen circumstance that warrants a reduction to the weight.

The direction and magnitude of the impact of the proposed adjustments may vary by ACO. However, by making these adjustments, we would be helping to ensure that no ACOs are held accountable, and financially penalized for SAHS billing activity that was outside their direct control while also protecting the Trust Funds from other ACOs potentially receiving windfall gains.

For this proposal, we rely on our authority under section 1899(d)(1)(B)(ii) of the Act. Section 1899(d)(1)(B)(ii) of the Act authorizes the Secretary to adjust the benchmark for beneficiary characteristics and such other factors as the Secretary determines appropriate. Here, we are proposing to adjust the benchmark in order to remove payments for HCPCS or CPT codes identified as exhibiting SAHS billing activity in CY 2024 or subsequent calendar years from the determination of benchmark expenditures when the calendar year serves as a benchmark year or from the determination of benchmark expenditures that will be used to reconcile the calendar year when it serves as a performance year.

We propose to use our authority under section 1899(i)(3) of the Act to remove payment amounts for HCPCS or CPT codes identified as exhibiting SAHS billing activity in CY 2024 or subsequent calendar years from the following calculations: (1) performance

[531] This includes provisions under §§ 425.600, 425.602, 425.603, 425.604, and 425.606 which are not relevant for the proposed policy because they are not applicable to PY 2024 or later performance years or for agreement periods where CY 2024 or later years are benchmark years. These provisions are relevant for the COVID–19 episode exclusion policy under § 425.611 because they are applicable to performance or benchmark years that overlap with the COVID–19 PHE.

[532] When establishing the ACPT in the CY 2023 PFS final rule, we noted that the first ACPT release would be published in 2024 for agreement periods beginning on January 1, 2024, and would provide a projected annualized growth rate (or rates) relative to the 2023 benchmark year (BY3). We noted further that to the extent that Medicare projections made at that time (2024) anticipated lingering effects from the COVID–19 pandemic then they would be reflected in the ACPT (see 87 FR 69894) and we opted not to amend § 425.611 to include adjustments of ACPT-related calculations. However, it is appropriate to propose making adjustments to ACPT-related calculations in this proposed rule.

year expenditures; (2) updates to the historical benchmark; and (3) ACO participants' Medicare FFS revenue used for multiple purposes across the Shared Savings Program, including determinations of loss sharing limits in the two-sided models of the BASIC track,[533] determinations of eligibility for advance investment payments,[534] and expanded criteria for certain low revenue ACOs participating in the BASIC track to qualify for shared savings in the event the ACO does not meet the minimum savings rate.[535] Section 1899(i)(3) of the Act requires that we determine that the alternative payment methodology adopted under that provision would improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without resulting in additional program expenditures. The adjustments we are proposing herein, which would remove payment amounts for codes with identified SAHS billing activity from the specified Shared Savings Program calculations as proposed in § 425.672(c) and (e), would capture and remove from program calculations expenditures that are outside of an ACO's control, but that could significantly affect the ACO's performance under the program. In particular, failing to remove these payments would likely create highly variable savings and loss results for individual ACOs that happen to have over-representation or under-representation of SAHS billing activity for the selected codes among their assigned beneficiary populations.

As described in the Regulatory Impact Analysis (section VII. of this proposed rule), excluding payment amounts for the selected codes from the specified calculations are not expected to result in an increase in spending beyond the expenditures that would otherwise occur under the statutory payment methodology in section 1899(d) of the Act. Further, these adjustments to our calculations to remove payment amounts for these codes would promote continued integrity and fairness and improve the accuracy of Shared Savings Program financial calculations. As a result, we expect these policies would support ACOs continued participation in the Shared Savings Program and the program's goals of lowering growth in Medicare FFS expenditures and improving the quality of care furnished to Medicare beneficiaries.

Based on these considerations, and as specified in the Regulatory Impact Analysis (section VII. of this proposed rule), we have determined that adjusting certain Shared Savings Program calculations to remove payment amounts for selected codes, in the event we determine SAHS billing activity occurs in CY 2024 or subsequent calendar years, from the calculation of performance year expenditures, updates to the historical benchmark, and ACO participants' Medicare FFS revenue used for multiple purposes across the Shared Savings Program, meets the requirements for use of our authority under section 1899(i)(3) of the Act when incorporated into the existing other payment model we have established pursuant to that section.

The changes that we are proposing in this section of this proposed rule would apply to address the impact of SAHS billing activity identified in CY 2024 or subsequent calendar years, and thus would apply to ACOs currently participating in PY 2024. Therefore, if finalized, these changes to policies applicable for PY 2024 would constitute retroactive rulemaking. Section 1871(e)(1)(A)(ii) of the Act permits a substantive change in regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability under Title XVIII of the Act to be applied retroactively to items and services furnished before the effective date of the change if the failure to apply the change retroactively would be contrary to the public interest.

Failing to apply the proposed changes retroactively to PY 2024 would be contrary to the public interest because it would unfairly punish Shared Savings Program ACOs by forcing them to unexpectedly assume a substantial magnitude of financial risk for costs outside of their control and not previously contemplated in the Shared Savings Program, undermining both the sustainability of the Shared Savings Program and the public's faith in CMS as a fair partner, in the event we determine SAHS billing activity impacts CY 2024. We did not fully contemplate the potential for SAHS billing activity outside of an ACO's control when the Shared Savings Program was established.[536] For this reason, the Shared Savings Program financial methodology and the procedures we have utilized in the past did not provide a means to adequately account for instances of SAHS billing activity outside of an ACO's control, and thereby the related financial risk is assumed entirely by ACOs. We view this outcome as particularly inequitable to ACOs because they have no direct means of controlling such costs. Unlike Medicare Advantage organizations, ACOs are not responsible for processing claims for their assigned beneficiaries and otherwise have no means of causing the denial of such claims. CMS thus cannot reasonably have expected ACOs to have intended to assume responsibility for all instances of SAHS billing activity outside of an ACO's control when they joined the Shared Savings Program. For these reasons, it would be contrary to the public interest for CMS to fail to apply a policy mitigating this issue retroactively.

We did not foresee the acute need to address SAHS billing activity impacting CY 2023, and the need for the related policy proposal for addressing SAHS billing activity in CY 2024 or subsequent calendar years, with sufficient time in advance of the start of PY 2024 to undertake notice and comment rulemaking earlier, and to avoid retroactive rulemaking. More specifically, we were only able to determine that the increase in billing on HCPCS codes A4352 and A4353 in CY 2023 represented SAHS billing activity after the calendar year ended. To identify that the billing activity in CY 2023 was significant, anomalous, and highly suspect, CMS reviewed actual billing levels after the calendar year closed and services furnished in CY 2023 had occurred and the billing level could then be compared to billing levels observed in prior calendar years.

We seek comment on our proposal to apply the policy retroactively to PY 2024, including whether failing to apply the policy retroactively would be contrary to the public interest and how it would affect ACOs and their ability to participate in the Shared Savings Program.

We are proposing a new § 425.672 to describe adjustments CMS could make to Shared Savings Program calculations to mitigate the impact of SAHS billing activity for CY 2024 or subsequent calendar years. We propose that § 425.672(b) specify that CMS, at its sole discretion, may determine that the billing of specified HCPCS or CPT codes represents SAHS billing activity in calendar year 2024 or subsequent calendar years that warrants adjustment to calculations made under this part. We propose under § 425.672(c) to specify the Shared Savings Program calculations for which CMS would exclude all Medicare Parts A and B FFS payment amounts for the specified

[533] Refer to § 425.605(d)(1)(iii)(D), (d)(1)(iv)(D), and (d)(1)(v)(D) for BASIC track Levels C, D and E, respectively.

[534] Refer to § 425.630(b).

[535] Refer to § 425.605(h).

[536] *See, for example,* 76 FR 67948 through 67950. Such approaches were more focused on policies to support monitoring of ACO performance and ensuring program integrity.

claim types associated with a HCPCS or CPT code identified in § 425.672(b) when an adjustment to the calculation is appropriate in light of the SAHS billing activity. The calculations specified in § 425.672(c) include all potentially relevant financial calculation provisions, including those covering the financial benchmarking methodologies (including the proposed HEBA scaler at § 425.662(b)(2)) and those covering calculation of shared savings and losses. We propose in § 425.672(d) that for calendar year 2024 or subsequent calendar years,[537] CMS would adjust Shared Savings Program calculations for SAHS billing activity identified under § 425.672(b) for the calendar year when it is either a performance year or a benchmark year, as well as the 3 most recent years prior to the start of the ACO's agreement period used in establishing the historical benchmark, when such a benchmark is used to reconcile the ACO for a performance year adjusted for SAHS billing activity. We propose to specify under § 425.672(e) that we would also make adjustments for any calendar year corresponding to BY3 in projecting per capita growth in Medicare Parts A and B FFS expenditures according to § 425.660(b)(1) for purposes of calculating the ACPT for agreement periods beginning on January 1, 2024, and in subsequent years. Additionally, we are proposing conforming revisions to §§ 425.601(a)(9) and 425.652(a)(9), as well as proposing new paragraphs at §§ 425.601(a)(9)(iv) and 425.652(a)(9)(ix) to include adjustments for SAHS billing activity as one of the reasons that CMS would adjust an ACO's benchmark during the term of its agreement period. While we expect that the identification of SAHS billing activity that triggers these proposed policies will be rare, we believe that, if finalized, these policies will allow us to proactively ensure the accuracy of program calculations and provide greater certainty for ACOs and the Trust Funds.

We seek comment on these proposals.

[537] We note that by anchoring this policy on the calendar year, this proposed provision differs from many other program regulations that are applicable for a given performance year or for agreement periods beginning on a given date or within a given range. However, we believe this approach is appropriate for this policy as (1) we would adjust expenditures for the affected calendar year both when it is a performance year and when it is a benchmark year and (2) it ties the policy to the period for which the SAHS billing activity was identified much in the way the policy for COVID–19 episodes of care specified in § 425.611 is tied to the related public health emergency.

e. Seeking Comment on Establishing Higher Risk and Potential Reward Under the ENHANCED Track

(1) Background

As described in the CY 2024 PFS final rule (88 FR 79223), CMS has considered a higher risk Shared Savings Program track under which the shared savings/loss rate would be somewhere between 80 percent and 100 percent (that is, a rate higher than that currently offered under the ENHANCED track) and that builds on the experience of the Next Generation ACO (NGACO) and ACO REACH Models. A higher risk track would offer ACOs increased incentives to generate savings, which would help improve care delivery by promoting innovations in the delivery of high-quality care that is more patient-centered. In other words, by increasing sharing rates for ACOs, ACOs will be better incentivized to develop innovations in the delivery of high-quality care and, therefore, improve the care they offer to their beneficiaries. A revised ENHANCED track could be implemented in accordance with section 1899(i)(3) of the Act, provided the Secretary determines that such other payment model enhances the quality and efficiency of items and services furnished under the Medicare program and does not result in program expenditures greater than those that would result under the statutory payment model.

In the CY 2024 PFS final rule (88 FR 79223), we summarized public comments received in response to our Request for Information (RFI) regarding a potential track within the Shared Savings Program with higher risk than the current ENHANCED track. For a full summary of the comments submitted in response to our comment solicitation, we refer readers to the relevant discussion in the CY 2024 PFS final rule (88 FR 79225 through 79227). Commenters were broadly supportive of such an approach and referenced existing policies under the ACO REACH Model, and the NGACO Model. Some commenters suggested features of such a track that would serve to encourage more participation in the Shared Savings Program and help ACOs deliver more person-centered care to beneficiaries in Traditional Medicare. These features included prospective payments, full sharing rates (a sharing rate of 100 percent, similar to the Global Risk Sharing Option in the ACO REACH Model) as well as a benchmark discount rate (a reduction of the benchmark by a predetermined percentage) to protect the Medicare Trust Funds.

A higher risk sharing arrangement could incentivize participating ACOs to improve performance in the program as they would receive a greater share of any gross savings. That improved performance may, in turn, result in reduced healthcare costs for Medicare and more effective, efficient care for beneficiaries. In addition, higher risk sharing could incentivize ACOs to develop new care delivery strategies in order to improve their financial performance, such as a focus on specialty care integration and reduced care fragmentation. Offering a higher risk sharing track may also help CMS reach our goal of having all beneficiaries in the traditional Medicare program in a care relationship with a health care provider who is accountable for the costs and quality of their care by 2030 by encouraging currently participating ACOs to continue participation in the Shared Savings Program, as well as encourage ACOs not participating in the Shared Savings Program to join as a result of increased potential reward.

A recent CBO report [538] proposed that higher sharing rates might incentivize providers to decrease spending as they would stand to gain a larger portion of the savings generated. While in the short term this might diminish CMS savings, the report postulates that this would increase participation in the Shared Savings Program and provide a means for CMS to manage long-term healthcare spending growth. The report also highlights the necessity of striking a delicate balance: devising financial incentives enticing enough for ACOs to participate actively in the Shared Savings Program, while ensuring that such participation leads to savings for the Medicare program.

We seek comment on a participation option that would allow for higher risk and reward than currently available under the ENHANCED track. A participation option of this type would replace the existing ENHANCED track in order to avoid the self-selection issues that would occur if a higher risk track were to be included alongside the ENHANCED track. If both participation options were made available to ACOs, we have concerns that only the highest-performing ACOs would self-select into the higher of the two risk tracks. While we included an RFI on the topic in CY 2024 PFS rulemaking, we are concerned that ACOs did not have enough detailed information to appropriately weigh the

[538] For more details, please refer to Congressional Budget Office (CBO), ''Medicare Accountable Care Organizations: Past Performance and Future Directions'', April 2024, available at *https://www.cbo.gov/system/files/2024-04/59879-Medicare-ACOs.pdf.*

tradeoffs associated with a higher risk/reward option than the current ENHANCED track, and that the additional information we have generated since then will allow ACOs and other interested parties to provide more forthright and helpful feedback. CMS is interested in public comments on the design of a higher risk option within the Shared Savings Program that could be enacted under our authority granted by section 1899(i)(3) of the Act and that would encourage ACOs to participate actively in the Shared Savings Program while ensuring that such participation leads to savings for the Medicare program.

(a) Current ENHANCED Track

Currently, under the Shared Savings Program, ACOs may enter participation agreements under the ENHANCED track. The ENHANCED track is a two-sided model that represents the highest level of risk and potential reward currently offered under the Shared Savings Program. The rules governing the participation options available to ACOs and the progression from lower to higher risk for ACOs entering the program are described in § 425.600 of the regulations. To qualify for a shared savings payment, an ACO must meet a minimum savings rate (MSR) requirement, meet the quality performance standard or alternative quality performance standard established under § 425.512, and otherwise maintain its eligibility to participate in the Shared Savings Program under 42 CFR part 425, subpart B (§§ 425.100 through 425.118). For ACOs meeting the applicable quality performance standard established under § 425.512(a)(2) or (a)(5)(i) (for PY 2024 and subsequent performance years), the final shared savings rate is equal to the maximum sharing rate of 75 percent, or savings at a rate of 75 percent multiplied by the ACO's health equity adjusted quality performance score if the ACO meets the alternative quality performance standard at § 425.512(a)(5)(ii). CMS computes an ACO's shared savings payment by applying the final sharing rate to the ACO's savings on a first dollar basis (meaning the final sharing rate is applied to the ACO's full total savings amount), with the payment subject to a cap that is equal to 20 percent of the updated benchmark (§ 425.610(e)(2)).

ACOs that operate under a two-sided model and have losses that meet or exceed a minimum loss rate (MLR) must share losses with the Medicare program (§ 425.100(c)). Once this MLR is met or exceeded, the ACO will share in losses at a rate determined according to the ACO's track/level of participation, up to a loss recoupment limit (also referred to as the loss sharing limit) (§ 425.605(d); § 425.610(f), (g)). In determining shared losses, ACOs participating in the ENHANCED track are subject to losses at a rate determined using a sliding scale based on ACO's health equity adjusted quality performance score, if the applicable quality performance standard established in § 425.512(a)(2) or (a)(5)(i) or the alternative quality performance standard at § 425.512(a)(5)(ii) is met; with minimum shared loss rate of 40 percent and maximum of 75 percent. If the ACO fails to meet the applicable quality performance standard established in § 425.512 or the alternative quality performance standard, the ACO is subject to 1st dollar losses at a rate of 75 percent (§ 425.610(f)(4)(ii)). Shared losses are subject to a cap that is equal to 15 percent of updated benchmark (§ 425.610(g)).

CMS adjusts historical benchmark expenditures by Medicare enrollment type by a percentage of the difference between the average per capita expenditure amount for the ACO's regional service area and the ACO's historical benchmark amount (referred to herein as the ''regional adjustment'') (§ 425.652(a)(8)). The weights used in the regional adjustment calculation are determined in accordance with§ 425.656(e) and are dependent on whether the ACO has lower or higher spending compared to the ACO's regional service area and the agreement period for which the ACO is subject to the regional adjustment. The *first time* that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment using either 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's initial or rebased historical benchmark, if the ACO is determined to have lower spending than the ACO's regional service area (§ 425.656(e)(1)(i)); or 15 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's initial or rebased historical benchmark, if the ACO is determined to have higher spending than the ACO's regional service area (§ 425.656(e)(1)(ii)). The *second time* that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment using either the 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area (§ 425.656(e)(2)(i)); or 25 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area (§ 425.656(e)(2)(ii)). The *third time* that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment using the 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area (§ 425.656(e)(3)(i)); or the 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area (§ 425.656(e)(3)(ii)). The *fourth or subsequent time* that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment to the historical benchmark using 50 percent of the difference between the average per capita expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark (§ 425.656(e)(4)). Among the ACOs participating in PY 2024, 78 percent of BASIC track ACOs (176 of 227) received a positive regional adjustment, whereas 95 percent (155 of 163) of ACOs in the ENHANCED track received a positive regional adjustment. A positive regional adjustment indicates that their expenditures were less than that of their regional service area. For ACOs receiving a positive regional adjustment, the average regional adjustment amount was 2.21 percent ($237) of historical benchmark expenditures.

As of January 1, 2024, 43 percent (207 of 480) Shared Savings Program ACOs are participating under the ENHANCED track. Under Shared Savings Program policies, all ACOs participating in a two-sided model can select a symmetrical MSR and MLR which applies for the duration of its agreement

period (§ 425.605(b)(2); § 425.610(b)(1)). Among ACOs participating in the ENHANCED track for PY 2024, 61 percent (126 of 207) have selected an MSR/MLR of 0.5 percent or greater while 39 percent (81 of 207) have selected an MSR/MLR of 0.0 percent. Among ACOs that participated in the ENHANCED track for PY 2022, 38 percent (55 of 146) generated gross savings between zero and 5 percent of their updated benchmark expenditures, and 12 percent (17 of 146) generated gross savings of 10 percent or more of their benchmark expenditures.

(b) Other CMS Innovation Center Models

In the NGACO Model, NGACOs were offered the choice between two risk arrangements, partial risk or full risk. Under both arrangements, the NGACO was responsible for 100 percent of performance year expenditures for services rendered to the NGACO's aligned beneficiaries. Under the partial risk arrangement, the NGACO could receive or owe up to 80 percent of savings/losses, whereas under the full risk arrangement, the NGACO could receive or owe up to 100 percent of savings/losses. To mitigate the ACO's risk of large shared losses, as well as to protect the Medicare Trust Funds against paying out excessive shared savings, NGACOs were required to choose a cap on gross savings/losses. The cap, expressed as a percentage of the benchmark, ranged from 5 percent to 15 percent. The risk arrangement chosen by the NGACO (80 or 100 percent) was applied to gross savings or losses after the application of the cap. In PYs 1–3, a discount was applied to the NGACO's benchmark that was set at a standard 3 percent, with various adjustments, that allowed the final discount to vary from 0.5 percent to 4.5 percent. In PYs 4–6, a discount of 0.5 percent was applied to the benchmark under the partial risk arrangement, and a discount of 1.25 was applied to the benchmark under the full risk arrangement. The purpose of the discount was to increase the likelihood that any savings achieved by the NGACOs participating in the model would also result in savings for the Medicare Program. The NGACO Model evaluation found that while NGACOs reduced gross Medicare Parts A and B expenditures relative to a comparison group of similar fee-for-service Medicare beneficiaries in their markets, they did not generate savings to the Medicare Trust Funds. ACOs that elected a risk cap greater than 5 percent and participated in model population-based payment mechanisms achieved greater declines in spending, suggesting that the combination of risk and payment flows is impactful. Spending reductions grew larger almost every year, reflecting a combination of NGACOs' improvements in infrastructure and clinical processes, exit by poorer-performing NGACOs, and the COVID–19 pandemic. While the NGACO Model reduced spending in Medicare Parts A and B, CMS paid back these reductions in the form of shared savings payments to ACOs. These results highlight the need to balance the tradeoff between incentivizing participation in higher levels of risk and reward, in alternative payment models such as the Shared Savings Program and ACO models tested by the Innovation Center, and reducing the risk of loss to the Medicare Trust Funds.

Under the ACO REACH Model, REACH ACOs are offered the choice of participating under the Global or the Professional Risk Sharing Options. As in the NGACO Model, under both risk sharing options, the REACH ACO is responsible for 100 percent of performance year expenditures for services rendered to aligned beneficiaries. Because ACOs electing the Global Risk Sharing Option retain up to 100 percent of the savings/losses on all savings up to 25 percent of their benchmark, with reduced sharing rates for savings exceeding 25 percent of their benchmark, a discount is applied to the benchmark to ensure savings are also generated for CMS. For ACOs in the Global Risk Sharing Option, the benchmark is reduced by a fixed percentage based on the performance year.[539] The discount rate for PYs 2021 and 2022 was 2 percent, for PYs 2023 and 2024 is 3 percent, and for PYs 2025 and 2026 will be above 3.5 percent. The benchmark for ACOs participating in the Professional Risk Sharing Option does not include this discount, and these ACOs are only eligible to retain 50 percent of savings or owe 50 percent of any losses.

Preliminary evaluation results of the first 2 performance years of the Global and Professional Direct Contracting Model, before its transition to the ACO REACH Model, suggest that participating ACOs had mixed results in gross spending but consistent, significant increases in net spending relative to a comparison group of similar FFS Medicare beneficiaries in their markets, which included beneficiaries assigned to ACOs participating in the Shared Savings Program. Standard ACOs, comprised of organizations that generally have experience serving Medicare FFS beneficiaries, increased gross spending. Standard ACOs also reduced acute care spending and utilization but comparison providers had larger reductions in acute care spending and utilization. Increased spending among Standard ACOs was concentrated among the integrated delivery system/hospital system ACOs in the model. High Needs ACOs that serve Medicare FFS beneficiaries with complex needs, including dually eligible beneficiaries, decreased gross spending. High Needs ACOs comprised of organizations that have not traditionally provided services to Medicare FFS beneficiaries favorably reduced acute and post-acute care utilization and spending. New Entrant ACOs had declines in gross spending but these declines were similar to those of providers within their same markets. Standard and New Entrant ACOs showed statistically significant improvement on at least one quality measure. These interim evaluation results are mixed, and additional analyses and years of experience with the Model will inform which features of ACO REACH could drive continued growth and innovation in the Shared Savings Program and the focus of future Innovation Center ACO models.

(2) Considerations for Incorporating Higher Risk and Potential Reward Under the ENHANCED Track

As we explained in the CY 2024 PFS final rule (88 FR 79223 through 79225), when considering a higher risk track, CMS would need to balance the incentives for ACOs to transition to higher levels of risk and potential reward and increase ACO participation in the Shared Savings Program and in two-sided risk tracks, all while ensuring sufficient financial safeguards to protect against inappropriately large shared losses for ACOs coordinating and improving quality of care for high-cost beneficiaries. Considerations must also be directed towards safeguarding the Medicare Trust Funds and ensuring that CMS satisfies any statutory requirements under section 1899(i)(3) of the Act.

A revised ENHANCED track could be implemented in accordance with section 1899(i)(3) of the Act, provided the Secretary determines that such other payment model enhances the quality and efficiency of items and services furnished under the Medicare program and does not result in program expenditures greater than those that would result under the statutory

[539] For more details, refer to CMS, ACO Realizing Equity, Access, and Community Health (REACH) Model, PY2023 Financial Settlement Overview, available at *https://innovation.cms.gov/media/document/aco-reach-py2023-fncl-settlement* (see Table 4: Schedule of Discounts by Risk Arrangement).

payment model. Increasing the sharing rate in the ENHANCED track may need to be accompanied by other modifications to prevent spending from increasing and possibly jeopardizing compliance with section 1899(i)(3) of the Act. One factor to consider is selective participation with regard to which ACOs would choose to participate in a higher risk track, if offered. For example, Shared Savings Program ACOs that have a history of high levels of earned shared savings or have received a favorable high regional adjustment to their benchmark may be more likely than other ACOs to switch to the higher risk track upon renewing or early renewing their participation in the program so they can receive additional benefit from the higher levels of potential reward offered in a higher risk track. This could result in increased spending on the part of CMS which may jeopardize compliance with section 1899(i)(3) of the Act. If a higher risk track were to be offered in the Shared Savings Program in the future, CMS would consider replacing the existing ENHANCED track in order to prevent further selective participation and maintain the balance between increased participation and compliance with applicable statutory requirements.

We are seeking comment on the following potential features of a revised ENHANCED track:

(a) Benchmark Discount Rate

Both the NGACO Model and the Global Risk Sharing Option of the ACO REACH Model feature a discount rate that is applied to benchmarks. The discount rate serves to protect the Medicare Trust Funds by reducing benchmarks and thereby improves the likelihood of achieving savings for the Medicare program for risk tracks that can feature up to 100 percent shared savings rates, such as the Global Risk Sharing Option in the ACO REACH Model. A discount would be applied to an ACO's updated historical benchmark before gross savings/losses are calculated, which increases the likelihood of savings for CMS and the Medicare program. If an ACO were to participate in a potential higher risk track and potentially share in 100 percent of gross savings, this discount would serve as the primary means for CMS to capture savings from ACOs participating in this option, as in the absence of a discount any and all gross savings would go to ACOs in the form of a shared savings payment. For example, consider an ACO with an updated benchmark of $10,000 and mean per-capita performance year expenditures of $9,500. Applying a discount rate of 1 percent to the benchmark would reduce the ACO's benchmark to $9,900. Gross savings would then be calculated based on the discounted benchmark, and the ACO's shared saving rate would be applied to the savings, provided these savings met or exceeded the ACO's selected MSR.

A discount to the benchmark could also include a guardrail policy similar to the guardrail implemented in the three-way blended update factor that was finalized in the CY 2023 PFS final rule (87 FR 69881). Under such an approach, if an ACO were to be liable for shared losses after discounting the benchmark, then gross savings or losses would be recalculated using a benchmark without the discount. However, if the ACO were to generate gross savings in excess of their MSR under the benchmark without the discount, they would still not be considered eligible to share in savings. This approach would help ensure that CMS shares in any savings generated by ACOs participating in a potential revised ENHANCED track while also not increasing downside risk for ACOs that may be liable for shared losses.

We seek comment on what rate would be appropriate for a discount to the benchmark that would protect the Medicare Trust Funds while providing an adequate incentive for ACOs to participate in a potential revised ENHANCED track. We also seek comment on whether the model features described in following subsections might replace a discount to the benchmark while balancing financial incentives for ACOs and risk to CMS. Additionally, we also seek comments from interested parties, including ACOs, on the discount to the benchmark and what level of discount would be acceptable to ACOs participating in the Shared Savings Program, as well as what would be considered too high of a discount.

(b) Tapered Sharing Arrangements

Currently in the ENHANCED track, ACOs can receive a shared savings payment of up to 20 percent of their updated benchmark (once the MSR is met or exceeded) (§ 425.610(e)(2)) or be liable for losses not to exceed 15 percent of their updated benchmark (once the MLR is met or exceeded) (§ 425.610(g)). Alternatively, CMS could set up marginal savings bands or risk corridors under which shared savings or losses rates would vary with the amount of gross savings or losses. As gross savings/losses increase, the ACO will retain a progressively smaller portion of the total savings or will be responsible for a progressively smaller portion of the total losses. For example, consider hypothetical marginal savings bands shown in Table 44. Under this arrangement, an ACO would share in all savings up to 10 percent of their updated benchmark at a rate of 100 percent. For savings between 10 to 15 percent, the ACO would share in 60 percent of savings and CMS would retain the remaining 40 percent. For savings between 15 to 20 percent, the ACO would share in 40 percent of savings and CMS would retain the remaining 60 percent. In case of losses, ACOs would be responsible for 50–100 percent of the losses, depending on the ACO's quality performance score.

TABLE 44: Hypothetical Marginal Shared Savings Bands

Gross savings as % of benchmark	*Shared Savings/Loss Rate*[1]
0-10%	100%
10-15%	60%
15-20%	40%
>20%	0%
Losses	50% - 100%[2]

[1] Percentage of savings or losses retained by the ACO.

[2] Shared Loss Rate would depend on an ACO's quality performance, similar to § 425.610(f)(4).

We seek comment on whether the hypothetical marginal shared savings bands shown in Table 44 represent an appropriate tapering schedule that would provide sufficient incentive for an ACO to participate in a potential revised ENHANCED track, as well as whether the tapering schedule should begin with lower shared savings rates and feature increasing rates as an ACO generates greater amounts of savings. We also seek comment on whether a potential tapering schedule should be symmetrical with respect to shared loss rates. Finally, we seek comment on whether marginal shared savings bands provide the right incentives to ACOs relative to the fixed savings rate in the current ENHANCED track.

(c) MSR/MLR

We are considering the option for all ACOs under a revised ENHANCED track to be subject to a symmetric MSR/MLR of 0 percent. This would increase many ACOs' exposure to both positive savings and negative risk. While this approach would guarantee that any ACO generating savings would share in those savings (provided they meet the quality performance standard established under § 425.512 and otherwise maintain their eligibility to participate in the Shared Savings Program), ACOs with performance year expenditures greater than their historical benchmark would be liable for those losses due to the 0 percent MLR. We are seeking comment on whether a potential revised ENHANCED track should retain the existing symmetric MSR/MLR selection options that currently exist for ACOs in a two-sided risk model under § 425.610(b)(1).

(d) Cap On Regional Adjustment Weight

We are seeking comment on adjusting the weights used to calculate the regional adjustment amounts under § 425.656(e) for ACOs in the revised ENHANCED track. This may take the form of applying a cap of 35 percent to all the weights used to calculate regional adjustment amounts. This would impact any ACOs in a second or subsequent agreement period subject to a regional adjustment if their historical benchmark spending is lower than their regional service area. If the cap were to apply to an ACO with lower spending than their regional service area, then this would result in a decreased regional adjustment to that ACO's historical benchmark. Overall, this feature would reduce the cost to CMS associated with high regional adjustments by reducing an ACO's historical benchmark in the event that an ACO in a second or subsequent agreement period receives a large positive regional adjustment, which may decrease the need for higher benchmark discount rates or lower tapered shared savings rates that are less favorable to ACOs and limit incentives for ACOs to transition from the BASIC track to the revised ENHANCED track. This feature may also increase the relative impact of the prior savings adjustment and the health equity benchmark adjustment proposed in section III.G.7.b. of this proposed rule. We seek comment on whether further reductions to or the removal of the regional adjustment to the historical benchmark would be appropriate as part of a potential revised ENHANCED track. We also seek comment on whether maintaining the regional adjustment in its current state would warrant further changes to the revised ENHANCED track features described above, including, but not limited to, a discount to the benchmark or lower tapered shared savings rates.

(e) Payment Mechanisms

We are seeking comments on alternative payment mechanisms the Innovation Center has tested and their ability to help transform care delivery and improve health outcomes for ACOs participating in the Shared Savings Program. These payment mechanisms test whether alternative payment flows (that is, those other than fee for service reimbursement) facilitate better investment in infrastructure and care coordination and encourage innovative downstream payment arrangements that can improve health outcomes for Medicare beneficiaries. The alternative payment mechanisms on which we seek comments are described below:

- *Infrastructure Payments:* Under these arrangements, CMS makes a payment to the ACO, in addition to FFS reimbursement to the providers and suppliers participating in the ACO, that is unrelated to claims. Infrastructure payments have been distributed either as a lump sum or per beneficiary per month payments. Infrastructure payments are recouped during the payment reconciliation process.
- *Population-Based Payment, All-Inclusive Population-Based Payment, or Advance Payment Option:* In this arrangement, CMS provides a percentage of FFS reimbursement to the ACO in the form of a monthly payment to support ongoing ACO activities and provide the ACO flexibility in the types of arrangements it enters into with provider/suppliers. The ACO and providers with whom it has a written business arrangement determine percentage reductions to the base FFS payments to the providers interested in this payment arrangement. Providers participating in this option have their FFS payments reduced by the agreed upon percentage, which range from 1–100 percent. CMS pays the projected total annual amount taken out of the base FFS rates to the ACO in monthly payments. At the end of each performance year, the amount of payment paid to ACOs participating in this type of payment option is reconciled against the reductions actually made to claims payments to providers participating in these arrangements, linking the amount of

these payments directly to utilization and FFS payment.

• *Capitation:* The ACO REACH Model [540] tests two capitation payment options—Primary Care Capitation and Total Care Capitation.

The Primary Care Capitation Payment is the payment for primary care services provided to aligned REACH beneficiaries by all Participant Providers and those Preferred Providers who have selected Primary Care Capitation Payment. In Primary Care Capitation, a per beneficiary, per month capitated payment is provided to an ACO for its aligned beneficiaries for the primary care services provided by the ACO's Participant Providers and its Preferred Providers who have opted to participate in Primary Care Capitation Payment. The Primary Care Capitation payment amount is generally equal to seven percent of the estimated total cost of care for the ACO's aligned population (that is, the risk adjusted, trended, and regionally blended benchmark).

The Primary Care Capitation payment includes two components, Base Primary Care Capitation and Enhanced Primary Care Capitation. The Base Primary Care Capitation amount is intended to cover primary care services furnished to aligned beneficiaries by Participant Providers and those Preferred Providers who have agreed to participate in Primary Care Capitation Payment that are thus subject to fee reductions under Primary Care Capitation Payment. The Enhanced Primary Care Capitation amount, which will be recouped by CMS in full during final financial settlement, is intended to enable ACOs to make upfront investments in infrastructure, technology, tools, and resources to support increased access to primary care, provision of care, and care coordination. The Primary Care Capitation Payment is expected to encourage greater flexibility in payment and innovative primary care service delivery as a means of improving the quality and cost effectiveness of care overall.

In Total Care Capitation, a per-beneficiary, per month capitated payment is provided to an ACO for all Medicare Part A and Part B services provided to aligned beneficiaries by the ACO's Participant Providers and its Preferred Providers who have opted to participate in Total Care Capitation payment. The Total Care Capitation payment amount reflects the estimated total cost of care for the ACO's aligned population (that is, the risk adjusted, trended, and regionally blended benchmark) and is only available to ACOs participating in the Global risk option. Participant Providers and those Preferred Providers that have elected to participate in the ACO's selected capitation payment mechanism continue to submit claims to CMS for services provided to aligned beneficiaries. The CMS FFS claims processing system reduces claims payment amounts according to the payment reduction arrangements with their providers. More details on ACO REACH Model's capitation payment mechanisms are available here: *https://www.cms.gov/files/document/aco-reach-py24-financial-ops-capitation-and-payment-mechanisms.pdf.*

Additionally, we are interested in feedback on the following questions related to implementation of a revised ENHANCED track with higher risk and potential reward, as well as comments that could inform changes to the Shared Savings Program and future Innovation Center ACO models:

1. What would the option of a revised ENHANCED track allow an ACO to do that they are unable to do currently?

2. How would higher downside risk impact an ACO's care delivery strategies, including advanced primary care, behavioral health, specialty integration, and integration with community-based organizations to improve health outcomes or advance health equity?

3. How does higher downside risk impact an ACO's downstream provider arrangements to further advance incentives to reduce delivery of low value services and the total cost of care, and to increase savings performance?

4. What types of organizations, including but not limited to ACOs and providers, are interested in a higher risk and reward option in the Shared Savings Program?

5. What additional flexibilities or features (for example, benefit enhancements, advance payments, capitation payments, etc.) would ACOs in a revised ENHANCED track with higher risk and potential reward want CMS to offer to help them be successful in improving the quality of care and reducing costs?

6. How should a revised ENHANCED track with higher risk and potential reward also require additional accountability for quality? Should ACOs in this revised track be required to report all payer/all patient quality measures?

7. Should a revised ENHANCED track with higher risk and potential reward require ACOs with earned shared savings to share savings with beneficiaries or spend a flat dollar amount or a certain percentage on beneficiaries in the form of items or services not covered by original Medicare (for example, meals, dental, vision, hearing, or Part B cost-sharing reductions)?

8. How should CMS consider the discount, sharing rate, and risk corridors or marginal savings bands in the design of a higher risk option that can realize savings for Medicare? Are there special considerations that CMS should bear in mind when thinking through such features for different types of ACOs (for example, low revenue, high revenue, health system-based, safety net, etc.)?

9. How might we improve beneficiary assignment and are there different considerations for different types of ACOs (for example, low revenue, high revenue, health system-based, safety net, etc.)?

10. What other features should CMS consider in designing financial benchmarks that balance prospectivity and accuracy, and that can lead to savings for both ACOs and Medicare? How might administratively set benchmarks achieve these goals and what considerations should we bear in mind if we test administrative benchmarking?

11. We are interested in ways to increase participation by healthcare providers and suppliers in the Shared Savings Program and future Innovation Center ACO models, including how an ACO model requiring provider participation or stronger participation incentives might be designed.

f. Proposed Technical Change for Consistency in Financial Calculations

(1) Background

For the benchmarking methodology applicable to agreement periods beginning on January 1, 2024, and in subsequent years, we cap ACO prospective hierarchical condition category (HCC) risk score growth between BY3 and the performance year (as finalized in the CY 2023 PFS final rule, refer to 87 FR 69932 through 69946), as well as prospective HCC risk score growth in an ACO's regional service area between BY3 and the performance year (as finalized in the CY 2024 PFS final rule, refer to 88 FR 79174 through 79185). The policy to cap ACO prospective HCC risk score growth between BY3 and the performance year relied on our authority granted by section 1899(d)(1)(B)(ii) of the Act to

[540] Refer to the ACO REACH Model Request for Applications, available at *https://www.cms.gov/priorities/innovation/media/document/aco-reach-rfa,* and the ACO REACH Model PY2024 Participant and Preferred Provider Management Guide, available at *https://www.cms.gov/files/document/aco-reach-py24-part-pref-provider-mgmt-guide.pdf.*

adjust the benchmark for beneficiary characteristics and such other factors as the Secretary determines appropriate (see 87 FR 69934). The policy to cap prospective HCC risk score growth in an ACO's regional service area between BY3 and the performance year by applying an adjustment factor in calculating the regional component of the three-way blended benchmark update factor required use of our statutory authority under section 1899(i)(3) of the Act (see 88 FR 79182 and 79183).

The current regulations describe how we cap ACO prospective HCC risk score growth at §§ 425.605(a)(1) and 425.610(a)(2). As specified, positive adjustments in prospective HCC risk scores are subject to a cap equal to the ACO's aggregate growth in demographic risk scores between BY3 and the performance year (positive or negative) plus 3 percentage points. The cap applies to prospective HCC risk score growth for any Medicare enrollment type only if the ACO's aggregate growth in prospective HCC risk scores between BY3 and the performance year across all of the Medicare enrollment type exceeds this cap. Growth in an ACO's risk scores by enrollment type is expressed as the ratio of the ACO's performance year risk score for that enrollment type to the ACO's BY3 risk score for that enrollment type. The aggregate growth in demographic and prospective HCC risk scores risk scores is calculated by taking a weighted average of the risk ratio for demographic risk scores or prospective HCC risk scores, as applicable, for each Medicare enrollment type using specified weights.

The current regulations further describe how we cap prospective HCC risk score growth in the ACO's regional service area at § 425.655. As specified, CMS determines aggregate growth in regional prospective HCC and demographic risk scores by calculating growth in prospective HCC and demographic risk scores between BY3 and the performance year for each Medicare enrollment type, where growth in an ACO's regional risk score by enrollment type is expressed as the ratio of the performance year regional risk score for a Medicare enrollment type to the BY3 regional risk score for that enrollment type. We then calculate aggregate risk score growth by taking a weighted average of the regional prospective HCC or demographic risk ratios, as applicable, across the four Medicare enrollment types, using specified weights. We next determine the cap on regional risk score growth (refer to § 425.655(e)),[541] and then determine if the ACO's regional risk score growth is subject to a cap and apply a regional risk score growth cap adjustment factor for each Medicare enrollment type, as applicable (refer to § 425.655(f)).[542]

When describing how we will cap prospective HCC risk score growth in the ACO's regional service area in the CY 2024 PFS final rule, we included a footnote (see 88 FR 79178) that indicated that the weights to be used to compute aggregate risk score growth for this calculation are the same as the weights to be used when calculating weighted average ACO prospective HCC and demographic risk ratios under the risk adjustment methodology for capping ACO risk score growth adopted in the CY 2023 PFS final rule and codified in §§ 425.605(a)(1)(ii)(C) and 425.610(a)(2)(ii)(C). That is, it was our intention to use the same weights in both the regional risk score growth cap calculation and the ACO risk score growth cap calculation. However, in codifying the methodology for the regional risk score growth cap in the new section of the regulations, § 425.655, we inadvertently introduced a discrepancy.

In §§ 425.605(a)(1)(ii)(C) and 425.610(a)(2)(ii)(C), where we codified how we will calculate aggregate risk score growth used in determining the cap to apply to ACO prospective HCC risk score growth, we describe the weight applied to the growth in demographic or prospective HCC risk scores for each Medicare enrollment type as equal to the product of the *historical benchmark expenditures* for that enrollment type and the performance year person years for that enrollment type. In § 425.655(d)(2), where we codified how we will calculate aggregate risk score growth used in determining the cap to apply to regional prospective HCC risks score growth, we describe the weight applied to the growth in demographic or prospective HCC risk scores for each Medicare enrollment type as equal to product of the ACO's *regionally adjusted historical benchmark expenditures* (emphasis added) for that enrollment type and the ACO's performance year assigned beneficiary person years for that enrollment type.

The regulations at §§ 425.605(a)(1)(ii)(C) and 425.610(a)(2)(ii)(C) provide that we will use the ACO's historical benchmark expenditures in calculating the weights used to cap ACO risk score growth. By contrast, the regulations at § 425.655(d)(2) provide that we will use an ACO's regionally adjusted historical expenditures in calculating the weights used in the calculation of regional risk score growth cap. As written, the regulations text at § 425.655(d)(2) is inconsistent with the language used in in §§ 425.605(a)(1)(ii)(C) and 425.610(a)(2)(ii)(C) despite the fact that we indicated in the CY 2024 PFS final rule that we would use the same weights in both calculations. Additionally, it is unclear how we would apply the calculation described at § 425.655(d)(2) in practice. As we describe in section III.G.7.b. of this proposed rule, for agreement periods beginning on January 1, 2024, and in subsequent years, in computing an ACO's historical benchmark, CMS determines the per capita Parts A and B fee-for-service expenditures for beneficiaries that would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period using the ACO participant TINs identified before the start of the agreement period as required under § 425.118(a) and the beneficiary assignment methodology selected by the ACO for the first performance year of the agreement period as required under § 425.400(a)(4)(ii). An ACO's historical benchmark may then be subject to a regional adjustment (refer to § 425.656), a prior savings adjustment (refer to § 425.658), or no adjustment (refer to § 425.652(a)(8) and (c)). This methodology, based on policies finalized in the CY 2023 and CY 2024 PFS final rules, under which an ACO may receive a prior savings adjustment, a regional adjustment, and or no adjustment at all, differs from the methodology that was in effect for ACOs in an agreement period beginning on or after July 1, 2019, but before January 1, 2024, under which all ACO historical benchmarks incorporated a regional adjustment (see § 425.601). Furthermore, in section III.G.7.b. of this proposed rule we are proposing to add a third type of adjustment that could be

[541] To determine the cap on regional risk score growth, we calculate the non-market share adjusted cap on the ACO's regional risk score growth as the sum of the aggregate growth in regional demographic risk scores and 3 percentage points, then adjust the cap to reflect the ACO's aggregate market share.

[542] If the aggregate regional prospective HCC risk score growth does not exceed the cap on regional risk score growth, the ACO's regional risk score growth is not subject to the cap. For these ACOs we set the risk score growth cap adjustment factor equal to 1 for each Medicare enrollment type. If the aggregate regional prospective HCC risk score growth exceeds the market share adjusted cap, the ACO's regional risk score growth is subject to the cap. For these ACOs we next determine whether the cap on regional risk score growth applies for each Medicare enrollment type.

applied to an ACO's historical benchmark, the health equity benchmark adjustment. If the health equity benchmark adjustment is finalized as proposed, an ACO may receive a regional adjustment, a prior savings adjustment, a health equity benchmark adjustment, or no adjustment to its historical benchmark.

(2) Proposed Revisions

As we described in a footnote in the CY 2024 PFS final rule (see 88 FR 79178), it was our intention at the time to use the same weights to calculate the cap for prospective HCC risk score growth in an ACO's regional service area as the weights used to calculate the cap on prospective HCC risk score growth for the ACO. We continue to believe that the same weights should apply to both calculations. However, the regulation text language is not currently aligned among the relevant provisions or with the preamble discussion and may also create confusion with respect to how CMS will compute the weights used in setting the caps on ACO and regional prospective HCC risk score growth, given that some ACOs will receive a regional adjustment to their benchmarks, some will receive a prior savings or, if finalized, a health equity benchmark adjustment, and some will receive no adjustment at all.

To address these issues, we are proposing technical changes to the regulation text at §§ 425.605(a)(1)(ii)(C), 425.610(a)(2)(ii)(C), and 425.655(d)(2) to align the language describing the calculation of the weights that will be used to compute aggregate risk score growth across the three provisions and to clarify that the weight applied to the growth in ACO and regional risk scores for each Medicare enrollment type, respectively, would be equal to the product of the ACO's historical benchmark expenditures, adjusted in accordance with § 425.652(a)(8), for that enrollment type and the ACO's performance year assigned beneficiary person years for that enrollment type. That is, we would use the ACO's historical benchmark expenditures that would have already been adjusted to reflect a prior savings adjustment, a regional adjustment, a health equity benchmark adjustment, if finalized, or no adjustment. Aligning the description of the weight calculation across the three provisions would address the discrepancy that exists between the current regulation text and the preamble discussion in the CY 2024 PFS final rule. Additionally, providing additional detail in the description of the weight calculation, namely by indicating that we will use an ACO's historical benchmark expenditures adjusted in accordance with § 425.652(a)(8), clarifies how we will operationalize the calculation which we believe is important, especially given the proposed health equity benchmark adjustment, which, if finalized, would add greater complexity to this historical benchmark calculation.

The technical changes that we are proposing in this section of this proposed rule relate to benchmark calculations for ACOs in agreement periods beginning on or after January 1, 2024. Although we will not implement the proposed methodologies for the first time until summer 2025 when we reconcile PY 2024, these policies, if finalized, would constitute retroactive rulemaking because they are the standards under which we will score ACOs that are currently participating in agreement periods that began on January 1, 2024, for PY 2024. Section 1871(e)(1)(A)(ii) of the Act permits a substantive change in regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability under Title XVIII of the Act to be applied retroactively to items and services furnished before the effective date of the change if the failure to apply the change retroactively would be contrary to the public interest. Here, we are proposing a technical change that would align the regulation text with our stated intention as described in previous rulemaking. The current regulation text, in combination with related discussion in the CY 2024 PFS final rule, fails to provide sufficient clarity with regard to how CMS will calculate the weights used to calculate aggregate ACO or regional risk score growth. While the discussion in the CY 2024 PFS final rule indicates that the same weights should be use in both calculations, the related regulation text does not make this clear and, furthermore, could raise questions for how CMS will perform calculations given that not all ACO historical benchmarks will include a regional adjustment. Failure to apply the proposed changes to our regulations at §§ 425.605(a)(1)(ii)(C), 425.610(a)(2)(ii)(C), and 425.655(d)(2) retroactively would be contrary to the public interest because it creates unintended ambiguity in the standard CMS will use when calculating risk score growth. Such ambiguity may make it difficult for ACOs and other interested parties to understand how CMS will perform these calculations or be interpreted to suggest that CMS would calculate risk score growth in a different manner, which was not the agency's intention.

We seek comment on these proposals.

8. Beneficiary Notification Requirements

a. Proposal To Modify the Requirements for When ACOs Must Provide the Beneficiary Information Follow-Up Communication

Under § 425.312(a), ACOs are required to notify beneficiaries about the ACO's participation in the Shared Savings Program, the beneficiary's ability to decline claims data sharing, and the beneficiary's ability to select a provider for the purposes of voluntary alignment. In the CY 2023 PFS final rule (87 FR 69961), CMS added the beneficiary information follow up communication requirement under § 425.312(a)(2)(v), which requires an additional follow up with a beneficiary who has received the beneficiary notification. In the CY 2023 PFS final rule (87 FR 69960 through 69963), CMS noted that the follow up communication promotes transparency and empowers beneficiaries to make an informed decision in choosing a primary care physician and how they share their health data. The beneficiary information follow-up communication affords the opportunity for additional direct engagement between the beneficiary and the ACO, or ACO participant, and provides a chance for a meaningful dialog between the patient and provider about the coordination of their care, the benefits of receiving care from an ACO provider/supplier (as defined in § 425.20), the organizational operations of the ACO, and how data is used to improve care and report quality outcomes.

Currently, under § 425.312(a)(2)(v)(A), ''The follow-up communication must occur no later than the earlier of the beneficiary's next primary care service visit or 180 days from the date the standardized written notice was provided.'' Regulations at § 425.312(a)(2)(v)(B) require ACOs to document the beneficiary information follow-up communication in a system of record supported by the ACO and to make the information available to CMS upon request.

Since CMS implemented the beneficiary information follow-up communication requirement, we have received feedback from ACOs that requiring the follow-up communication no later than the earlier of the beneficiary's next primary care service visit or 180 days from the date the standardized written notice was provided is difficult for ACOs to

operationalize as they do not always know when the beneficiary's next primary care service will be and in some cases it can be very soon after the beneficiary receives the original beneficiary notification.

In order to address this issue and the burden it creates, CMS is proposing to remove the requirement that ACOs must provide this follow up at the beneficiary's next primary care visit. Specifically, we propose to modify § 425.312(a)(2)(v)(A) to read ''The follow-up communication must occur no later than 180 days from the date the standardized written notice was provided.'' This would provide ACOs with more flexibility to implement their strategy for following up with beneficiaries after they receive the beneficiary notice, while still providing the opportunity for a meaningful dialog between a beneficiary and their provider. We seek comment on this proposal. If finalized, this proposal would be effective beginning January 1, 2025.

b. Limit the Distribution of the Beneficiary Notification to Beneficiaries Likely To Be Assigned for ACOs Under Preliminary Prospective Assignment With Retrospective Reconciliation

ACOs that select preliminary prospective assignment with retrospective reconciliation are assigned beneficiaries in a preliminary manner and before the start of the performance year. Beneficiary assignment for these ACOs is then updated quarterly based on the most recent 12 or 24 months of data, as applicable. This assignment methodology is codified at § 425.400(a)(2). We are proposing to limit the distribution of the beneficiary notification under § 425.312(a)(2)(iii) to beneficiaries who are more likely be assigned to ACOs that select preliminary prospective assignment with retrospective reconciliation, when compared to the population of beneficiaries who must receive the beneficiary notification under current § 425.312(a)(2)(iii). Please note that this is not a proposal to modify the Shared Savings Program's assignment methodology.

Currently, ACOs that select preliminary prospective assignment with retrospective reconciliation are required to send a beneficiary notice to ''each fee-for-service beneficiary'' under § 425.312(a)(2)(iii). Under § 425.312(a)(2)(iii), the standardized written notice must be furnished to ''all fee-for-service beneficiaries prior to or at the first primary care service visit during the first performance year in which the beneficiary receives a primary care service from an ACO participant.'' This can result in ACOs sending notices each year to beneficiaries who may not ultimately be assigned to the ACO, as there are ''fee-for-service beneficiar[ies]'' to whom ACOs must send notices under § 425.312(a)(2)(iii) and who are not eligible to be assigned to those ACOs for a variety of reasons. This policy was intended to ensure that all beneficiaries who receive a primary care visit from a ACO provider/supplier receive the beneficiary notice. However, we have heard feedback from ACOs that this creates confusion for the beneficiary and unnecessary administrative work for the ACO.

To reduce burden on ACOs and confusion for beneficiaries, we are proposing to update the beneficiary notice requirement for ACOs that select preliminary prospective assignment with retrospective reconciliation to focus on beneficiaries that are likely to be assigned to the ACO. These beneficiaries are those who received at least one primary care service during the assignment window or applicable expanded window for assignment (as defined in § 425.20) from a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in § 425.402(c), a FQHC or RHC that is part of the ACO, or an ACO professional in the ACO whom the beneficiary designated as responsible for coordinating their overall care under § 425.402(c).

This proposal would reduce the burden of sending the beneficiary notice to all ''fee for service beneficiar[ies],'' including those who ultimately would not be eligible to be assigned to ACOs that select preliminary prospective assignment with retrospective reconciliation. Specifically, we propose to modify § 425.312(a)(2)(iii) to state in the case of an ACO that has selected preliminary prospective assignment with retrospective reconciliation, the beneficiary notice must be provided by the ACO or ACO participant to each beneficiary who received at least one primary care service during the assignment window or applicable expanded window for assignment (as defined in § 425.20) from a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in § 425.402(c), a FQHC or RHC that is part of the ACO, or an ACO professional in the ACO whom the beneficiary designated as responsible for coordinating their overall care under § 425.402(e). Each such beneficiary must receive a standardized written notice at least once during an agreement period in the form and manner specified by CMS. The standardized written notice must be furnished to all of these beneficiaries prior to or at the first primary care service visit during the first performance year in which the beneficiary receives a primary care service from an ACO participant.

For ACOs that select prospective assignment, beneficiaries are prospectively assigned to the ACO at the beginning of each benchmark or performance year based on the beneficiary's use of primary care services in the most recent 12 or 24 months, as applicable, for which data are available, using the assignment methodology described in §§ 425.402 and 425.404. *See* § 425.400(a)(3)(i). Beneficiaries that are prospectively assigned to an ACO under § 425.400(a)(3)(i) remain assigned to the ACO at the end of the benchmark or performance year unless they meet any of the exclusion criteria under § 425.401(b). *See* § 425.400(a)(3)(ii). We note that ACOs that select prospective assignment are subject to § 425.312(a)(2)(iv). Under this regulation, ACOs that select prospective assignment are required to furnish the beneficiary notice to all prospectively assigned beneficiaries once during an agreement period. We seek comment on this proposal. If finalized, this proposed change would be effective beginning on January 1, 2025.

H. Medicare Part B Payment for Preventive Services (§§ 410.10, 410.57, 410.64, 410.152)

1. Part B Preventive Vaccines and Their Administration

a. Statutory Background

Under section 1861(s)(10) of the Act, Medicare Part B covers both the vaccine and vaccine administration for the specified preventive vaccines—pneumococcal, influenza, hepatitis B and COVID–19 vaccines. Section 1861(s)(10)(B) of the Act specifies that the hepatitis B vaccine and its administration is only covered for those who are at high or intermediate risk of contracting hepatitis B, as defined at § 410.63. Under sections 1833(a)(1)(B) and (b)(1) of the Act, respectively, there is no applicable beneficiary coinsurance, and the annual Part B deductible does not apply for these vaccines or the services to administer them. Per section 1842(o)(1)(A)(iv) of the Act, payment for these vaccines is based on 95 percent of the Average Wholesale Price (AWP) for the vaccine

product, except when furnished in the settings for which payment is based on reasonable cost, such as a hospital outpatient department (HOPD), rural health clinic (RHC), or federally qualified health center (FQHC). Some other preventive vaccines, such as the zoster vaccine for the prevention of shingles, are not specified for Medicare Part B coverage under section 1861(s)(10) of the Act and are instead covered under Medicare Part D.

b. Pneumococcal, Influenza and Hepatitis B Vaccine Administration

In the CY 2022 PFS final rule (86 FR 65185), we finalized a uniform payment rate of $30 for the administration of a pneumococcal, influenza or hepatitis B vaccine covered under the Medicare Part B preventive vaccine benefit. We explained that since payment policies for the administration of the preventive vaccines described under section 1861(s)(10) of the Act are independent of the PFS, these payment rates will be updated as necessary, independent of the valuation of any specific codes under the PFS. (Please see COVID–19 vaccine administration payment information in the next section.) The CY 2022 PFS final rule (86 FR 65180 through 65182) provides a detailed discussion on the history of the valuation of the three Level II Healthcare Common Procedure Coding System (HCPCS) codes, G0008, G0009, and G0010, which describe the services to administer an influenza, pneumococcal, and hepatitis B vaccine, respectively.

In the CY 2023 PFS final rule (87 FR 69984), we finalized a policy to annually update the payment amount for the administration of Part B preventive vaccines based upon the percentage increase in the Medicare Economic Index (MEI). Additionally, we finalized the use of the PFS Geographical Adjustment Factor (GAF) to adjust the payment amount to reflect cost differences for the geographic locality based upon the fee schedule area where the preventive vaccine is administered. These adjustments and updates apply to HCPCS codes G0008, G0009, G0010.

These adjustments and updates also apply to Current Procedural Terminology (CPT) code 90480 (Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV–2) (coronavirus disease [COVID–19]) vaccine, single dose) that describe the service to administer COVID–19 vaccines and HCPCS code M0201 (Administration of pneumococcal, influenza, hepatitis b, and/or covid–19 vaccine inside a patient's home; reported only once per individual home per date of service when such vaccine administration(s) are performed at the patient's home), discussed below in section III.H.1.c and III.H.1.d, respectively, of this proposed rule.

The current payment rates for G0008, G0009, and G0010, as finalized in the CY 2024 PFS final rule, can be found on the CMS Vaccine Pricing website under the ''Seasonal Flu Vaccines'' tab, and then under the heading ''Locality-Adjusted Payment Rates.'' [543] The payment rates for these services, with the annual update applied for CY 2025, will be made available at the time of publication of the CY 2025 PFS final rule. The current forecast of the increase in the MEI for CY 2025 is 3.6 percent based on the 2017-based MEI. We note that the CY 2025 MEI increase factor for the final rule will be based on historical data through the 2nd quarter of 2024. Tables 45 and 46 in section III.H.1.f. of this proposed rule provide the CY 2025 projected payment rates for G0008, G0009, and G0010.

c. COVID–19 Vaccine Administration

In the CY 2022 PFS final rule (86 FR 65181 and 65182), we provided a detailed history regarding the determinations of initial payment rates for the administration of COVID–19 vaccines, and an explanation of how the payment policy evolved to a rate of $40 per dose. For CY 2022, we maintained the payment policy for the administration of COVID–19 vaccines and stated that while we believe it is appropriate to establish a single, consistent payment rate for the administration of all four Part B preventive vaccines in the long term, we will pay a higher, $40 payment rate for administration of COVID–19 vaccines in the short term, while pandemic conditions persisted (86 FR 65185).

In the CY 2023 PFS final rule (87 FR 69988 through 69993), we stated that due to timing distinctions between a PHE declared under section 319 of the Public Health Service (PHS) Act and an Emergency Use Authorization (EUA) declaration under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), we reconsidered the policies finalized in the CY 2022 PFS final rule in light of our goal to promote broad and timely access to COVID–19 vaccines. We explained that our goal would be better served if our policies with respect to payment for administration of these products, as addressed in the November 6, 2020 COVID–19 IFC (85 FR 71142) and CY 2022 PFS final rule (85 FR 18250), continue until the EUA declaration for drugs and biological products with respect to COVID–19 is terminated. Therefore, we finalized that we would maintain the current payment rate of $40 per dose for the administration of COVID–19 vaccines through the end of the calendar year in which the March 27, 2020 EUA declaration under section 564 of the FD&C Act (EUA declaration) for drugs and biological products ends. Effective January 1 of the year following the year in which the EUA declaration ends, the COVID–19 vaccine administration payment would be set at a rate to align with the payment rate for the administration of other Part B preventive vaccines, that is, approximately $30 per dose. As mentioned above, we also finalized that, beginning January 1, 2023, we would annually update the payment amount for the administration of all Part B preventive vaccines based upon the percentage increase in the MEI, and that we would use the PFS GAF to adjust the payment amount to reflect cost differences for the geographic locality based upon the fee schedule area where the vaccine is administered.

On September 11, 2023, the Food and Drug Administration (FDA) announced its recommendation to shift to a monovalent severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2) (coronavirus disease 2019 [COVID–19]) vaccine that targets the predominant XBB lineage virus strain for the 2023–2024 vaccine administration season.[544] In anticipation of this recommendation, in August 2023, the CPT Editorial Panel approved five new monovalent COVID–19 vaccine product codes for Pfizer and Moderna vaccines. In addition, they approved a new vaccine administration code (90480) for reporting the administration of any COVID–19 vaccine for any patient (pediatric or adult), replacing all previously approved specific vaccine administration codes. All previously approved COVID–19 vaccine product and vaccine administration codes were deleted from the CPT code set effective November 1, 2023, except for product code 91304, which represents the

[543] *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price/vaccine-pricing,* under the tab ''Seasonal Flu Vaccines'', and then under the header ''Locality-Adjusted Payment Rates.''

[544] *https://www.fda.gov/news-events/press-announcements/fda-takes-action-updated-mrna-covid-19-vaccines-better-protect-against-currently-circulating.*

Novavax COVID–19 vaccine product and remains active.[545]

The current payment rate for CPT code 90480 is available on the CMS COVID–19 Vaccine Pricing website, under ''COVID–19 Vaccines & Monoclonal Antibodies''.[546] The payment rate for this service, with the annual update applied for CY 2025, will be made available at the time of publication of the CY 2025 PFS final rule. As noted above, the current forecast of the increase in the MEI for CY 2025 is 3.6 percent based on the 2017-based MEI, however, the CY 2025 MEI increase factor for the final rule will be based on historical data through the 2nd quarter of 2024.

Due to the uncertainty surrounding the future of the EUA declaration for drugs and biological products for COVID–19, Tables 45 and 46, at the end of section III.H.1.f. of this proposed rule, reflect the potential alternative payment amounts for Part B preventive vaccine administration for CY 2025. Table 45 displays the CY 2025 Part B payment rates for preventive vaccine administration if the EUA declaration continues into CY 2025, and Table 46 displays the CY 2025 Part B payment rates for preventive vaccine administration if the EUA declaration ends on or before December 31, 2024.

d. In-Home Additional Payment for Administration of Preventive Vaccines

In the CY 2022 PFS final rule (86 FR 65187 and 65190), we provide a detailed discussion on the payment policy for COVID–19 vaccine administration in the home. In summary, providers and suppliers that administer a COVID–19 vaccine in the home, under certain circumstances, could bill Medicare for one of the existing COVID–19 vaccine administration CPT codes along with HCPCS code M0201 (*COVID–19 vaccine administration inside a patient's home; reported only once per individual home per date of service when only COVID–19 vaccine administration is performed at the patient's home*). For CY 2022, we continued to make an additional payment when a COVID–19 vaccine was administered in a beneficiary's home under certain circumstances and stated that we would make this payment until the end of the year in which the PHE expires.

In the CY 2023 PFS final rule (87 FR 69984 through 69986), we discussed that we had received many comments and requests from interested parties that the in-home add-on payment be applied more broadly to all preventive vaccines. Commenters also expressed concerns that discontinuation of the in-home additional payment would negatively impact access to the COVID–19 vaccine for underserved homebound beneficiaries. Therefore, we continued the policy of making an additional payment when a COVID–19 vaccine is administered in a beneficiary's home, under the certain circumstances for the duration of CY 2023. We explained that we were continuing the policy of additional payment for at-home COVID–19 vaccinations for another year in order to provide us time to track utilization and trends associated with its use, in order to inform the Part B preventive vaccine policy on payments for in-home vaccine administration for CY 2024. In addition, for CY 2023 we updated the payment amount by the CY 2023 MEI percentage increase and adjusted for geographic cost differences as we do the payment for the preventive vaccine administration service, that is, based upon the fee schedule area where the COVID–19 vaccine is administered, by using the PFS GAF (87 FR 69986).

In the CY 2024 PFS final rule (88 FR 79235 through 79237), we discussed the policy for the in-home additional payment for COVID–19 vaccine administration under the Part B preventive vaccine benefit for CY 2024 and subsequent years. We maintained the payment policy for COVID–19 vaccine administration and extended the additional payment to the administration of the other three preventive vaccines included in the Part B preventive vaccine benefit—the pneumococcal, influenza, and hepatitis B vaccines. As described at § 410.152(h)(3), effective January 1, 2024, the payment amount for the in-home administration of all four vaccines is identical, that is, Medicare Part B pays the same additional payment amount to providers and suppliers that administer a pneumococcal, influenza, hepatitis B, or COVID–19 vaccine in the home. This additional payment amount is annually updated using the percentage increase in the MEI and is adjusted to reflect geographic cost variations with the PFS GAF.

We stated that the in-home additional payment is limited to one payment per home visit, even if multiple vaccines are administered during the same home visit. We noted that every vaccine dose that is furnished during a home visit still receives its own unique vaccine administration payment. The additional payment for in-home Part B vaccine administration is only made if certain circumstances are met, as outlined at § 410.152(h)(3)(iii). Providers and suppliers that administer one of the Part B preventive vaccines in the home, under those circumstances, can bill Medicare for one of the existing Part B vaccine administration CPT codes along with HCPCS code M0201 (Administration of pneumococcal, influenza, hepatitis b, and/or covid–19 vaccine inside a patient's home; reported only once per individual home per date of service when such vaccine administration(s) are performed at the patient's home) (88 FR 79235 through 79237).

The current *payment* rate *for* M0201 can be found on the CMS Vaccine Pricing website under ''COVID–19 Vaccines & Monoclonal Antibodies''.[547] The M0201 payment rate with the annual update applied for CY 2025 will be made available at the time of publication of the CY 2025 PFS final rule. The current forecast of the increase in the MEI for CY 2025 is 3.6 percent based on the 2017-based MEI. We note that the CY 2025 MEI increase factor for the final rule will be based on historical data through the 2nd quarter of 2024. Tables 45 and 46 in section III.H.1.f. of this proposed rule provide the CY 2025 projected payment rate for M0201.

e. COVID–19 Monoclonal Antibodies and Their Administration

In CY 2023 PFS final rule (87 FR 69987 through 69993), we discussed that all COVID–19 monoclonal antibody products and their administration are covered and paid for under the Part B preventive vaccine benefit through the end of year in which the Secretary terminates the EUA declaration for drugs and biological products with respect to COVID–19. In addition, we explained that, under the authority provided by section 3713 of the CARES Act, we have established specific coding and payment rates for the COVID–19 vaccine, as well COVID–19 monoclonal antibodies and their administration, through technical direction to Medicare Administrative Contractors (MACs) and information posted publicly on the CMS website (87 FR 69987).

In the CY 2023 PFS final rule, we also established a policy to continue coverage and payment for monoclonal antibodies that are used for pre-exposure prophylaxis (PrEP) of COVID–

[545] CPT® Assistant Special Edition: August Update/Volume 33/2023. *https://www.ama-assn.org/system/files/cpt-assistant-guide-coronavirus-august-2023-updated.pdf.*

[546] *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price/vaccine-pricing,* under ''COVID–19 Vaccines & Monoclonal Antibodies''.

[547] *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price/vaccine-pricing,* under ''COVID–19 Vaccines & Monoclonal Antibodies''.

19 under the Part B preventive vaccine benefit if they meet applicable coverage requirements (87 FR 69992). We explained that we will continue to pay for these products and their administration even after the EUA declaration for drugs and biological products is terminated, so long as after the EUA declaration is terminated, such products have market authorization. Additionally, we established that payments for the administration of monoclonal antibodies that are used for PrEP of COVID–19 would be adjusted for geographic cost variations using the PFS GAF. In the CY 2024 PFS rule (88 FR 79239 through 79240), we codified these policies in regulations at §§ 410.10(l) and 410.57(c).

In CY 2024 PFS final rule (88 FR 79239 through 79240), we noted that we did not finalize any payment regulations regarding monoclonal antibodies for PrEP of COVID–19, since at the time of the publication of the CY 2024 PFS final rule, there were no COVID–19 monoclonal antibodies approved or authorized for use against the dominant strains of COVID–19 in the United States. We stated that if a new monoclonal antibody for PrEP of COVID–19 became authorized for use, we would use the authority provided by section 3713 of the CARES Act, as discussed in the CY 2023 PFS final rule (87 FR 69987), to establish specific coding and payment rates for the administration of that product through technical direction to MACs and information posted publicly on the CMS website. We explained that we would subsequently propose coding and payment rates for the administration of that product via rulemaking.

We also noted that, for the purposes of the in-home additional payment discussed above in section III.H.1.d. of this proposed rule, that additional payment is not applicable to the administration of monoclonal antibodies for PrEP of COVID–19. For monoclonal antibodies for PrEP of COVID–19, we set the coding and payment rates for the administration of COVID–19 monoclonal antibodies in the home (when applicable) to be higher than those in other health care settings, and therefore such amounts already account for the higher costs of administering the product in the home.

On March 22, 2024, the FDA issued an EUA for Pemgarda (pemivibart) injection, for intravenous use.[548] Pemgarda is a monoclonal antibody product indicated for use for pre-exposure prophylaxis to help prevent COVID–19 in adults and children 12 years of age and older who weigh at least 88 pounds (40 kg) who:

- Are not currently infected with SARS–CoV–2 and who have not been known to be exposed to someone who is infected with SARS–CoV–2 and
- Have moderate-to-severe immune compromise because of a medical condition or because they receive medicines or treatments that suppress the immune system and they are unlikely to have an adequate response to COVID–19 vaccination.

Therefore, under the authority provided by section 3713 of the CARES Act, we established specific coding and payment rates for the administration of Pemgarda through technical direction to MACs and information posted publicly on the CMS website. Since Pemgarda is used for pre-exposure prophylaxis of COVID–19, which CMS is covering under the Part B preventive vaccine benefit even after the EUA declaration for drugs and biological products is terminated (so long as such products still have market authorization), we plan to propose long-term coding and payment rates for the administration of this product in future rulemaking. The current payment rates for Pemgarda and its administration can be found on the CMS Vaccine Pricing website under ''COVID–19 Vaccines & Monoclonal Antibodies''.[549] These payment rates are also listed below in Tables 45 and 46.

More information on our coding and payment policies for COVID–19 monoclonal antibodies is available at *https://www.cms.gov/monoclonal*.

f. Summary of Payment Amounts for CY 2025

Due to the uncertainty surrounding the future of the EUA declaration for drugs and biological products for COVID–19, we are including Tables 45 and 46, which summarize Medicare Part B the potential alternative preventive vaccine administration payment amounts at the time of the publication of this proposed rule. If the EUA declaration continues to be in effect on January 1, 2025, we propose that the payment rates in Table 45 will apply. If the EUA declaration is terminated before January 1, 2025, we propose that the payment rates in Table 45 will apply.

For CY 2025, the proposed growth rate of the 2017-based MEI is estimated to be 3.6 percent, based on the IHS Global, Inc. (IGI) first quarter 2024 forecast with historical data through fourth quarter 2023. Therefore, Table 45 represents our CY 2024 payment rates for the listed items, multiplied by 1.036. We propose that if more recent data are subsequently available (for example, a more recent estimate of the MEI percentage increase), we would use such data, if appropriate, to determine the CY 2025 MEI percentage increase in the CY 2025 PFS final rule; we would apply that updated MEI percentage increase to the rates found in the Tables 45 and 46 where applicable.

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[548] *https://www.fda.gov/media/177068/download?attachment.*

[549] *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price/vaccine-pricing,* under ''COVID–19 Vaccines & Monoclonal Antibodies''.

TABLE 45: CY 2025 Part B Payments for Preventive Vaccine Administration if the EUA Declaration for Drugs and Biologicals with Respect to COVID-19 Continues into CY 2025

Category of Part B Product Administration	Part B Payment Amount (Unadjusted)	Annual Update[6]	Geographic Adjustment
Influenza, Pneumococcal, Hepatitis B Vaccines[1,4]	$33.74	MEI	GAF
COVID-19 Vaccine[2,4]	$44.99	MEI	GAF
In-Home Additional Payment for Part B Vaccine Administration (M0201)[4]	$39.94	MEI	GAF
COVID-19 Monoclonal Antibodies (for Treatment or Post-Exposure Prophylaxis)[3,4,5]	N/A	N/A	N/A
COVID-19 Monoclonal Antibodies (for Pre-Exposure Prophylaxis)[3,4]			
Intravenous Infusion: Health Care Setting	$450	N/A	GAF

[1] HCPCS Codes G0008, G0009, G0010.
[2] CPT code 90480.
[3] *https://www.cms.gov/monoclonal.*
[4] Beneficiary coinsurance and deductible are not applicable.
[5] As of the issuance of the CY 2025 PFS proposed rule, there are no monoclonal antibodies approved or authorized for the treatment or for post-exposure prophylaxis of COVID-19
[6] The proposed CY 2025 percentage increase of the 2017-based MEI is 3.6 percent based on IGI's first quarter of 2024 forecast with historical data through the 4th quarter of 2023.

TABLE 46: Part B Payments for Preventive Vaccine Administration Beginning January 1, 2025, if the EUA Declaration for Drugs and Biologicals with Respect to COVID 19 is Terminated on or Before December 31, 2024

Category of Part B Product Administration	Part B Payment Amount (Unadjusted)	Annual Update[6]	Geographic Adjustment
Influenza, Pneumococcal, Hepatitis B[1,4]	$33.74	MEI	GAF
COVID-19[2,4]	$33.74	MEI	GAF
In-Home Additional Payment for Part B Vaccine Administration (M0201)[4]	$39.94	MEI	GAF
COVID-19 Monoclonal Antibodies (for Treatment or Post-Exposure Prophylaxis)[3]	Medicare payment under the applicable payment system		
COVID-19 Monoclonal Antibodies (for Pre-Exposure Prophylaxis)[4,5]	TBD[5]	N/A	GAF

[1] HCPCS Codes G0008, G0009, G0010.
[2] CPT code 90480
[3] Payment is in accordance with the applicable payment system of the setting in which the product is administered. Beneficiary coinsurance and deductible are applicable.
[4] Beneficiary coinsurance and deductible are not applicable.
[5] Please see section III.H.1.e. of this proposed rule.
[6] The proposed CY 2025 percentage increase of the 2017-based MEI is 3.6 percent, based on IGI's first quarter of 2024 forecast with historical data through the 4th quarter of 2023.

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2. Revised Payment Policies for Hepatitis B Vaccine Administration

In section III.M of this proposed rule, CMS proposes to improve access and utilization of hepatitis B vaccines by expanding the list of individuals who are at high or intermediate risk of contracting hepatitis B at § 410.63. Specifically, CMS proposes to expand coverage of hepatitis B vaccinations by revising § 410.63(a)(2), Intermediate Risk Groups, by adding a new paragraph (a)(2)(iv) to include individuals who have not previously received a completed hepatitis B vaccination series and individuals whose previous vaccination history is unknown. CMS believes that this proposed coverage change will help protect Medicare beneficiaries from acquiring hepatitis B infection, contribute to eliminating viral hepatitis as a public health threat in the United States, and is in the best interest of the Medicare program and its beneficiaries. Below, we discuss how the proposal to expand coverage may impact Part B payment policy for hepatitis B vaccines and administration.

a. Background

Section 2323 of the Deficit Reduction Act of 1984 (Pub. L. 98–369) amended section 1861(s)(10) of the Act by adding subparagraph (B) to provide Medicare Part B coverage for the hepatitis B vaccine and its administration for those individuals who are at high or intermediate risk of contracting hepatitis B. The statute required the Secretary to determine, by regulations, criteria for identifying individuals who are at high or intermediate risk of contracting hepatitis B. In addition, section 2323 of the Deficit Reduction Act of 1984 added section 1833(k) of the Act, which states that the Secretary may provide, instead of the amount of payment otherwise provided under Part B for the hepatitis B vaccine and its administration, for payment of such an amount or amounts as reasonably reflects the general cost of efficiently providing such services.

In the June 4, 1990 **Federal Register**, CMS issued a final rule to implement section 2323 of the Deficit Reduction Act of 1984 and the coverage provisions were codified in regulation at § 410.63(a) (55 FR 22785). In the preamble to 1990 rule, we stated that, ''[f]or Medicare payment purposes, the hepatitis B vaccine may be administered—upon the order of a doctor of medicine or osteopathy—by qualified staff of home health agencies, skilled nursing facilities, ESRD facilities, hospital outpatient departments, HMO's, persons recognized under the 'incident to physician's services' provision of the law (section 1861(s)(2)(A) of the Act), as well as doctors of medicine and osteopathy.'' This policy is included in the Medicare Claims Processing Manual, Chapter 18, section 10.1.3.

In the CY 2013 PFS final rule (77 FR 69363), CMS amended the regulations at § 410.63(a) to include those diagnosed with diabetes mellitus in the list of groups at high risk of contracting hepatitis B. In the November 6, 2020 COVID–19 IFC (85 FR 71145), in preamble discussions surrounding the implementation of coverage and payment for the COVID–19 vaccine, we mentioned the unique coverage and payment requirements related the hepatitis B vaccine under Part B. We noted that, unlike pneumococcal, influenza and COVID–19 vaccines, hepatitis B vaccines require an assessment of a patient's risk of contracting hepatitis B. Because, hepatitis B vaccinations claims needed a physician's order, they could not be roster billed by mass immunizers. More information on the current physician's order policy for the administration of hepatitis B vaccines in Part B can be found in the Medicare Benefit Policy Manual, Chapter 15, Section 50.4.4.2.

b. Revisions to Payment Policies for Hepatitis B Vaccinations

As discussed above, section III.M of this proposed rule revises § 410.63(a) to provide coverage under Part B for hepatitis B vaccines and their administration for an expanded range of Medicare enrollees. We explain that Medicare coverage of hepatitis B vaccination is outdated in light of recent information about the risks of contracting hepatitis B, and that current research indicates that individuals who remain unvaccinated against hepatitis B are at intermediate risk of contracting hepatitis B virus. Under the new proposal, an assessment of an individual's vaccination status could now be made without the clinical expertise of a physician. Thus, if the rule is finalized, we would remove our policy in the manual that the administration of a Part B hepatitis B vaccine be preceded by a doctor's order. If the new definition at § 410.63(a) is finalized as proposed, then a doctor's order would no longer be necessary for the administration of a hepatitis B vaccine under Part B.

If the physician's order requirement is eliminated, then we would also change our procedures to allow mass immunizers to use the roster billing process to submit Medicare Part B claims for hepatitis B vaccines and their administration.

Currently, instructions regarding hepatitis B vaccine administration under part B are contained in CMS manual guidance. If changes to § 410.63(a) are finalized, then we would make corresponding changes to guidance in the Medicare Benefit Policy Manual and Medicare Claims Processing Manual. More information on roster billing is available on the CMS web page at *https://www.cms.gov/roster-billing*.

We note that the current payment rates for HCPCS code G0010, ''*Administration of hepatitis b vaccine,*'' as finalized in the CY 2024 PFS final rule, can be found on the CMS Vaccine Pricing website under ''Seasonal Flu Vaccines''.[550] The payment rates for G0010, with the annual update applied for CY 2025, will be made available at the time of publication of the CY 2025 PFS final rule. Tables 45 and 46 in section III.H.1.f. of this proposed rule provide the CY 2025 projected payment rates for G0010. More information on other policies related to the administration of G0010 can be found in the section preceding this one (section III.H.1. of this proposed rule), and proposed revisions to payment policies for the administration of G0010 in RHCs and FQHCs can be found in the section immediately below (section III.H.2.c. of this proposed rule).

c. Revisions to Payment Policies for Hepatitis B Vaccinations in Rural Health Clinics (RHC) and Federally Qualified Health Centers (FQHC)

When section 2323 of the Deficit Reduction Act of 1984 added section 1861(s)(10)(B) to the Act to add Medicare Part B coverage for the hepatitis B vaccine and its administration, it limited that coverage to certain settings. In RHCs and FQHCs, the law specified at section 1833(a)(3)(A) of the Act that the vaccines mentioned at section 1861(s)(10)(A) of the Act—namely, pneumococcal and influenza (and later, COVID–19) vaccines—are not included in the all-inclusive payment rate for an RHC or FQHC visit, but are reimbursed as a separate payment. Pneumococcal, influenza and COVID–19 vaccines and their administration are paid at 100 percent of reasonable cost when administered in an RHC or FQHC, in accordance with section 1833(a)(1)(B) of the Act. By contrast, hepatitis B vaccines and the cost of administration

[550] *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price/vaccine-pricing,* under ''Seasonal Flu Vaccines''; see links to the relevant year under ''Locality-Adjusted Payment Rates.''

are included in the capitated payment for an RHC or FQHC visit. RHCs and FQHC visits are generally paid at 80 percent of reasonable costs, and thus, they are subject to coinsurance for Medicare Part B enrollees. The Deficit Reduction Act of 1984 also added section 1833(k) to the Act, which states that, for hepatitis B vaccines and their administration as described at section 1861(s)(10)(B), the Secretary may provide, instead of the amount of payment otherwise dictated in statute, for payment that ''reasonably reflects the general cost of efficiently providing such services.''

In CY 2011 PFS final rule (75 FR 73418), we addressed the issue of coinsurance for hepatitis B vaccines and their administration in FQHCs. The CY 2011 PFS final rule, which implemented the expansion of preventive services in Medicare as mandated by the ACA, stated that effective January 1, 2011, Part B coinsurance on hepatitis B vaccinations was waived, as the vaccine and its administration were deemed ''preventive services'' per section 1861(ddd)(3)(A) of the Act as cross-referenced to section 1861(ww)(2) of the Act. (More information on preventive services is provided immediately below at section III.H.3. of this proposed rule). The CY 2011 PFS final rule codified this FQHC policy in regulation at § 405.2449. In the CY 2014 FQHC PPS final rule (79 FR 25474), at § 405.2410(b), we codified regulations regarding coinsurance in RHCs and FQHCs which exempt from coinsurance ''preventive services for which Medicare pays 100 percent under § 410.152(l) of this chapter'', which explicitly includes the hepatitis B vaccine. In the CY 2016 PFS final rule (80 FR 71088), we clarified that these waivers of cost-sharing (both coinsurance and deductible) for preventive services applied to RHCs as well, and we subsequently clarified in subregulatory guidance that these waivers apply to the administration of hepatitis B vaccines in RHC and FQHCs.[551] We note that FQHC services are always exempt from the Part B deductible, per section 1833(b)(4) of the Act.

Even though hepatitis B vaccines and their administration are deemed preventive services for which coinsurance (and deductible in RHCs) is waived, hepatitis B vaccines are still currently paid differently than other Part B vaccines in RHCs and FQHCs. Due to the statutory differences explained above, pneumococcal, influenza and COVID–19 vaccines and their administration are paid at 100 of reasonable cost in RHCs and FQHCs—that is, they are paid separately from the FQHC PPS or the RHC All-Inclusive Rate (AIR) methodology—while hepatitis B vaccines and their administration are paid as part of the FQHCs PPS or the RHC AIR, which means that they are paid through changes to the facilities' capitated rate.

In light of the proposal to expand coverage for hepatitis B vaccination in section III.M. of this proposed rule, we propose to use the aforementioned authority at section 1833(k) of the Act to align payment for hepatitis B vaccinations in RHCs and FQHCs with the payment for pneumococcal, influenza and COVID–19 vaccinations in those settings. That is, we propose to pay for hepatitis B vaccines and their administration in RHCs and FQHCs at 100 percent of reasonable cost, separate from the FQHCs PPS and the RHC AIR methodology, for all populations identified for coverage at § 410.63(a). As is the case for pneumococcal, influenza and COVID–19 vaccine administration, under this proposal, a hepatitis B vaccine administration would not be considered an RHC or FQHC visit. If this policy is finalized, then effective January 1, 2025, RHCs and FQHCs would bill for Part B hepatitis B vaccines in the same manner as they currently bill for pneumococcal, influenza and COVID–19 vaccines, that is, on their cost report. We note that we proposed above, in section III.B.5 of this proposed rule, to allow for billing and payment of all Part B preventive vaccines and their administration at the time of service in RHCs and FQHCs, with annual reconciliation on the facilities' cost reports. That policy, if finalized as proposed, would be effective for dates of service on or after July 1, 2025. Both proposals together support our goal of streamlining payment for all Part B vaccines across Part B settings of care. We believe that streamlining Part B vaccine and vaccine administration payments among care settings aligns with the stated goals of section 1833(k) of the Act, since those payment policy changes will allow for increased efficiency in Part B claims processing on both the part of the RHCs and FQHCs and on the part of CMS. We also believe that the increased efficiency will promote vaccine access, and thus health equity in general, in RHCs and FQHCs that already serve vulnerable populations.

To implement this proposal regarding payment for hepatitis B vaccines and their administration in RHCs and FQHCs, we also propose to amend the regulations at § 405.2466(b)(1)(iv), to add hepatitis B vaccines to the list of vaccines covered in RHCs and FQHCs at 100 percent of reasonable cost. Upon the publication of the CY 2025 PFS final rule, if revisions to § 405.2466(b)(1)(iv) are finalized as proposed, we would make corresponding changes to guidance in the Medicare Benefit Policy Manual, Chapter 13 and Medicare Claims Processing Manual, Chapter 9. If finalized, we also plan to facilitate the necessary operational systems updates needed to implement these changes.

d. Regulations Concerning Hepatitis B Vaccines and their Administration

Listed below are several Medicare Part B regulations that mention the hepatitis B vaccine and refer to § 410.63(a) for a definition of hepatitis B vaccine coverage. Since we are proposing to revise § 410.63(a) in section III.M. of this proposed rule, we do not believe additional regulation text changes are needed to conform to the coverage proposal, as the update to the definition at § 410.63(a) will apply to the use of the definition in these regulations:

- Section 410.10(p).
- Section 410.57(d).
- Section 411.15(e)(3) and (k)(5).
- Section 414.707(a)(2)(iii).
- Section 414.904(e)(1).

In addition, we note that there are no conforming regulation text changes needed to the payment regulations at § 410.152, paragraphs (h) and (l)(1), to conform to the coverage proposal.

3. Payment for Drugs Covered as Additional Preventive Services (§ 410.152)

a. Statutory Background

Section 101 of the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 (Pub. L. 110–275) added section 1861(ddd)(1) and (2) of the Act to effectuate ''improvements to coverage of preventive services'' in the Medicare program. Under section 1861(ddd)(1) of the Act, Medicare Part B covers ''additional preventive services'' that identify medical conditions or risk factors and that the Secretary determines are reasonable and necessary

[551] Updates were made to Chapter 13, section 220.1 of Medicare Benefit Policy Manual via Change Request 9864, R2186CP, December 9, 2016, ''Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Updates'': *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R230BP.pdf.*Updates were also made to Chapter 9, section 60.3 of the Medicare Claims Processing Manual via Change Request 9397, R3434CP, December 31, 2015, ''Reorganization of Chapter 9'': *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3434CP.pdf.*

for: (A) the prevention or early detection of an illness or disability; (B) that are recommended with a grade of A or B by the United States Preventive Services Task Force; and (C) that are appropriate for individuals entitled to benefits under Part A or enrolled under Part B. Section 1861(ddd)(2) of the Act states that, in making determinations under section 1861(ddd)(1) of the Act, the Secretary should use the process for making National Coverage Determinations (NCD) in the Medicare program.

Section 101 of MIPPA also added section 1833(a)(1)(W) of the Act, which provides requirements for payment of additional preventive services. Section 1833(a)(1)(W)(i) establishes requirements for payment of additional preventive services that are clinical diagnostic laboratory tests, and section 1833(a)(1)(W)(ii) establishes requirements for payment of all other services. Section 1833(a)(1)(W)(ii) (as amended by section 4104 of the Affordable Care Act (Pub. L. 111–148) requires that the amount paid for the provision of all other additional preventive services is 100 percent of the lesser of the actual charge for the service, or the amount determined under a fee schedule established by the Secretary for purposes of this subparagraph.

We note that ''additional preventive services'' are a subset of ''preventive services'' under Medicare Part B, per section 1861(ddd)(3) and 1861(ww)(2)(O) of the Act, respectively. Section 1833(b)(1) of the Act states that the annual Part B deductible does not apply to preventive services, and section 1833(a)(1)(Y) of the Act waives coinsurance for preventive services that are recommended with a grade of A or B by the USPSTF for any indication or population. Based on all the above statutory authorities, there is no cost-sharing under Part B for additional preventive services for Medicare enrollees, that is, there is no applicable beneficiary coinsurance or deductible for these services.

The term ''preventive services'' is defined at § 410.2, and coverage for ''additional preventive services'' is delineated at § 410.64. At § 410.152(l), we list the Part B preventive services that are paid at 100 percent of the Medicare payment amount, that is, for which zero coinsurance is charged. There, at § 410.152(l)(11), we include ''additional preventive services identified for coverage through the national coverage determination (NCD) process''. At § 410.160(b), we list the Part B services that are not subject to the Part B annual deductible and do not count toward meeting that deductible, and ''additional preventive services identified for coverage through the national coverage determination (NCD) process'' is included there at § 410.160(b)(13).

The payment authority under section 1833(a)(1)(W)(ii) of the Act has not been utilized to date because CMS has not yet covered any additional preventive service that would require use of that payment authority. While CMS currently covers certain screenings and therapies as additional preventive services under the section 1861(ddd) of the Act, those screenings and therapies are currently paid under the existing PFS fee schedule for physician services. Furthermore, the Medicare Diabetes Prevention Program, described at section III.E of this proposed rule, uses the section 1833(a)(1)(W)(ii) authority to waive the coinsurance and deductible as described above, but its payment policy is based on separate authorities under the model.

Specifically, we note that CMS has not yet covered or paid for any drugs or biologicals (hereinafter, referred to as drugs) under the benefit category of additional preventive services. This was highlighted when CMS released a Proposed NCD for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention on July 12, 2023. This proposed NCD announced CMS' intention to cover and pay for those drugs under section 1861(ddd) of the Act's additional preventive services authority, and a decision on the NCD is forthcoming. We note that CMS covers and pays for Part B vaccines, which are also considered preventive services under sections 1861(ddd)(3) and 1861(ww)(2)(A) of the Act, but they have unique payment rates specified in statute at section 1842(o)(1)(A)(iv) of the Act (for more information, see above at section III.H.1.a. of this proposed rule).

b. Proposed Fee Schedule for Drugs Covered as Additional Preventive Services (DCAPS)

As discussed above, the authority at section 1833(a)(1)(W)(ii) of the Act provides for payment for additional preventive services, including drugs. This authority differs from the authority used to pay drugs that are separately paid as drugs and biologicals under other Part B payment authorities. Specifically, payment for most drugs separately payable under Part B is authorized at section 1833(a)(1)(S) of the Act and outlined at section 1842(o)(1)(C) of the Act, and those payments are generally made according to the Average Sales Price (ASP) methodology that is described at section 1847A of the Act. In addition, because drugs covered as additional preventive services (hereinafter, DCAPS; we will use the term ''DCAPS drugs'' for the ease of the reader) are not described in section 1842(o)(1)(C) of the Act, provisions under section 1847A of the Act would not apply, including requirements for manufacturers to report ASP to CMS on a quarterly basis (see sections 1847A(f) and 1927(b)(3)(A)(iii) of the Act). When manufacturers are not required to report the manufacturer's ASP for a drug, they may do so voluntarily, but the availability of voluntarily reported ASP data cannot be guaranteed, and the data may not reflect all available NDCs for the drug. However, we emphasize that DCAPS drugs that are also covered under Part B for non-preventive indications (that is, are also used for diagnosis or treatment) would be subject to ASP reporting requirements.

Above, we mentioned that section 1833(a)(1)(W)(ii) of the Act requires that the amount paid for the provision of additional preventive services is 100 percent of the lesser of the actual charge for the service, or the amount determined under a fee schedule established by the Secretary for purposes of this subparagraph. For purposes of this policy, we refer to the amount determined under the fee schedule as the payment limit, which we discuss in detail below.

We are proposing a fee schedule for DCAPS drugs that uses existing Part B drug pricing mechanisms, because we believe that it is preferable to set all drug payment limits under Part B, including those for DCAPS, as consistently as possible. Accordingly, we propose that the payment limit for a DCAPS drug be determined using the methodology described in section 1847A of the Act (also referred to as ASP methodology), or, if ASP data is not available for a particular drug, to use an alternative pricing mechanism, as described below. We propose to update the fee schedule quarterly, on the same schedule as the ASP pricing file, which is updated each calendar quarter.

(1) Payment Limit Based on Section 1847A of the Act

To determine the payment limit for the applicable billing and payment code for a DCAPS drug under the fee schedule, we propose to apply ASP methodology described in section 1847A of the Act when ASP data is available for the drug. We believe the use of ASP data would be preferable for determining the payment limit for DCAPS drug billing and payment codes

for two reasons. First, this approach would determine the payment limit for these drugs in the same way as the payment limit is usually determined for other drugs that are separately payable under Part B, when possible. This would include the application of payment limit calculations for multiple source drugs, single source drugs and biologicals, and biosimilar biological products, as is done for products under section 1847A of the Act, for each applicable billing and payment code. Second, because section 1847A(c)(3) of the Act requires that calculation of the manufacturer's ASP for an NDC must include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid drug rebate program, discounts under the 340B Program, and rebates under the Part B and Part D Medicare inflation rebate program), this would set a payment limit that would likely better reflect acquisition cost of the drug than list prices in available compendia (such as Wholesale Acquisition Cost (WAC)).

We propose that CMS would determine the payment limit for DCAPS drugs as the amount that would result from application of ASP methodology in section 1847A of the Act only if ASP data for the drug is available for a given quarter (that is, positive manufacturer's ASP data is reported by the drug manufacturer, as explained in section III.A.2 of this proposed rule). We propose that if ASP data is available for a DCAPS drug, the payment limit would be the amount described in section 1847A(b) of the Act, which is usually 106 percent of ASP.

(2) Payment Limit Based on National Average Drug Acquisition Cost (NADAC) Pricing

If ASP data for a DCAPS drug (as described in the previous section) is not available (as defined in the prior paragraph), we propose to determine the payment limit for the applicable billing and payment code using the most recently published amount for the drug in Medicaid's National Average Drug Acquisition Cost (NADAC) survey (OMB control number 0938–1041).[552] When using NADAC data, we propose to determine the payment limit per billing unit, which would be an average of NADAC prices for all NDCs for the drug. If a drug is available in generic and brand formulations, we propose all NDCs will be averaged together to determine the payment limit.

Since the timing of ASP reporting and publishing has a two-quarter lag (for example, payment limits calculated using data reported from the first quarter of sales become effective two quarters later), we propose that ''most recently published'' for purposes of this policy means the most recently updated NADAC survey available 30 days after the close of the quarter for which ASP data would have been reported if it were available.[553] For example, in the calculation of the payment limit for dates of service in the third calendar quarter, if NADAC is used to determine the payment limit, CMS would use the most recent NADAC survey update available on the 30th day after the close of the first calendar quarter to determine the payment limit for the third quarter.

The NADAC survey provides a national drug pricing benchmark for certain drugs that is adequately comprehensive to serve as the first alternative pricing source in the case that ASP data is not available. CMS conducts surveys of retail community pharmacy prices to develop the NADAC pricing benchmark in the annual NADAC pricing file. The pricing benchmark is reflective of the prices paid by retail community pharmacies to acquire prescription and over-the-counter covered outpatient drugs. NADAC data is publicly available and it can be accessed at *https://data.medicaid.gov/nadac*.

In the CY 2020 PFS final rule (84 FR 62655), we similarly finalized the use of NADAC pricing as a pricing alternative for oral drugs under the Part B Opioid Treatment Program (OTP) benefit when ASP data is not available. There, we stated that ''[s]urvey data on invoice prices provide the closest pricing metric to ASP that we are aware of.'' Because the previous statement continues to be true, it is an appropriate alternative in the pricing framework for DCAPS drugs when ASP data is not available.

(3) Payment Limit Based on the Federal Supply Schedule (FSS)

Since NADAC pricing is only available for drugs typically dispensed through retail community pharmacies, there could be circumstances in which ASP and NADAC data are not available for DCAPS drugs. Therefore, if both ASP and NADAC pricing data are not available for a DCAPS drug, we propose to use the most recently published and listed prices for pharmaceutical products in the Federal Supply Schedule (FSS) to calculate the payment limit for the applicable billing and payment code. In the same manner as discussed in the previous section, we propose that ''most recently published'' for purposes of this policy means the most recently updated FSS survey available 30 days after the close of the quarter for which ASP data would have been reported if it were available.[554] For example, in the calculation of the payment limit for dates of service in the third calendar quarter, if FSS is used to determine the payment limit, CMS would use the most recent FSS update available on the 30th day after the close of the first calendar quarter to determine the payment limit for the third quarter. When using the FSS, we would calculate the average price per billing unit (as described in the billing and payment code for the drug) for all NDCs listed for a drug.

Drug pricing information from the Veterans Affairs' (VA's) FSS pharmaceutical pricing database is publicly available at the NDC level and published at *https://www.va.gov/opal/nac/fss/pharmPrices.asp*. We propose to use FSS data when ASP and NADAC data are not available because FSS data is one of the few existing options for drug pricing that includes a wide variety of drug formulations, including both self-administered drugs typically dispensed through retail community pharmacies and drugs administered incident to a physician's service. We believe that using FSS data to calculate the payment limit for DCAPS drugs is preferable to instructing MACs to determine DCAPS drug payment limits according to invoice (as discussed below), because invoice-based pricing requires MACs to manually process claims and is therefore burdensome to the MACs.

(4) Invoice Pricing

Finally, if ASP, NADAC, and FSS pricing are not available for a particular drug covered as an additional preventive service, then MACs will determine the payment for that drug according to invoice. Since one of the three above pricing mechanisms should be available in nearly all cases, we expect that invoice pricing would be necessary only in rare situations. Specifically, we believe that invoice pricing would likely only be necessary for new drugs before pricing data is available.

To summarize, we propose to establish a fee schedule using the following pricing mechanisms to determine the payment limit for DCAPS

[552] *https://www.medicaid.gov/medicaid/prescription-drugs/retail-price-survey/index.html.*

[553] 42 CFR 414.804(a)(5).

[554] 42 CFR 414.804(a)(5).

drugs under Part B, which would be updated quarterly:

(1) If ASP data is available for the DCAPS drug, the payment limit would be determined based on the methodology under section 1847A(b) of the Act (usually 106 percent of ASP);

(2) If ASP data is not available, the payment limit would be calculated using NADAC prices for the drug;

(3) If ASP data and NADAC prices are not available, the payment limit would be calculated using the FSS prices for the drug; and

(4) If ASP data, NADAC prices, and FSS prices are not available, payment limit would be the invoice price determined by the MAC.

We are proposing to amend § 410.152 by adding paragraph (o) to establish the fee schedule and the pricing methodologies used to determine the payment limit for DCAPS drugs under Part B. In addition, to highlight that coinsurance does not apply to DCAPS drugs, we propose to publish the payment limits for DCAPS drugs along with other separately payable Part B drugs on the ASP pricing file.

We invite public comment on the proposed fee schedule for drugs paid as additional preventive services.

c. Payment for Supplying and Administration of Drugs Under the Additional Preventive Services Benefit

As explained above, DCAPS drugs are subject to payment under section 1833(a)(1)(W)(ii) of the Act. Because the fee schedule authorized under such section has not yet been established, and since DCAPS drugs are not covered by Part B under the same authority as other separately payable Part B drugs that would provide for administration or supplying fees, there is no existing policy regarding payment for the administration of DCAPS drugs or the supplying of DCAPS drugs by suppliers and providers. In a similar manner to the DCAPS drug pricing mechanisms described above, we propose administration and supplying fees for DCAPS drugs that mirror existing policies under the PFS and Part B drug payment. We anticipate that an NCD that adds drugs to the additional preventive services benefit would include coverage for the supplying or administration of the drug, as appropriate, and those fees would therefore be considered payment for additional preventive services as well. Therefore, we are proposing payment limits for the supply and administration of DCAPS drugs to be included on the DCAPS fee schedule. As stated above, section 1833(a)(1)(W)(ii) of the Act requires that the amount paid for the provision of additional preventive services is 100 percent of the lesser of the actual charge for the service, or the amount determined under a fee schedule established by the Secretary for purposes of this subparagraph. That is, the amount paid for the administration or supplying of the DCAPS drug will be the lesser of either the actual charge for the service or the payment limit.

For drugs that are supplied by a pharmacy, we propose that the fee schedule include a payment limit for a supplying fee that is similar to the supplying fee for other Part B-covered drugs dispensed from a pharmacy, to allow for consistency among similar payments in Part B. These other groups of drugs covered under Part B include immunosuppressives, oral anti-cancer, and oral anti-emetic drugs, and supplying fees for these drugs are described at 42 CFR part 414, subpart L (§§ 414.1000 and 414.1001). Generally, Medicare pays $24 for the first prescription of one of these drugs supplied by a pharmacy in a 30-day period, and pays $16 for each subsequent prescription, after the first one, supplied in that 30-day period.[555] We propose similar payment limits for supplying fees for DCAPS drugs. Specifically, we propose that CMS will establish payment limit of $24 to a pharmacy for the first DCAPS prescription that the pharmacy supplies to a beneficiary in a 30-day period, and a payment limit of $16 to a pharmacy for all subsequent DCAPS prescriptions that the pharmacy supplies to a beneficiary in that 30-day period. We are proposing that the same fees would apply regardless of the number of days' supply that is dispensed.

As discussed in section III.A.4.c of this proposed rule, we intend to further study the supplying fees for certain drugs paid under Part B (for example, immunosuppressive drugs) and are not proposing to make any changes to the supplying fee amounts at this time (meaning the current 30-day supplying fees would apply to any amount of days' supply). The dispensing and supplying fees under Part B (§ 414.1001) have been shown to be higher than dispensing fees paid in the commercial market.[556] So, until additional study is done regarding input costs for dispensing drugs billed to Medicare Part B and subsequent notice-and-comment rulemaking can be done, if appropriate, in response to such information, we aim to continue the current fee schedule for such Part B drugs regardless of the days' supply dispensed. Therefore, we propose to use the same approach for payment limits that are paid to pharmacies that supply DCAPS prescriptions.

For drugs that are administered by a physician or a non-physician practitioner, we propose that the fee schedule include a payment limit for such administration that aligns with the administration fee for other drugs provided as incident to physician services, as paid according to the PFS. To operationalize this, we propose that CMS determine the payment limit for administration of a DCAPS drug provided incident to a physician service via a crosswalk to an existing, corresponding drug administration code under the PFS. Exact details on coding and corresponding crosswalks would be included on the published fee schedule once DCAPS drugs are finalized for coverage via the NCD process. The fee schedule would be published quarterly on the CMS website and implemented in the Medicare claims processing systems.

No cost sharing would apply for the administration or supplying of DCAPS drugs, because we are proposing that such administration or supplying would be considered an additional preventive service, and as explained above, there is no cost-sharing for any additional preventive services under section 1833(a)(1)(W) of the Act. We propose to codify these policies at the newly added § 410.152(o).

We note that with regard to the July 12, 2023 Proposed NCD for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention, in section II.E.4.b. of this proposed rule, in item 37, we propose national rates for HCPCS code G0012 (*Injection of pre-exposure prophylaxis (PrEP) drug for HIV prevention, under skin or into muscle*) that are crosswalked from CPT code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*). Please see that section for more information.

d. Payment for Drugs Covered as Additional Preventive Services in RHCs and FQHCs

Above, we mentioned that section 4104 of the ACA amended payment for additional preventive services, to increase payment to the lesser of 100 percent of charges, or the amount

[555] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf.*

[556] *https://www.pcmanet.org/rx-research-corner/mandating-pharmacy-reimbursement-increase-spending/08/31/2021/#::text=The%20average%20dispensing%20fee%20in,the%20state's%20Medicaid%20FFS%20rate.*

determined under a fee schedule established by the Secretary, per Section 1833(a)(1)(W)(ii). This change waived coinsurance for additional preventive services. Section 4104 of the ACA also removed several other barriers to access to preventive services in Medicare. Specifically, section 4104 of the ACA amended section 1833 of the Act to waive the deductible for preventive services at section 1833(b)(1) of the Act, and to waive coinsurance for preventive services that are recommended with a grade of A or B by the USPSTF for any indication or population by adding section 1833(a)(1)(Y) of the Act. We also mentioned above that ''additional preventive services'' are a subset of ''preventive services'' under Medicare Part B, per section 1861(ddd)(3) and 1861(ww)(2)(O) of the Act, respectively.

In the CY 2011 PFS final rule, we interpreted the above waivers of cost-sharing for preventive services to apply to FQHCs (75 FR 73417); we note that FQHC services were already exempt from the Part B deductible, per section 1833(b)(4) of the Act. The CY 2011 PFS final rule codified this FQHC policy in regulation at § 405.2449 (75 FR 73613), and in sub-regulatory guidance, we clarified that these waivers of cost-sharing for preventive services applied to RHCs as well.[557] In the CY 2014 FQHC PPS final rule (79 FR 25474), at § 405.2410(b), we codified regulations regarding coinsurance in RHCs and FQHCs, ''[E]xcept for preventive services for which Medicare pays 100 percent under § 410.152(l) of this chapter.'' In the CY 2016 PFS final rule (80 FR 71088), we clarified explicitly that these waivers of cost-sharing (that is, both coinsurance and deductible) for preventive services applied to RHCs.

In the previous sections of III.H.3. of this proposed rule, we discussed drugs covered as additional preventive services (henceforth ''DCAPS drugs,'' for the ease of the reader). In this section, we are clarifying that drugs covered as additional preventive services, and any accompanying administration and supplying fees, are not subject to cost-sharing in RHCs and FQHCs. Since DCAPS drugs and the services to administer and supply them are all considered additional preventive services, as explained in the previous section, they are paid at 100 percent of the Medicare payment amount in RHCs and FQHCs per §§ 405.2410 and 410.152(l) and they are paid on a claim-by-claim basis.

In addition, we are proposing that DCAPS drugs, when administered and supplied in an RHC or FQHC, as well as any administration and supply fee for those drugs, would be paid according to the fee schedule payment limits described above at section III.H.3.b. of this proposed rule. Since regulations at § 405.2460 allow the payment limitations set out in Part 410 to apply to payment for services provided by RHCs and FQHCs, we believe it is consistent with our current RHC and FQHC payment policies to apply the proposed DCAPS fee schedule payment limits, as discussed above, to those same DCAPS drugs when furnished in an RHC or FQHC. Those payment limits are described earlier in section III.H.3.b., and if finalized as proposed, they would be codified at § 410.152(o)(1). We propose to codify this RHC/FQHC DCAPS policy in regulation as well, at a new § 405.2464(h).

We welcome comments on these proposals.

I. Medicare Prescription Drug Inflation Rebate Program

1. Background

a. Overview of the Medicare Prescription Drug Inflation Rebate Program

The Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169, enacted August 16, 2022) established new requirements under which drug manufacturers must pay inflation rebates if they raise their prices for certain Part B and Part D drugs faster than the rate of inflation. Drug manufacturers are required to pay rebates to Medicare if prices for certain Part B drugs increase faster than the rate of inflation for a calendar quarter beginning with the first quarter of 2023; drug manufacturers are required to pay rebates to Medicare if prices for certain Part D drugs increase faster than the rate of inflation over a 12-month period, starting with the 12-month period that began October 1, 2022.

Section 11101 of the IRA amended section 1847A of the Act by adding a new subsection (i), which establishes a requirement for drug manufacturers to pay rebates into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund for Part B rebatable drugs if the specified amount exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. The IRA also provides for an adjustment to the beneficiary coinsurance amount in cases where the price of a Part B rebatable drug increases faster than the rate of inflation such that the beneficiary coinsurance is calculated based on the lower inflation-adjusted payment amount instead of the applicable payment amount. Section 1847A(i)(2) of the Act defines a ''Part B rebatable drug,'' in part, as a single source drug or biological product (as defined in section 1847A(c)(6)(D) of the Act), including a biosimilar biological product (as defined in section 1847A(c)(6)(H) of the Act), but excluding a qualifying biosimilar biological product (as defined in section 1847A(b)(8)(B)(iii) of the Act) for which payment is made under Part B.

Section 11102 of the IRA added section 1860D–14B of the Act, which requires drug manufacturers to pay rebates into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund for each 12-month applicable period, starting with the applicable period beginning on October 1, 2022, for Part D rebatable drugs if the annual manufacturer price (AnMP) of such drug exceeds the inflation-adjusted payment amount. Section 1860D–14B(g)(1)(A) of the Act defines a ''Part D rebatable drug,'' in part, as a drug or biological described at section 1860D–14B(g)(1)(C) of the Act that is a ''covered Part D drug'' as that term is defined in section 1860D–2(e) of the Act. The definition of a Part D rebatable drug includes drugs approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act (that is, brand name drugs), generic drugs approved under section 505(j) of the FD&C Act that meet certain statutory criteria (that is, sole source generic drugs), and biologicals licensed under section 351 of the Public Health Service Act (PHS), including biosimilars.

Under the IRA, certain statutory requirements vary for implementation of the Medicare Part B Drug Inflation Rebate Program and the Medicare Part D Drug Inflation Rebate Program. For example, section 1847A(i) of the Act requires CMS to calculate Part B drug inflation rebates for a calendar quarter, whereas section 1860D–14B of the Act requires CMS to calculate Part D drug inflation rebates for each 12-month applicable period. With respect to invoicing manufacturers for the rebate amount owed, under section 1847A(i)(1) of the Act, CMS must report rebate amounts to each manufacturer of a Part B rebatable drug no later than 6 months after the end of each calendar quarter, except that for calendar quarters beginning in 2023 and 2024, CMS has until September 30, 2025, to invoice manufacturer for rebates. In contrast,

[557] Change Request 7208, R2186CP, 03/28/2011 Waiver of Coinsurance and Deductible for Preventive Services in Rural Health Clinics (RHCs), Section 4104 of Affordable Care Act (ACA): *https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r2186cp.pdf.*

under section 1860D–14B(a) of the Act, CMS must report rebate amounts to each manufacturer of a Part D rebatable drug no later than 9 months after the end of each applicable period, except that for the first two applicable periods (that is, October 1, 2022, to September 30, 2023, and October 1, 2023, to September 30, 2024), CMS has until December 31, 2025, to invoice manufacturers for Part D inflation rebates. Additionally, there are statutory differences in the inputs used to calculate the rebate amounts for Part B and Part D. As a result, CMS is proposing to use different methodologies to calculate inflation rebates for Part B rebatable drugs and Part D rebatable drugs. However, CMS has attempted to align policies across the Medicare Part B Drug Inflation Rebate Program and Medicare Part D Drug Inflation Rebate Program to the extent possible.

b. Summary of Proposed Policies for the Medicare Prescription Drug Inflation Rebate Program

CMS is proposing to codify policies established in the revised guidance for the Medicare Part B Drug Inflation Rebate Program and the Medicare Part D Drug Inflation Rebate Program [558] (collectively referred to as the ''Medicare Prescription Drug Inflation Rebate Program'') in regulatory text. Specifically, CMS is proposing to codify with limited modification policies set forth in guidance for the Medicare Prescription Drug Inflation Rebate Program by adding new parts 427 and 428 to title 42, chapter IV of the Code of Federal Regulations for Part B and Part D, respectively, and welcomes comments on these proposals.

In addition, CMS is proposing new policies for the Medicare Part B Drug Inflation Rebate Program as follows:

- Proposed § 427.201(b) provides that CMS would compare the payment amount in the quarterly pricing files published by CMS to the inflation-adjusted payment amount for a given quarter when determining whether the criteria for a coinsurance adjustment are met.
- Proposed § 427.302(c)(3) provides that for a Part B rebatable drug first approved or licensed by the FDA on or before December 1, 2020 but with a first marketed date after December 1, 2020, the payment amount benchmark quarter for such drug is the third full calendar quarter after the drug's first marketed date. Proposed § 427.302(c)(4) further provides that for a Part B rebatable drug that was billed under a NOC code during the calendar quarter beginning July 1, 2021, or the third full calendar quarter after such drug's first marketed date, whichever is later, the payment amount benchmark quarter is the third full calendar quarter after the drug is assigned a billing and payment code other than a NOC code.
- Proposed § 427.303(b)(1)(i) provides that CMS would remove 340B units for professional claims with dates of service during 2024 (in addition to 2023) submitted by Medicare suppliers that are listed by the Health Resources and Services Administration (HRSA) 340B Office of Pharmacy Affairs Information System as participating in the 340B Program, by using National Provider Identifiers and/or Medicare Provider numbers to identify these suppliers and the claims submitted with such identifiers.
- Proposed § 427.303(b)(5) provides that CMS would remove units of refundable single-dose container or single-use package drugs subject to discarded drug refunds, from the calculation of rebate amounts, generally in the reconciliation process.
- Proposed § 427.501 describes CMS' method and process for reconciliation of a rebate amount for a Part B rebatable drug, including the circumstances that may trigger such a reconciliation.
- Proposed § 427.600 establishes a civil money penalty process in accordance with section 1847A(i)(7) of the Act to address when a manufacturer of a Part B rebatable drug fails to pay the rebate amount in full by the payment deadline for such drug for such applicable calendar quarter.
- Proposed § 427.10 provides that, were any provision of part 427 to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, such provisions would be severable from part 427 and the invalidity or unenforceability would not affect the remainder thereof or any other part of this subchapter or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances.

CMS also is proposing new policies for the Medicare Part D Drug Inflation Rebate Program as follows:

- Proposed § 428.202(c)(3) provides that if a Part D rebatable drug first approved or licensed by the FDA on or before October 1, 2021, does not have AMP data reported under section 1927(b)(3) of the Act for any quarters during the period beginning on January 1, 2021 and ending on September 30, 2021, CMS would identify the payment amount benchmark period as the first calendar year, which would be no earlier than calendar year 2021, in which such drug has at least 1 quarter of AMP reported. Proposed § 428.202(c)(4) further provides that for a Part D rebatable drug first approved or licensed after October 1, 2021 (that is, a subsequently approved drug), for which there are no quarters during the first calendar year beginning after the drug's first marketed date for which AMP has been reported under section 1927(b)(3), the payment amount benchmark period would be the first calendar year in which such drug has at least 1 quarter of AMP reported. CMS is also soliciting comments on alternative policies to address certain instances in which AMP are not reported for certain NDC–9s of a Part D rebatable drug.
- Proposed § 428.203(b)(2) provides that, for claims with dates of service on or after January 1, 2026, and with respect to an applicable period, CMS would exclude from the total number of units used to calculate the total rebate amount for a Part D rebatable drug those units of the Part D rebatable drug for which a manufacturer provided a discount under the 340B Program. To determine the total number of such units for which a manufacturer provided a discount under the 340B Program, CMS would use data reflecting the total number of units of a Part D rebatable drug for which a discount was provided under the 340B Program and that were dispensed during the applicable period. CMS may apply adjustment(s) to these data as needed. CMS is also soliciting comments on alternative policies for collecting and using 340B data to calculate rebate amounts for Part D rebatable drugs.
- Proposed § 428.401 describes CMS' method and process for reconciliation of a rebate amount for a Part D rebatable drug, including the circumstances that may trigger such a reconciliation.
- Proposed § 428.500 establishes a civil money penalty process in accordance with section 1860D–14B(e) of the Act to address when a manufacturer of a Part D rebatable drug fails to pay the rebate amount in full by

[558] Medicare Part B Drug Inflation Rebate Revised Guidance: *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-revised-guidance.pdf*; Medicare Part D Drug Inflation Rebate Revised Guidance: *https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-revised-guidance.pdf* (collectively referred to as the ''revised guidance''). These revised guidance documents, published December 14, 2023, implemented policies relating to the Medicare Prescription Drug Inflation Rebate Program for 2022, 2023, and 2024. CMS also published guidance on the use of the 340B modifier to report separately payable Part B drugs and biologicals acquired under the 340B program (Revised Part B Inflation Rebate Guidance: Use of the 340B Modifier, *https://www.cms.gov/files/document/revised-part-b-inflation-rebate-340b-modifier-guidance.pdf).*

the payment deadline for such drug for such applicable period.

• Proposed § 428.10 provides that, were any provision of part 428 to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, such provisions would be severable from this part and the invalidity or unenforceability would not affect the remainder thereof or any other part of this subchapter or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances.

Unless otherwise specified, CMS proposes that the provisions herein would apply, with respect to Part B rebatable drugs, for all calendar quarters beginning with January 1, 2023, and with respect to Part D rebatable drugs, for all applicable periods beginning with October 1, 2022. The IRA directs the Secretary to calculate rebate amounts for Part B rebatable drugs beginning on January 1, 2023, and Part D rebatable drugs beginning on October 1, 2022, using pricing data from past periods of time, including benchmark data from periods prior to the statute's enactment. In some cases, the time periods during which prices are subject to rebates began as early as several weeks after the IRA was enacted. In recognition of this timing, section 1860D–14B(h) of the Act specifically requires CMS to use program instruction to implement the Medicare Part D Drug Inflation Rebate Program for 2022, 2023, and 2024. Similarly, the existing provision at section 1847A(c)(5)(C) of the Act, provides authority for CMS to implement the Medicare Part B Drug Inflation Rebate Program using program instruction or other guidance. In addition, sections 1847A(i)(1)(C) and 1860D–14B(a)(3) of the Act, as added by the IRA, permit the Secretary to delay the issuance of Rebate Reports for certain initial calendar quarters and applicable periods until 2025.

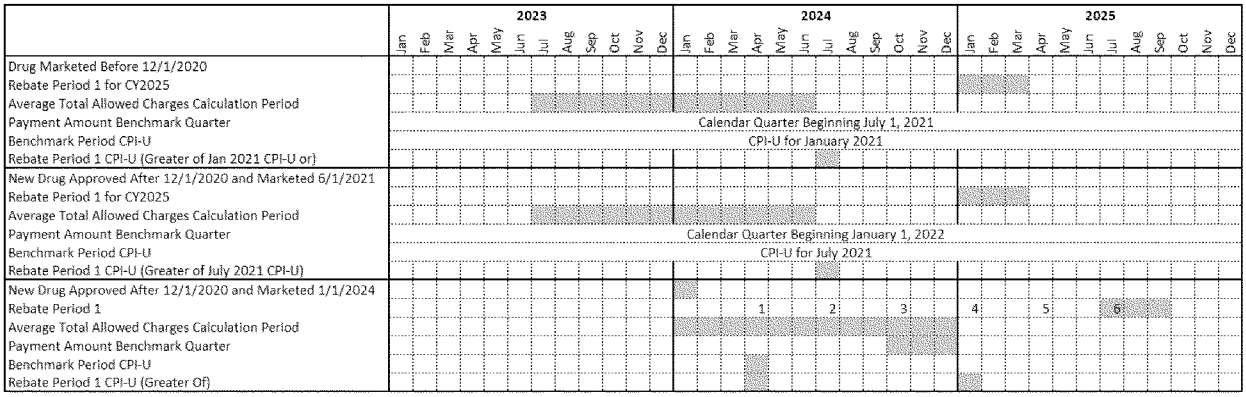
Section 1871(e)(1)(A) of the Act provides that a substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under Title XVIII of the Act may not apply retroactively unless the Secretary has determined that such retroactive application is necessary to comply with statutory requirements or that failure to apply such policies retroactively would be contrary to the public interest. To the extent any proposed provisions in this section III.I of this proposed rule are considered to apply retroactively, CMS has determined that such retroactive application would be both necessary to establish policies to implement the statutory requirements that CMS perform various calculations that involve pricing activities from prior periods and also consistent with the statutory provisions expressly allowing the agency to delay the issuance of rebate reports for initial applicable periods until 2025. In addition, such retroactive application would be in the public interest because it would ensure that the proposed regulations address the same time periods and manufacturer pricing conduct Congress sought to address in the IRA and would promote consistency and continuity in program implementation.

c. Timeline of Key Dates for the Medicare Prescription Drug Inflation Rebate Program

As sections 1847A(i)(2)(C) and 1860D–14B(a)(3) of the Act allow for delayed reporting and invoicing of rebates amounts for applicable calendar quarters in 2023 and 2024 for Part B rebatable drugs and the first two applicable periods for Part D rebatable drugs, Figures 1 and 2 provide example timelines for how rebates will be calculated for applicable calendar quarters and one applicable period in calendar year 2025. The figures also depict how the rebate period and components of the rebate calculation may shift based on the marketing and approval dates for a rebatable drug or biological product.

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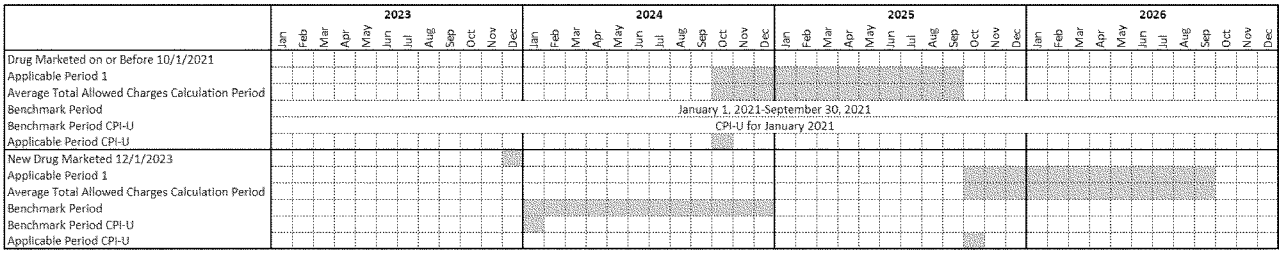
FIGURE 1: Summary of Data Timelines for Part B Drug Inflation Rebate Provisions for Calendar Year 2025[a]



[a] This graphic is an illustrative example of how rebates for quarters in calendar year 2025 will be calculated.

Note: A drug will be included on the six full calendar quarters (denoted with the numbers in the figure) after the day the drug was first marketed or the first quarter of 2023, whichever is later. The Rebate Period CPI-U is the greater of the benchmark period CPI-U or the CPI-U of the first month of the quarter two quarters prior to the rebate period.

FIGURE 2: Summary of Data Timelines for Part D Drug Inflation Rebate Provisions for Calendar Year 2025[a]



[a] *This graphic is an illustrative example of how rebates for one applicable period including months in calendar year 2025 will be calculated.*

Table 47 describes a summary timeline for inflation rebate amount reports and deadlines for applicable calendar quarters in calendar year 2025 and thereafter for Part B rebates and for the Part D rebate applicable period beginning on October 1, 2024, and applicable periods thereafter.

TABLE 47: Summary of Part B and D Drug Inflation Rebate Amount Reports and Deadlines[a]

Milestone	Timing/Deadline
Part B Rebate – CMS must invoice manufacturers not later than 6 months after each calendar quarter	
Preliminary Rebate Report sent to Manufacturers	Not later than 5 months after the end of the calendar quarter
Manufacturer Reviews	Manufacturer Suggestion of Error must be submitted to CMS not later than 10 calendar days following receipt of the Preliminary Rebate Report
Rebate Report sent to Manufacturers	Not later than 6 months after the end of the calendar quarter
Manufacturer Rebate Amount Due (if applicable)	Not later than 30 calendar days after receipt of the Rebate Report
Preliminary Reconciliation Rebate Report sent to Manufacturers	Not later than 11 months after receipt of the Rebate Report
Manufacturer Reviews	Manufacturer Suggestion of Error must be submitted to CMS not later than 10 calendar days following receipt of the Preliminary Reconciliation Rebate Report
Reconciliation Rebate Report sent to Manufacturers	Not later than 12 months after receipt of the Rebate Report
Manufacturer Reconciled Rebate Amount Due (if any)	Not later than 30 calendar days after receipt of the Reconciliation Rebate Report
Part D Rebate – CMS must invoice manufacturers not later than 9 months after the end of each applicable period	
Preliminary Rebate Report sent to Manufacturers	Not later than 8 months after the end of the applicable period
Manufacturer Reviews	Manufacturer Suggestion of Error must be submitted to CMS not later than 10 calendar days following receipt of the Preliminary Rebate Report
Rebate Report sent to Manufacturers	Not later than 9 months after the end of the applicable period
Manufacturer Rebate Amount Due (if applicable)	Not later than 30 calendar days after receipt of the Rebate Report
First Reconciliation Preliminary Rebate Report sent to Manufacturers	Not later than 11 months after the receipt of the Rebate Report
Manufacturer Reviews	Manufacturer Suggestion of Error must be submitted to CMS not later than 10 calendar days following receipt of the First Reconciliation Preliminary Rebate Report
First Reconciliation Rebate Report sent to Manufacturers	Not later than 12 months after the receipt of the Rebate Report
Manufacturer Reconciled Rebate Amount Due (if any)	Not later than 30 calendar days after receipt of the First Reconciliation Rebate Report
Second Reconciliation Preliminary Rebate Report sent to Manufacturers	Not later than 35 months after the receipt of the Rebate Report
Manufacturer Reviews	Manufacturer Suggestion of Error should be submitted to CMS not later than 10 calendar days following receipt of the Second Reconciliation Preliminary Rebate Report
Second Reconciliation Rebate Report sent to Manufacturers	Not later than 36 months after the receipt of the Rebate Report
Manufacturer Reconciled Rebate Amount Due (if any)	Not later than 30 calendar days after receipt of the Second Reconciliation Rebate Report

[a] *The months referred to in these timelines represent calendar months. This means, for example, that if a Preliminary Rebate Report is issued on August 15, 2027, the Rebate Report could be issued up until September 30, 2027.*

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2. Medicare Part B Drug Rebates for Single Source Drugs and Biological Products With Prices That Increase Faster Than the Rate of Inflation

a. Definitions (§ 427.20)

In this proposed rule, CMS proposes to codify the definitions of terms consistent with the meanings given in section 1847A(i) of the Act or established in the revised Medicare Part B Drug Inflation Rebate Guidance, as applicable, as well as new definitions based on policies detailed in this proposed rule.

At proposed § 427.20, CMS is proposing that the following terms in section 1847A of the Act are defined:

- ''Benchmark period CPI–U''.
- ''Biosimilar biological product''.
- ''Inflation-adjusted payment amount''.
- ''Part B rebatable drug''.
- ''Payment amount benchmark quarter''.
- ''Payment amount in the payment amount benchmark quarter''.
- ''Rebate period CPI–U''.
- ''Single source drug or biological product''.
- ''Specified amount''.
- ''Subsequently approved drug''.
- ''Unit''.

Further, in § 427.20 of this proposed rule, CMS proposes to codify definitions established in the revised Medicare Part B Drug Inflation Rebate Guidance and new definitions based on policies detailed in this proposed rule for the following terms:

- ''Allowed charges''.
- ''Applicable calendar quarter''.
- ''Applicable threshold''.
- ''Average sales price (ASP)''.
- ''Billing and payment code''.
- ''Billing unit''.
- ''CPI–U''.[559]
- ''FDA application''.
- ''Final action claim''.
- ''First marketed date''.
- ''Grouped billing and payment code''.
- ''Manufacturer''.
- ''National Drug Code'' (NDC).
- ''Not Otherwise Classified (NOC) code''.

b. Determination of Part B Rebatable Drugs (§§ 427.100 Through 427.101)

i. Definitions

In proposed § 427.100, CMS proposes to define the following terms applicable to proposed subpart B (§§ 427.100 through 427.101):

- ''EUA Declaration''.
- ''Individual who uses such a drug or biological''.

ii. Identification of Part B Rebatable Drugs

Section 1847A(i)(2) of the Act defines a ''Part B rebatable drug,'' in part, as a single source drug or biological product (as defined in section 1847A(c)(6)(D)), including a biosimilar biological product (as defined in section 1847A(c)(6)(H)), but excluding a qualifying biosimilar biological product (as defined in section 1847A(b)(8)(B)(iii)), for which payment is made under Part B. The definitions for a biosimilar biological product and a qualifying biosimilar biological product are codified in § 414.902.

In § 427.101, CMS proposes to codify the policies established in section 30.1 of the revised Medicare Part B Drug Inflation Rebate Guidance to identify Part B rebatable drugs by (1) identifying the applicable billing and payment code for each single source drug or biological product, including biosimilar biological products, for which payment is made under Part B and (2) excluding any billing and payment code corresponding to a drug or biological product in excluded product categories or that have average total allowed charges below an applicable threshold, to be codified in proposed § 427.101(b) and (c), respectively.[560]

iii. Excluded Product Categories

Section 1847A(i)(2)(A) of the Act excludes qualifying biosimilar biological products (as defined in section 1847A(b)(8)(B)(iii) of the Act) from the definition of a Part B rebatable drug. As such, in § 427.101(b)(1) CMS proposes to codify the policy established in section 30.2 of the revised Medicare Part B Drug Inflation Rebate Guidance to exclude such products from the definition of a Part B rebatable drug and not subject them to Part B inflation rebates.

Section 1847A(i)(2) of the Act defines a Part B rebatable drug as a ''single source drug or biological as defined in section 1847A(c)(6)(D) of the Act'' which requires that a single source drug not be a multiple source drug. CMS has interpreted section 1847A(c)(6)(C)(ii) of the Act to mean that single source drugs or biological products are treated as multiple source drugs if they were within the same billing and payment code as of October 1, 2003. Accordingly, in § 427.101(b)(2), we are proposing to codify the existing policy established in section 30.1 of the revised Medicare Part B Drug Inflation Rebate Guidance to exclude drugs and biological products described in section 1847A(c)(6)(C)(ii) of the Act from the definition of a Part B rebatable drug and not subject them to Part B inflation rebates.

For drugs and biological products that are billed using a HCPCS code that represents a NOC code, CMS has a process to determine the allowed payment amount for such billing and payment codes; however, current Medicare claims data do not allow CMS to determine the average total allowed charges for such drug or biological product for a year per individual that uses such a drug or biological product or to identify units billed. CMS must perform these steps to determine if a drug or biological product is a Part B rebatable drug. Therefore, in § 427.101(b)(3), we are proposing to codify the policy in section 30.1 of the revised Medicare Part B Drug Inflation Rebate Guidance to exclude drugs and biological products that are billed using a billing and payment code that represents a NOC code drug or biological product or claims for such drugs and biological products when no other billing and payment code is applicable. CMS notes that few Part B drugs and biological products are billed with such codes and the quarterly process for updating billing and payment codes, including establishing new billing and payment codes, provides an existing mechanism for CMS to minimize the number of Part B rebatable drugs that are billed with such codes. As discussed in §§ 90.2 and 90.3 in Chapter 17 of the Medicare Claims Processing Manual, CMS believes NOC codes are generally used to bill Medicare for new-to-market, FDA-approved drug products until a specific billing and payment code is assigned; and so, CMS expects that the impact of this exclusion will be limited.[561]

Consistent with section 303(h) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, radiopharmaceutical drugs and biologicals are not paid under section 1847A of the Act. Manufacturers of radiopharmaceuticals are therefore not required to report ASP under section 1927(b)(3) of the Act and are not

[559] These data are referenced to 1982–84=100—that is, the average of pricing data for the 36 months from 1982 through 1984 serve as the basis for the index and are assigned a value of 100. These data are not seasonally adjusted.

[560] For more information on HCPCS codes and how they are applied, see ''HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS) LEVEL II CODING PROCEDURESHCPCS'' at *https://www.cms.gov/medicare/coding/medhcpcsgeninfo/downloads/2018-11-30-hcpcs-level2-coding-procedure.pdf.*

[561] See: *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf.*

otherwise required to report ASP data to CMS for separately payable radiopharmaceuticals. In addition, different payment methodologies across the outpatient setting result in data variations that could inappropriately trigger an inflation rebate amount due to methodological differences in reimbursement. Therefore, although some radiopharmaceuticals may appear on quarterly pricing files, in § 427.101(b)(4) CMS proposes to codify the revised Medicare Part B Drug Inflation Rebate Guidance policy (as described in section 30.1) that excludes separately payable radiopharmaceuticals for the purposes of identifying Part B rebatable drugs. Additionally, CMS proposes to codify the existing policy not to subject these units to the inflation-adjusted beneficiary coinsurance at § 427.201(c) and described further in the following section of this preamble.[562]

CMS aims to create a consistent coding and payment approach for the suite of products currently referred to as skin substitutes as stated in section 30.1 of revised Medicare Part B Drug Inflation Rebate Guidance. In the CY 2024 PFS proposed rule, CMS solicited comments on potential changes to payment for skin substitutes. In the CY 2024 PFS final rule, CMS acknowledged the comments received in response to this solicitation and stated that CMS would take these comments into consideration for future rulemaking.[563] In § 427.101(b)(5) CMS proposes to codify existing policy to exclude cellular- and tissue-based products that would aid wound healing, currently referred to as skin substitutes, for the purposes of identifying Part B rebatable drugs. In addition, CMS proposes not to subject these products to the beneficiary coinsurance adjustment at § 427.201(c).

Section 1847A(i)(2)(A) of the Act excludes from the definition of a Part B rebatable drug a drug or biological if, as determined by the Secretary, the average total allowed charges for such drug or biological product under Part B for a year per individual who uses such a drug or biological product are less than $100. Section 1847A(i)(2)(B) of the Act provides that the $100 amount for 2023 will be increased for 2024 and subsequent years by the percentage change in the CPI–U for the 12-month period ending with June of the previous year, rounded to the nearest multiple of $10. Therefore, in § 427.101(b)(6) CMS proposes to codify the policy established in revised Medicare Part B Drug Inflation Rebate Guidance to exclude from the definition of a Part B rebatable drug those drugs and biologicals for which the Part B average total allowed charges for a year per individual who uses such drug or biological is below the applicable threshold.

Section 1847A(i)(2)(A)(ii) of the Act excludes vaccines described in subparagraph (A) or (B) of section 1861(s)(10) of the Act from the definition of a Part B rebatable drug. Such vaccines include the pneumococcal vaccine, the influenza vaccine, the COVID–19 vaccine; and the hepatitis B vaccine when furnished to an individual who is at high or intermediate risk of contracting hepatitis B (as determined by the Secretary under regulations). As such, in § 427.101(b)(7), CMS proposes to codify the existing policy established in section 30.3 of the revised Medicare Part B Drug Inflation Rebate Guidance to exclude vaccines described in subparagraph (A) or (B) of section 1861(s)(10) of the Act from the definition of a Part B rebatable drug and not subject them to Part B inflation rebates. In addition, with respect to monoclonal antibodies used for treatment or post-exposure prophylaxis of COVID–19, which are covered and paid for under section 1861(s)(10) of the Act, CMS proposes to exclude these products from the definition of Part B rebatable drugs for applicable quarters through the end of the calendar year in which the EUA declaration under section 564 of the FD&C Act for drugs and biological products is terminated. With respect to monoclonal antibodies that are used for pre-exposure prophylaxis of COVID–19 that are covered and paid for under section 1861(s)(10) of the Act, CMS proposes to exclude these products from the definition of Part B rebatable drug for applicable calendar quarters even after the year in which the EUA Declaration ends, as long as these products have an FDA-approved application or license after the EUA Declaration is terminated.

Finally, Part B drugs approved under an Abbreviated New Drug Application (ANDA) submitted under 505(j) of the FD&C Act do not meet the definition of ''single source drug or biological product,'' as defined under section 1847A(c)(6)(D) of the Act, and thus, are not Part B rebatable drugs. We propose to codify this exclusion at § 427.101(b)(8).

iv. Drugs and Biological Products With Average Total Allowed Charges Below the Applicable Threshold

Pursuant to section 1847A(i)(2) of the Act, drugs and biological products, for which the average total allowed charges for such drug or biological under Part B for a year per individual who uses such drug or biological are below the applicable threshold, as determined by the Secretary, are excluded from the definition of Part B rebatable drugs. As explained in section 30.2 of the revised Medicare Part B Drug Inflation Rebate Guidance, CMS uses the term ''applicable threshold'' to mean $100 for all four calendar quarters in 2023. For all four calendar quarters in 2024, the applicable threshold will be $100 as increased in accordance with section 1847A(i)(2)(B) of the Act. For calendar quarters in 2025 and beyond, the applicable threshold will be equal to the unrounded applicable threshold calculated for the prior calendar year, increased by the percentage increase in the CPI–U for the 12-month period ending with June of the previous year.

In § 427.101(c), CMS is proposing to codify policies from the revised Medicare Part B Drug Inflation Rebate Guidance to exclude these drugs from the definition of a Part B rebatable drug. To do so, in accordance with the statute, for each applicable calendar quarter, CMS proposes to identify drugs and biological products with Part B average total allowed charges for a year per individual that uses such a drug or biological product below the applicable threshold.

In § 427.101(c)(1), CMS is proposing that to identify the average total allowed charges for a year per individual, for each Part B rebatable drug, CMS would:

- For single source drugs and biological products assigned to only one billing and payment code, sum the allowed charges from final action claims greater than $0 and divide the summed amount by the number of individuals who use such a drug or biological.
- For single source drugs and biological products assigned to more than one billing and payment code, sum the allowed charges from final action claims greater than $0 for all billing and payment codes and divide the summed amount by the number of individuals who use such a drug or biological.

CMS may move a drug or biological product from a grouped billing and payment code to a unique billing and payment code in instances where the

[562] In this proposed rule, CMS also is proposing to clarify how radiopharmaceuticals are paid for in the physician's office and to codify these policies in regulation. Specifically, CMS proposes to clarify that for radiopharmaceuticals furnished in a setting other than the hospital outpatient department, MACs can determine payment limits for radiopharmaceuticals based on any methodology in place on or prior to November 2003.

[563] See 88 FR 78818, November 16, 2023 (*https://www.federalregister.gov/public-inspection/2023-24184/medicare-and-medicaid-programs-calendar-year-2024-payment-policies-under-the-physician-fee-schedule*).

drug is either approved through the pathway established under section 505(b)(2) of the FD&C Act (hereinafter ''section 505(b)(2) drug products'') that CMS initially assigned to the same billing and payment code as its reference drug for a period of time, or the drug was previously a multiple source drug but is now a single source drug that was moved to its own billing and payment code. There may be instances where a single source drug or biological product was previously crosswalked to a grouped billing and payment code (other than a NOC code) during the *full* year. In such instances, CMS proposes to calculate the average total allowed charges per individual per year for the drug using allowed charges and the number of individuals who used the drug or biological product based on claims for the previously grouped billing and payment code during the year. Such instances would apply to section 505(b)(2) drug products, drugs that were previously multiple source drugs where all other drugs under the same billing and payment code were discontinued (applicable only if the sole remaining product was not approved under an ANDA), and to any other situations where a drug was previously in a grouped billing and payment code (other than a NOC code).

Finally, there may be instances where a single source drug or biological product was initially billed under a grouped billing and payment code (other than a NOC code) and was later billed under a unique billing and payment code for *some* of the year. In such instances, CMS proposes to calculate the average total allowed charges per individual for a year by: summing the total allowed charges billed under the unique billing and payment code for the drug with dates of service on or after the Medicare effective date for this unique billing and payment code and identifying the individuals on those claims; summing the total allowed charges on claims billed under the previously grouped billing and payment code and identifying the individuals with claims prior to the unique billing and payment code's effective date; and then summing the total allowed charges under both billing and payment codes across the full year and dividing by the total number of individuals (de-duplicated for those individuals identified under both the previously grouped billing and payment code and the unique billing and payment code). If the average total allowed charges for a year per individual who uses such drug or biological product are less than the applicable threshold, CMS proposes to exclude the billing and payment code for that calendar quarter. CMS welcomes comment on the proposed implementation of the exclusion for drugs and biologicals with average total allowed charges below the applicable threshold.

CMS proposes in § 427.101(c)(2) to calculate the applicable threshold as follows:

- For applicable calendar quarters in 2023, the applicable threshold is equal to $100.
- For applicable calendar quarters in 2024, the applicable threshold is equal to $100 increased by the percentage increase in the CPI–U for the 12-month period ending with June of 2023.
- For applicable calendar quarters in each subsequent calendar year, the applicable threshold is equal to the unrounded applicable threshold calculated for the prior calendar year increased by the percentage increase in the CPI–U for the 12-month period ending with June of the previous year.
- If the resulting amount from these calculations is not a multiple of $10, CMS will round that amount to the nearest multiple of $10.[564]

Accordingly, the formula to determine the applicable threshold for calendar quarters in 2024 is $100 *multiplied by* (CPI–U for June 2023 *divided by* CPI–U for June 2022) (apply rounding to the nearest multiple of $10). To illustrate, the 2024 threshold is: $100 \times (305.109/296.311) = 102.969178$ (which rounds down to $100 after applying CMS rounding) so the threshold for calendar quarters in 2024 = $100.

For the purposes of this calculation, CMS proposes that ''a year'' means the 4 consecutive calendar quarters beginning 6 calendar quarters before the applicable calendar quarter. CMS also proposes using final action claims from the Medicare fee-for-service claims repository to identify claims where separate payment was allowed for the applicable HCPCS code for dates of service within a year. Drugs and biological products that do not meet the applicable threshold are not considered Part B rebatable drugs. For example, for the calendar quarter beginning July 1, 2025, CMS would use available final action Medicare Part B claims with dates of service beginning January 1, 2024, and ending December 31, 2024, because January 1, 2024, is the beginning of the calendar quarter that is 6 quarters before the applicable calendar quarter beginning on July 1, 2025.

[564] CMS will round any amount less than $5 over a multiple of $10 down to that multiple of $10, and any amount $5 or more over a multiple of $10 up to the next multiple of $10.

In § 427.101(c)(3), CMS proposes to codify the policies and methodological steps as described in section 30.2 of the revised Medicare Part B Drug Inflation Rebate Guidance for excluding drugs and biological products with average total allowed charges below the applicable threshold at the billing and payment code level. For each applicable calendar quarter, CMS would identify the applicable billing and payment codes for drugs and biological products with average total allowed charges for a year per individual less than the applicable threshold and exclude such drugs and biological products from the definition of Part B rebatable drug in accordance with proposed § 427.101(b)(6). When a single source drug or biological product with average total allowed charges below the applicable threshold is assigned to a unique billing and payment code, CMS would exclude the assigned billing and payment code for the applicable calendar quarter. There also may be instances where a single source drug or biological product is assigned to more than one billing and payment code during a year and the average total allowed charges for a year per individual that uses such drug or biological product are less than the applicable threshold. In such instances, CMS proposes to exclude all assigned billing and payment codes for such single source drug or biological product for that applicable calendar quarter.

c. Inflation-Adjusted Beneficiary Coinsurance Adjustment and Adjusted Medicare Payment for Part B Rebatable Drugs With Price Increases Faster Than Inflation (§§ 427.200 Through 427.201)

Section 1847A(i)(5) of the Act requires that for Part B rebatable drugs, as defined in section 1847A(i)(2)(A) of the Act, furnished on or after April 1, 2023, in quarters in which the payment amount described in section 1847A(i)(3)(A)(ii)(I) of the Act (or, in the case of selected drugs described under section 1192(c) of the Act, the payment amount described in section 1847A(b)(1)(B) of the Act), exceeds the inflation-adjusted payment amount determined in accordance with section 1847A(i)(3)(C) of the Act, the coinsurance will be 20 percent of the inflation-adjusted payment amount for such quarter (hereafter, the inflation-adjusted coinsurance amount). This inflation-adjusted coinsurance amount is applied as a percent, as determined by the Secretary, to the payment amount that would otherwise apply for such calendar quarter in accordance with section 1847A(b)(1)(B) or (C) of the Act, as applicable, including in the case of a

selected drug. In the CY 2024 Hospital Outpatient Prospective Payment System (OPPS) final rule and the CY 2024 PFS final rule, CMS codified this inflation-adjusted coinsurance amount at §§ 419.41(e), 410.152(m), and 489.30(b)(6), respectively.

Beginning with the April 2023 quarterly pricing files, the applicable beneficiary coinsurance percentage is shown for each HCPCS code in the pricing files that are posted on the CMS website. For example, the ASP Pricing files are posted at *https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files*. The applicable beneficiary coinsurance percentage for certain drugs and biologicals used predominantly in the hospital outpatient setting are listed in the Hospital Outpatient Prospective Payment System (OPPS) Addenda A and B, which can be found at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates*. The applicable beneficiary coinsurance percentage for certain drugs and biologicals used predominantly in the ambulatory surgical center setting are listed in the ASC Addendum, which can be found at *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-payment-rates-addenda*. The percentage is expressed as two digits with three decimal places, for example, 18.760. If an adjusted beneficiary coinsurance does not apply, the percentage would show as 20.000.

Section 11101(b) of the IRA amended section 1833(a)(1) of the Act by adding a new subparagraph (EE), which requires that if the payment amount under section 1847A(i)(3)(A)(ii)(I) of the Act or, in the case of a selected drug, the payment amount described in section 1847A(b)(1)(B) of the Act, for that drug exceeds the inflation-adjusted payment amount for a Part B rebatable drug, the Part B payment amount would, subject to the Part B deductible and sequestration, equal the difference between the payment limit and the inflation-adjusted coinsurance amount. Consistent with the clarification in section 40 of the revised Medicare Part B Drug Inflation Rebate Guidance and with the application of sequestration in the context of Medicare payment and beneficiary coinsurance in general, we note that the calculation to determine the applicable beneficiary coinsurance amount would not be adjusted for sequestration. CMS codified the Medicare payment for Part B rebatable drugs in the CY 2024 PFS final rule by adding new paragraph (m) to § 410.152.

In this proposed rule, CMS proposes to adopt new provisions at §§ 427.200 and 427.201 to codify the policies regarding the computation of the inflation-adjusted beneficiary coinsurance, defined in § 427.200, for Part B rebatable drugs as required by section 1847A(i)(5) of the Act. This proposed new provision includes references to the existing provisions at §§ 410.152(m), 419.41(e), and 489.30(b)(6). CMS further proposes at § 427.201(c) that any category of products that is excluded from the identification of Part B rebatable drugs at § 427.101(b) is not subject to the inflation-adjusted beneficiary coinsurance. Examples of these excluded products include separately payable radiopharmaceuticals, skin substitute products, and qualifying biosimilar biological products.

Additionally, CMS proposes at § 427.201(b) that CMS will use the published payment amount in quarterly pricing files[565] [566] [567] to determine if a Part B rebatable drug should have an adjusted beneficiary coinsurance equal to 20 percent of the inflation-adjusted payment amount as described in section 1847A(i)(3)(C) for a calendar quarter. This proposed approach deviates from the rebate calculation approach proposed in § 427.302, which relies on the specified amount defined at § 427.20 even when the specified amount and the published payment amount in quarterly pricing files differ. The approach proposed at § 427.201(b) would be used only to determine whether there should be a coinsurance adjustment and would not impact the applicability or calculation of inflation rebates. CMS believes this approach is consistent with the statutory language and appropriately reflects the differences in the statutory text of section 1847A(i)(5) of the Act, which sets forth the payment amount that is used to determine whether coinsurance should be adjusted, and section 1847A(i)(3)(A) of the Act, which sets forth the ''specified amount'' used to determine rebate amounts.

CMS' intent with this proposed policy is to hold beneficiaries harmless in situations where the payment amount is calculated differently from the specified amount. Though the payment amount is generally based on the same provisions as the specified amount, there may be situations where the payment amount is updated or adjusted under other provisions of 1847A of the Act, such as when ASP data are not available under section 1847A(c)(5)(B). For example, if the specified amount is very low due to negative ASP data and the payment amount is updated using other available data resulting in a payment amount that exceeds the inflation-adjusted payment amount, beneficiaries would not receive the benefit of adjusted coinsurance. There may also be situations where the payment amount is lower than the inflation-adjusted payment amount, but the specified amount is higher than the inflation-adjusted payment amount. In such a situation, if the ''specified amount'' was used as the comparator to determine whether coinsurance should be adjusted, beneficiaries would pay a coinsurance *higher* than 20 percent, because 20 percent of the inflation-adjusted payment amount would be higher than 20 percent of the payment amount. As such, we propose to codify at § 427.201(b) that we will compare the published payment amount in the quarterly pricing files published by CMS to determine whether a coinsurance adjustment applies. This policy would provide an adjusted beneficiary coinsurance amount only when the payment amount for a Part B rebatable drug exceeds the inflation-adjusted payment amount in a given quarter.

CMS believes this approach is valid and gives effect to the differing statutory language in sections 1847A(i)(3)(A), 1847A(i)(5), and 1833(a)(1)(EE) of the Act, which sets forth the coinsurance adjustment for Part B rebatable drugs. Unlike the ''specified amount'' in section 1847A(i)(3)(A), sections 1847A(i)(5) and 1833(a)(1)(EE) both refer to a ''payment amount.'' Fundamentally, a payment amount cannot be a negative number; if the specified amount and payment amount were the same amount, it would result in situations where the payment amount at section 1833(a)(1)(EE) was a negative number. Rather, we believe that the term ''payment amount'' in both sections 1847A(i)(5) and 1833(a)(1)(EE) is most naturally read to include the amount, as updated and adjusted for the purposes of providing payment to providers, that CMS publishes as the payment amount in quarterly pricing files; and that section 1833(a)(1)(EE) operates to adjust the *percentage* of such payment amount. Furthermore, section 1847A(i)(5)(B) of the Act provides the Secretary with discretion to apply the adjusted coinsurance percentage to the payment amount that would otherwise apply under section 1847A(b)(1)(B) or (C) of the Act. Lastly, sections 1847A(i)(8)(D) and (E) of the Act

[565] *See: https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files.*

[566] *See: https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates.*

[567] *See: https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-payment-rates-addenda.*

preclude administrative and judicial review of the computation of the adjusted coinsurance and amounts paid to the provider under section 1833(a)(1)(EE).

In summary, we are proposing CMS will use the payment amount in quarterly pricing files to determine if a Part B rebatable drug should have an adjusted beneficiary coinsurance, the calculation to determine the adjusted Medicare payment (if applicable) will not be adjusted for sequestration, and drugs excluded from the identification of Part B rebatable drugs will not be subject to the inflation-adjusted beneficiary coinsurance. CMS invites comment on these proposals.

d. Determination of the Rebate Amount for Part B Rebatable Drugs (§§ 427.300 Through 427.304)

i. Definitions

In proposed § 427.300, CMS proposes to define the following terms applicable to subpart D (§§ 427.300 through 427.304):

- ''340B Program''.
- ''Refundable single-use dose container or single-use package drug''.

ii. Calculation of the Total Part B Rebate Amount To Be Paid by Manufacturers

Section 1847A(i)(3) of the Act specifies the calculation of the rebate amount for a Part B rebatable drug assigned to a billing and payment code for an applicable calendar quarter for which a manufacturer must pay a rebate. CMS proposes to codify the rebate calculation, as established in revised Medicare Part B Drug Inflation Rebate Guidance, as the estimated amount is equal to the product of the total number of billing units determined in accordance with section 1847A(i)(3)(B) of the Act (proposed at § 427.303) and the amount (if any) by which the specified amount (proposed at § 427.302(b)) exceeds the inflation-adjusted payment amount determined in accordance with section 1847A(i)(3)(C) of the Act (proposed at § 427.302(g)) for the drug or biological product for an applicable calendar quarter. The Part B drug inflation rebate amount calculated in accordance with this subpart is subject to adjustment based on any reductions in accordance with subpart E of this part or any reconciliations in accordance with subpart F of the part.

Because Part B rebatable drugs are single source drugs or biologicals, they typically will have one manufacturer. However, a Part B rebatable drug could have more than one manufacturer. For example, a Part B rebatable drug could be produced by one or more manufacturer(s) that is a repackager or relabeler. Multiple manufacturers of a rebatable drug also could occur in the case of one or more authorized generic products that are marketed under the same FDA-approval as the original FDA applicant. In such instances, all the NDCs for the drug typically are assigned to the same billing and payment code(s), and each manufacturer is responsible for reporting ASP data to CMS. When calculating the rebate owed by manufacturers for a rebatable drug that has more than one manufacturer, CMS proposes to codify the policy from section 50.13 of the revised Medicare Part B Drug Inflation Rebate Guidance to multiply the total rebate amount calculated for the billing and payment code by the following quotient:

(Sum of the individual manufacturer's billing units sold during the applicable calendar quarter for all NDCs of the manufacturer assigned to the billing and payment code, as reported in the ASP data submissions) *divided by* (Sum of all manufacturers' total billing units sold during the applicable calendar quarter for all NDCs of the Part B rebatable drug assigned to the billing and payment code, as reported in the ASP data submissions)

CMS welcomes comment on this calculation approach.

Based on further review, CMS has observed that there are several instances where there are multiple manufacturers in a billing and payment code and the ASP data, including the number of units sold, for all or some manufacturers' NDCs within a billing and payment code may be negative, zero, or missing. To enable CMS to calculate the respective rebate amounts attributable to each manufacturer when the ASP units are negative, zero, or missing, CMS is soliciting comments on the new proposed policies outlined below and any other alternative options.

(1) Scenarios in Which All NDCs Within a Billing and Payment Code Have Negative, Zero, or Missing ASP Units

If there are NDCs of multiple manufacturers in a billing and payment code, to determine the respective rebate amount when the manufacturer-reported ASP units for all NDCs are either negative, zero, or missing but there is a positive rebate amount calculated for the Part B rebatable drug, CMS proposes to: (1) apportion a $0 rebate amount when the reported units for all NDCs are missing for NDCs not marketed or sold during the applicable calendar quarter, negative, and/or zero; and (2) equally apportion a positive rebate amount to each NDC with missing units when the NDCs were marketed or sold during the applicable calendar quarter. If the NDCs within a billing and payment code have a mix of negative units, zero units, missing units for NDCs marketed or sold during the applicable calendar quarter, or missing units for NDCs not marketed or sold during the applicable calendar quarter, CMS will apportion a $0 rebate amount to the NDCs with missing units that are not marketed or sold during the applicable calendar quarter, NDCs with negative units, and NDCs with zero units, and will equally apportion the positive rebate amount across all NDCs with missing units that are marketed or sold during the applicable quarter. CMS understands that this approach would treat missing units for NDCs not marketed or sold during the applicable calendar quarter, negative units, and zero units as representing zero sales, and we welcome comments on the extent to which this approach could potentially exclude from rebate liability a manufacturer of a drug that did have sales in that quarter (for example, if negative units represent price concessions). In addition, CMS welcomes comments on the extent to which, in a scenario with a billing and payment code with multiple manufacturers, a single manufacturer with missing ASP units could assume full rebate liability for the entire billing and payment code if the manufacturer's NDCs have missing units and are marketed or sold during the applicable calendar quarter.

CMS also considered several alternative policies for attributing rebate amounts to each respective manufacturer in this scenario, including: (1) using the reported ASP units from the calendar quarter prior to the applicable calendar quarter; (2) using an average of units sold based on sales data for several calendar quarters prior to the applicable calendar quarter (for example, an average of the previous four calendar quarters); and (3) validation of ASP data based on review of AMP data in combination with one of the aforementioned alternative proposed policies to determine inflation rebate amounts. However, CMS has observed that ASP units are often negative, zero, or missing for several quarters in a four-quarter lookback, so including additional quarters may not necessarily yield additional data that could be used to apportion inflation rebate amounts (and could complicate the calculation of an average by introducing a mix of zero,

negative, missing, and positive units within a single NDC). In addition, the AMP validation of ASP sales could add another layer of complexity and potential bias as AMP data represent only sales to retail community pharmacies, and ASP data represent all sales of a drug. CMS welcomes comments on these alternatives.

(2) Scenarios in Which Some (But Not All) NDCs Have Negative, Zero, or Missing ASP Units

When some manufacturers' NDCs within a billing and payment code report negative, zero, or missing ASP units, CMS proposes to: (1) treat any NDCs with missing units that are not marketed or sold during the applicable calendar quarter, negative units, or zero units as not having any sales for the applicable calendar quarter and apportion a $0 rebate amount to them; (2) treat NDCs with missing units that are marketed or sold during the applicable calendar quarter as though they had the same units as that of the NDC with the lowest positive units; and (3) apportion rebate amounts across NDCs with missing units that are marketed or sold during the applicable calendar quarter and NDCs with positive units based on the share of ASP units sold in accordance with the policy outlined in section 50.13 of the revised Medicare Part B Drug Inflation Rebate Guidance. CMS welcomes comments on the extent to which, in a scenario where NDCs of multiple manufacturers are assigned to the same billing and payment code, a single manufacturer that accounts for all positive ASP units could potentially be responsible for the full rebate amount for the entire billing and payment code.

CMS also considered proposing other alternative policies for attributing rebate amounts to each respective manufacturer in this scenario, including: (1) review of historical ASP data to identify the most recent calendar quarter with positive ASP units for any of the NDCs with negative, zero, or missing units in the applicable calendar quarter and allocation of financial responsibility across NDCs with positive ASP units in that quarter (excluding NDCs without positive units in that quarter); (2) using an average of units sold based on sales data for several calendar quarters prior to the applicable quarter (for example, an average of the previous four calendar quarters); (3) apportionment of rebates based on units at the NDC–9 level rather than the NDC–11 level; and (4) apportionment of rebates to only those manufacturers within a HCPCS code that reported positive ASP units for the applicable calendar quarter.

CMS elected to not propose use of a historical lookback approach (under options 1 and 2) since ASP units are often negative, zero, or missing for the most recent calendar quarter and/or over several quarters in a four-quarter lookback period, and so including additional quarters may not necessarily yield additional data that could be used to apportion inflation rebate amounts (and could complicate the calculation of an average by introducing a mix of zero, negative, missing, and positive units within a single NDC). CMS also understands that a historical lookback approach could create outliers that could affect the resulting allocation. When evaluating option 3, CMS observed that ASP units are often negative, zero, or missing for several calendar quarters when aggregating units sold at the NDC–9 level. Consequently, this approach may not necessarily yield additional data that could be used to apportion inflation rebate amounts and doing so would differ from our general policy on using NDC–11s as set forth in the revised guidance. Finally, CMS decided not to propose apportioning the full rebate amount to only those manufacturers that reported positive ASP units within a billing and payment code under option 4, as we questioned whether that policy could inadvertently disfavor manufacturers that reported units while benefiting manufacturers that did not report ASP data. We continue to evaluate these alternative policy approaches for apportioning rebate liability and may adopt changes to this proposed policy in the final rule.

CMS reminds manufacturers of their reporting obligations under sections 1847A(f)(2) and 1927(b) of the Act and that failure to provide timely information may result in penalties as detailed in sections 1847A(d)(4)(B) and (C) and 1927(b)(3)(C)(i) of the Act.

CMS welcomes comments on these proposed approaches as well as alternative policy options on how CMS could apportion rebate amounts among multiple manufacturers' NDCs that reported negative, zero, and/or missing units for NDCs.

iii. Calculation of the Per Unit Part B Drug Rebate Amount

(1) Identification of the Specified Amount for the Applicable Calendar Quarter

In the calculation of the rebate amount for a Part B rebatable drug, CMS is statutorily required to compare the inflation-adjusted payment amount to the specified amount, which is the amount set forth in section 1847A(i)(3)(A)(ii)(I) of the Act. Statute also requires CMS to impose an inflation rebate if the specified amount exceeds the inflation-adjusted payment amount. CMS proposes to codify at § 427.302(a) the policy established in revised Medicare Part B Drug Inflation Rebate Guidance to calculate the Part B per unit rebate amount for the applicable calendar quarter by determining the amount by which the specified amount exceeds the inflation-adjusted payment amount, after accounting for exclusions under § 427.303(b). CMS proposes to codify the current operational steps for calculating Part B inflation rebates as described in section 50 of the revised Medicare Part B Drug Inflation Rebate Guidance.

In § 427.302(b), CMS proposes to codify the policy established in section 50.2 of the revised Medicare Part B Drug Inflation Rebate Guidance on how to calculate the specified amount for the applicable calendar quarter. The ''specified amount'' refers to the amount specified in section 1847A(i)(3)(A)(ii)(I)(aa) or (bb) of the Act, as applicable. In general, section 1847A(i)(3)(A)(ii)(I)(aa) and (bb) of the Act cross-reference provisions governing quarterly payment limits for single source drugs and biological products that are typically, but not always, reflected in the quarterly pricing files. Specifically, the specified amount for single source drugs and biological products is 106 percent of the amount determined under section 1847A(b)(4) of the Act—that is, the lesser of ASP or WAC—for the applicable calendar quarter. For biosimilar biological products, the specified amount is the payment amount under section 1847A(b)(1)(C) of the Act, which is based on 100 percent of the ASP for the biosimilar biological product plus 6 percent of the lesser of ASP or WAC for the reference biological product.

In § 427.302(b)(1), CMS proposes that the first applicable calendar quarter for a Part B rebatable drug will be the earliest applicable calendar quarter that follows the payment amount benchmark quarter identified in § 427.302(c)(1) through (6).

Additionally, for the purposes of determining the rebate amount for a Part B rebatable drug, based on further consideration of data availability in specific circumstances, CMS proposes to clarify the policy established in section 50 of the revised Medicare Part B Drug Inflation Rebate Guidance and use the most updated price information reported by manufacturers, determined

in accordance with section 1847A(i)(3)(A)(ii)(I)(aa) or (bb) of the Act as applicable, as the specified amount for the applicable calendar quarter for each HCPCS code identified in accordance with § 427.101. That is, CMS would use the most updated price information reported by manufacturers to compare whether 106 percent of WAC or 106 percent of ASP is less, and would use the lower value for the specified amount. In circumstances in which all NDCs in the HCPCS code have neither manufacturer-reported ASP nor WAC price data available for the applicable calendar quarter, CMS proposes to use WAC price data from other public sources, if available, to calculate 106 percent of WAC, which will serve as the specified amount. CMS proposes to adopt this approach regardless of whether there is a price substitution for Medicare's payment during the quarter or whether other policies cause the published payment limit to differ from the specified amount. In circumstances in which negative or zero manufacturer ASP data is reported for all NDCs for a given quarter, that negative or zero ASP amount would be used to compare 106 percent of WAC to 106 percent of ASP to determine the lower value for use as the specified amount. CMS believes these proposals on treatment of missing pricing data and treatment of pricing differences between reported prices and the published payment limit for a billing and payment code will further clarify the application of the specified amount in the calendar quarter are consistent with the requirements set forth in section 1847A(i)(3)(A)(ii)(I) of the Act. CMS solicits comments on this policy.

(2) Identification of the Payment Amount Benchmark Quarter

In § 427.302(c), CMS proposes to codify policies from section 50.3 of the revised Medicare Part B Drug Inflation Rebate Guidance to identify the applicable payment amount benchmark quarter. Specifically, for drugs first approved or licensed by the FDA on or before December 1, 2020, and with a first marketed date on or before December 1, 2020, the payment amount benchmark quarter would be the calendar quarter beginning July 1, 2021. For subsequently approved drugs—that is, drugs approved or licensed by the FDA after December 1, 2020—the payment amount benchmark quarter would be the third full calendar quarter after a drug's first marketed date. Additionally, there may be cases where a drug was first approved or licensed on or before December 1, 2020, but with a first marketed date after December 1, 2020, and the drug lacks ASP or WAC data to calculate the payment amount for the applicable calendar quarter beginning July 1, 2021. Under the policy applicable to drugs approved or licensed and with a first marketed date before December 1, 2020, such drugs would not have data to calculate the payment amount in the payment amount benchmark quarter. In these cases, CMS proposes to treat such drugs in the same manner as it would treat subsequently approved drugs and identify the payment amount benchmark quarter as the third full calendar quarter after a drug's first marketed date. CMS solicits comments on this policy proposal and specifically on our proposal to treat drugs approved or licensed on or before December 1, 2020, but with a first marketed date after December 1, 2020 as subsequently approved drugs.

For Part B rebatable drugs that were billed under a NOC code during the payment amount benchmark quarter, CMS stated in the revised Medicare Part B Drug Inflation Rebate Guidance that it would use the third full quarter after a drug was assigned a unique HCPCS code as the payment amount benchmark quarter. In this rulemaking, CMS proposes to determine the payment amount benchmark quarter as follows: For a Part B rebatable drug that was billed under a NOC code during the calendar quarter beginning July 1, 2021, or the third full calendar quarter after such drug's first marketed date, whichever is later, CMS proposes that the payment amount benchmark quarter be the third full calendar quarter after the Part B rebatable drug is assigned a billing and payment code other than a NOC code. CMS solicits comments on these proposals.

CMS continues to consider whether there is a need to identify additional or modified methodologies to appropriately determine the payment amount benchmark quarter for products with insufficient pricing data in the payment amount benchmark quarter or that otherwise do not fall squarely into the categories otherwise described in § 427.302(c) and in a manner that enables the calculation of rebate amounts consistent with section 1847A(i)(3) of the Act.

CMS has determined that ASP data are the most appropriate for identifying (1) the day on which the drug was first marketed and (2) which calendar quarter is the third full calendar quarter thereafter as the payment amount benchmark quarter for drugs first approved or licensed by the FDA after December 1, 2020, or licensed on or before December 1, 2020, but with a first marketed date after December 1, 2020. CMS also has determined that it is most appropriate and administratively feasible to identify the first marketed date as the date of first sale of any NDC–11 within a billing and payment code among all products and package sizes under the same FDA application.

Additionally, CMS believes ASP data are accurate and reliable because manufacturers attest to the accuracy of their submitted data and have the ability to update these data quarterly. Therefore, in § 427.302(c), CMS proposes to codify existing policy from the revised Medicare Part B Drug Inflation Rebate Guidance on the identification of the payment amount benchmark quarter for each Part B rebatable drug. CMS would use the earliest first marketed date of any NDC ever marketed under any FDA application under which any NDCs that have ever been assigned to the billing and payment code for that Part B rebatable drug as of the applicable calendar quarter have ever been marketed. The earliest first marketed date would apply to all NDCs within a billing and payment code and to all products and package sizes marketed under the same FDA approved application. If the original NDC on which the first marketed date is based is terminated, the first marketed date for the associated billing and payment code would remain the same. By defining the first marketed date for the Part B rebatable drug at the level of the product's FDA approval, CMS would retain the same first marketed date for the billing and payment code even if the NDCs and/or billing and payment codes used to bill for the Part B rebatable drug change over time. In addition, when the date of first sale is missing from ASP data, CMS proposes to identify the first marketed date from alternative public sources, such as the National Institutes of Health's DailyMed.

Table 48 in this section provides an example, for illustration purposes only, of the application of first marketed date based on the earliest date of first sale of any NDC ever marketed under any NDA or BLA under which any NDCs that have ever been assigned to the billing and payment code as of the applicable calendar quarter have ever been marketed. In the example, NDC1 (marketed under NDA 000000) is first sold on January 15, 2022, and NDC2 (also marketed under NDA 000000) is first sold on October 15, 2023. Both NDCs are marketed under an NDA associated with HCPCS code X0000. The first marketed date for HCPCS code X0000 would be January 15, 2022,

because that date is the earliest date of first sale for any NDC that has ever been associated with an NDA or BLA within that HCPCS code as of the calendar quarter. If NDC2 were subsequently assigned to a new HCPCS code Y0000, the first marketed date for HCPCS Y0000 would similarly be January 15, 2022. In cases when NDCs that are marketed under different NDA/BLAs are assigned to the same HCPCS code, using the example in the table in this section, NDC3 (marketed under NDA 111111) was first sold on November 1, 2024, and first billed under HCPCS Y0000, and the first marketed date for HCPCS Y0000 would remain January 15, 2022, as noted, given that HCPCS Y0000 includes NDC2, associated with NDA 000000. NDC3 was later assigned to a new HCPCS code Z0000. Following CMS' approach, the first marketed date for HCPCS code Z0000 is November 1, 2024, because that is the earliest date of first sale for any NDC ever marketed under NDA 111111, which is the only NDA ever associated with Z0000 as of the calendar quarter.

TABLE 48: Example of Application of First Marketed Date at the FDA Approval Level

Calendar Quarter	HCPCS Code	NDC	FDA Application Number	Date of First Sale for NDC	HCPCS Code Effective Date	Date of First Sale for Any NDC in NDA/BLA	First Marketed Date
2023 Q2	X0000	NDC1	000000	1/15/2022	4/1/2023	1/15/2022	1/15/2022
2023 Q3	X0000	NDC1	000000	1/15/2022	4/1/2023	1/15/2022	1/15/2022
		NDC2	000000	10/15/2023	4/1/2023	1/15/2022	
2023 Q4	X0000	NDC1	000000	1/15/2022	4/1/2023	1/15/2022	1/15/2022
		NDC2	000000	10/15/2023	4/1/2023	1/15/2022	
2024 Q1	X0000	NDC2	000000	10/15/2023	4/1/2023	1/15/2022	1/15/2022
2024 Q2	X0000	NDC2	000000	10/15/2023	4/1/2023	1/15/2022	1/15/2022
2024 Q3	Y0000	NDC2	000000	10/15/2023	7/1/2024	1/15/2022	1/15/2022
2024 Q4	Y0000	NDC2	000000	10/15/2023	7/1/2024	1/15/2022	1/15/2022
		NDC3	111111	11/1/2024	7/1/2024	11/1/2024	
2025 Q1	Y0000	NDC2	000000	10/15/2023	7/1/2024	1/15/2022	1/15/2022
	Z0000	NDC3	111111	11/1/2024	1/1/2025	11/1/2024	11/1/2024

(3) Identification of Payment Amount in the Payment Amount Benchmark Quarter

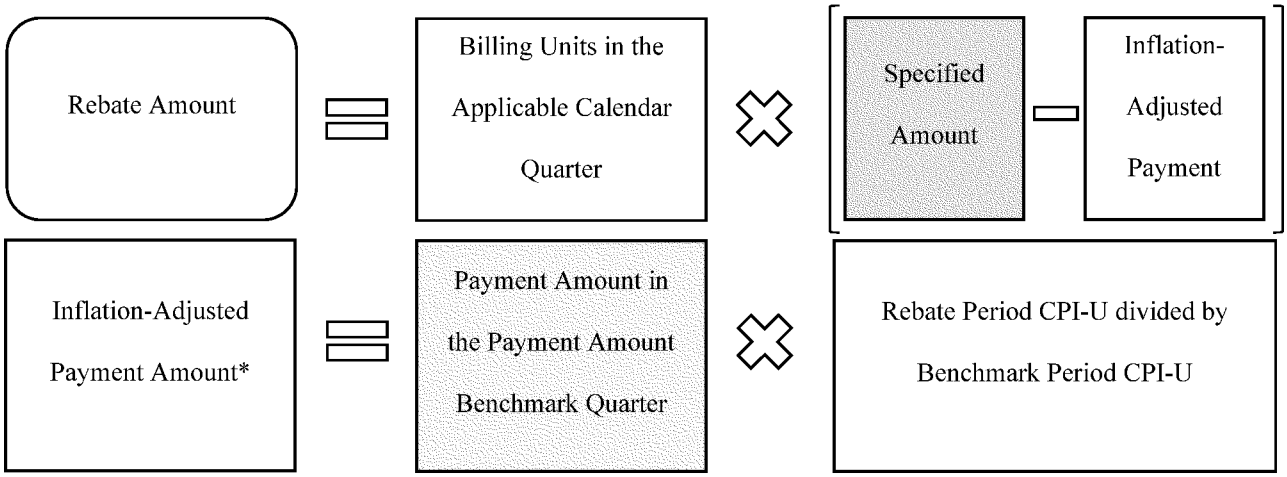
Section 1847A(i)(3)(C) of the Act specifies use of the ''payment amount for the billing and payment code for such drug in the payment amount benchmark quarter'' (''payment amount in the payment amount benchmark quarter'') in the determination of the inflation-adjusted payment amount. While the specified amount and the payment amount in the payment amount benchmark quarter are similar, the statutory requirements for determining these two amounts differ. The specified amount for a Part B rebatable drug, as set forth in section 1847A(i)(3)(A)(ii)(I) of the Act, is based on item (aa) (for example, lesser of ASP+6 percent or WAC+6 percent) or (bb) (that is, 100 percent of the ASP for the biosimilar biological product plus 6 percent of the lesser of ASP or WAC for the reference biological product). The payment amount in the payment amount benchmark quarter under section 1847A(i)(3)(C)(i) is based on various provisions within section 1847A of the Act (for example, the lesser of 106 percent ASP or WAC, WAC+3 percent, and price substitutions). To identify the payment amount in the payment amount benchmark quarter for the Part B rebatable drug by billing and payment code, in § 427.302(d), CMS proposes to codify the policies established in section 50.4 of the revised Medicare Part B Drug Inflation Rebate Guidance. CMS would use the published payment limit (as available) for the billing and payment code for the applicable payment amount benchmark quarter determined in accordance with section 1847A of the Act. If a published payment limit is not available for the applicable payment amount benchmark quarters, CMS would use the lower of 106 percent of manufacturer-reported ASP or 106 percent of manufacturer-reported WAC. If neither a published payment limit nor manufacturer-reported ASP or WAC data are available, CMS would use WAC data from other public sources to calculate 106 percent of WAC, which, solely for the purposes of identifying the payment amount in the payment amount benchmark quarter, CMS would consider to be the payment amount for the payment amount benchmark quarter. Table 49 and Figure 3 illustrate the specified amount and payment amount in the payment amount benchmark quarter.

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TABLE 49: Comparison of Specified Amount and Payment Amount in the Payment Amount Benchmark Quarter

Specified Amount		Payment Amount in the Payment Amount Benchmark Quarter	
Purpose in Rebate Calculation	**Pricing Methodology Under 1847A(i)(3)(A)(ii)(I)**	**Purpose in Rebate Calculation**	**Pricing Methodology Under 1847A(i)(3)(C)(i)**
Part B amount described under 1847A(i)(3)(A)(ii)(I) for the calendar quarter in which a rebate may be assessed	• Lesser of ASP+6% or WAC+6% • In the case of a biosimilar biological product, 100% of ASP for the biosimilar biological product + 6% of the lesser of ASP or WAC for the reference biological product	Part B published payment limit for the payment amount benchmark quarter, which is generally the quarter beginning July 1, 2021	• Various Part B pricing provisions consistent with section 1847A of the Act

FIGURE 3: Use of the Specified Amount and the Payment Amount in the Benchmark Quarter in Rebate Calculations



* See the next section for information about identification and calculation of the inflation-adjusted payment amount.

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CMS notes that there may be situations when a Part B rebatable drug was previously billed under a grouped billing and payment code during the benchmark quarter and later billed under a unique billing and payment code, such as certain section 505(b)(2) drug products and single source drugs that were previously multiple source drugs. For example, a multiple source drug approved under an NDA may become a single source drug if all other therapeutically equivalent drugs are no longer marketed and the now-single source NDA is later shifted into a separately payable code. To identify the payment amount in the payment amount benchmark quarter for such drugs, CMS proposes to codify policy established in section 50.4 of the Medicare Part B Drug Inflation Rebate Guidance and identify the grouped billing and payment code payment limit used by CMS for the payment amount in the payment amount benchmark quarter and use that payment limit for the benchmark quarter.

Finally, consistent with the policy established in section 50.4 of the revised Medicare Part B Drug Inflation Rebate Guidance, CMS would not apply a sequestration reduction to the payment amount in the payment amount benchmark quarter as part of the methodology to calculate a Part B inflation rebate amount.

(4) Identification of the Benchmark Period CPI–U

For each Part B rebatable drug by HCPCS code, the statute requires CMS to identify the applicable benchmark period CPI–U. In accordance with section 1847A(i)(3)(E) of the Act, the benchmark period CPI–U for drugs first approved or licensed by the FDA on or before December 1, 2020, and with a first marketed date on or before December 1, 2020, is the CPI–U for January 2021, which is 261.582.[568] CMS proposes to codify in § 427.302(e) policies established in section 50.5 of the revised Medicare Part B Drug Inflation Rebate Guidance. Specifically, the benchmark period CPI–U for drugs first approved or licensed on or before December 1, 2020, with a first marketed date after December 1, 2020, would be the CPI–U for the first month of the

[568] CMS retrieved the January 2021 CPI–U from *bls.gov* on March 22, 2024.

third full calendar quarter after a drug's first marketed date. Additionally, CMS proposes to codify policies in revised guidance that the benchmark period CPI–U for subsequently approved drugs would be the first month of the first full calendar quarter after a drug's first marketed date in accordance with section 1847A(i)(4)(A) of the Act. Furthermore, CMS proposes to determine the benchmark period CPI–U for certain drugs previously billed under NOC codes as follows: For a Part B rebatable drug that was billed under a NOC code during the calendar quarter beginning July 1, 2021, or the third full calendar quarter after such drug's first marketed date, whichever is later, CMS proposes that the benchmark period CPI–U would be first month of the third full calendar quarter after the drug is assigned a billing and payment code other than a NOC code. CMS solicits comments on these proposals.

(5) Identification of the Rebate Period CPI–U

As specified in section 1847A(i)(3)(F) of the Act, in § 427.302(f), CMS proposes to codify the policy described in section 50.6 of the revised Medicare Part B Drug Inflation Rebate Guidance, that the rebate period CPI–U means the greater of the benchmark period CPI–U index level and the CPI–U index level for the first month of the calendar quarter that is 2 calendar quarters prior to the applicable calendar quarter in which the Part B rebatable drug is furnished. CMS will retrieve the CPI–U index level information from *bls.gov.*

(6) Determination of the Inflation-Adjusted Payment Amount

Section 1847A(i)(3)(C) of the Act specifies the determination of the inflation-adjusted payment amount. In § 427.302(g), CMS proposes to codify the policy established in section 50.7 of revised Medicare Part B Drug Inflation Rebate Guidance for determining the inflation-adjusted payment amount in accordance with this section of the Act. For each applicable calendar quarter and for each Part B rebatable drug by billing and payment code, CMS proposes to use the payment amount in the payment amount benchmark quarter (per § 427.302(d)), benchmark period CPI–U (per § 427.302(e)), and rebate period CPI–U (per § 427.302(f)) to identify the inflation-adjusted payment amount. Specifically, CMS would calculate the inflation-adjusted payment amount by dividing the rebate period CPI–U by the benchmark period CPI–U and then multiplying the quotient by the payment amount in the payment amount benchmark quarter.

iv. Determination of Total Number of Billing Units

For calendar quarters starting on or after January 1, 2023, CMS proposes in § 427.303 to codify policies established in section 50.8 of the revised Medicare Part B Drug Inflation Rebate Guidance to determine the number of billing units for each Part B rebatable drug by HCPCS code. Section 1847A(i)(3)(B) describes the total number of billing units of Part B rebatable drugs that should be included in the rebate calculation. These billing units include the number of billing units for the HCPCS code of the Part B rebatable drug furnished during the relevant calendar quarter minus billing units of drugs with respect to which the manufacturer provides a discount under the 340B Program, billing units with respect to which the manufacturer could have paid a Medicaid rebate, and billing units that are packaged into the payment amount for an item or service and are not separately payable. CMS further proposes codifying policy set forth in revised Medicare Part B Drug Inflation Rebate Guidance in § 427.303 to exclude billing units when a drug is no longer a Part B rebatable drug.

After identifying Part B rebatable drugs by HCPCS code (in accordance with policy proposed in §§ 427.10, 427.20, and 427.100 through 427.101) using final action claims in the CMS Medicare fee-for-service claims repository, CMS proposes to codify existing policy in the revised Medicare Part B Drug Inflation Rebate Guidance in § 427.303 to determine the total number of billing units for each HCPCS code as follows. CMS identifies claim lines for such HCPCS code for dates of service in the calendar quarter, excludes billing units in claim specified in section 1847A(i)(3)(B)(ii) of the Act, as applicable, and sums the number of billing units in the remaining claim lines for which Medicare payment was allowed and greater than zero. Including billing units where Medicare payment was allowed would ensure that billing units for which Medicare and some beneficiaries have financial liability would be counted in the total number of billing units.

CMS proposes to codify the policy in the revised Medicare Part B Drug Inflation Rebate Guidance in § 427.303 and will perform this process at least 3 months after the end of a calendar quarter to allow time for claims to be submitted, processed, and finalized. Subpart F of this proposed rule describes the proposed rebate process, including reports of rebate amounts, suggestion of error, and restatements. CMS welcomes comment on the following policies and comments on any additional units that should be excluded from the rebate amount calculation.

(1) Units of Drugs Acquired Through the 340B Program

Section 1847A(i)(3)(B)(ii)(I) of the Act specifically excludes billing units of drugs for which the manufacturer provides a discount under the 340B Program from the billing units of drugs for which a manufacturer may otherwise have a Part B inflation rebate liability. CMS proposes codifying the policy described in section 50.8.1 of the revised Medicare Part B Drug Inflation Rebate Guidance in § 427.303 to remove separately payable billing units in claim lines that are billed with the ''JG'' or ''TB'' modifiers from identified final action claim lines.

On December 20, 2022, CMS issued program guidance that requires all 340B covered entities to include the ''JG'' or ''TB'' modifier, as applicable, on separately payable claim lines for drugs acquired through the 340B Program with dates of service beginning no later than January 1, 2024.[569] CMS proposes to codify this requirement in § 427.303(b)(1)(ii). Furthermore, on November 22, 2023, in the CY 2024 OPPS final rule (88 FR 81791 through 81792), CMS finalized a policy to utilize a single 340B modifier (''TB''), requiring hospitals that currently report the ''JG'' modifier to use the ''TB'' modifier beginning January 1, 2025. As described in the final rule, in CY 2024, these hospitals can choose to continue to use the ''JG'' modifier or choose to transition to the use of ''TB'' modifier during that year. On December 14, 2023, CMS updated the December 20, 2022 guidance titled ''Part B Inflation Rebate Guidance: Use of the 340B Modifiers'' to align with the updated single modifier requirement.[570]

CMS proposes in § 427.303(b)(1)(i) to exclude separately payable billing units in claim lines for professional claims with dates of service during 2023 from suppliers that are covered entities listed by the HRSA 340B Office of Pharmacy Affairs Information System as participating in the 340B Program. CMS will use National Provider Identifier numbers and/or Medicare Provider Numbers to identify these suppliers and the claims submitted with such identifiers. CMS proposes to continue this approach for professional claims

[569] See: *https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf.*

[570] See: *https://www.cms.gov/files/document/revised-part-b-inflation-rebate-340b-modifier-guidance.pdf.*

with dates of service during 2024. Consistent with the CMS updated 340B modifier guidance, CMS proposes in § 427.303(b)(1)(ii) excluding separately payable billing units in claim lines for institutional providers with the ''JG'' and ''TB'' modifiers from identified final action claims with dates of service through December 31, 2024. CMS proposes to codify policies established in section 50.8.1 of the revised Medicare Part B Drug Inflation Rebate Guidance in § 427.303(b)(1)(iii) by excluding separately payable billing units in claim lines with the ''TB'' modifier from identified final action claims with dates of service on or after January 1, 2025. CMS is proposing to use these modifiers to identify and exclude billing units for which a discount was acquired under the 340B Program because the ''TB'' modifier is an existing mechanism used to identify drugs acquired through the 340B Program and familiar to most 340B covered entities paid under the OPPS.

(2) Units With a Rebate Under Section 1927 of the Social Security Act

To receive payment under Medicaid for covered outpatient drugs, manufacturers must participate in the Medicaid Drug Rebate Program (that is, have a drug rebate agreement in effect with the Secretary of HHS) and are required to report certain pricing and drug product information and pay Medicaid drug rebates for covered outpatient drugs furnished and paid for under the Medicaid State plan. States invoice manufacturers no later than 60 days after the end of each calendar quarter on the number of units of each dosage form and strength of each covered outpatient drug furnished and paid for under the State plan. This invoice includes units of covered outpatient drugs that are furnished to dually eligible beneficiaries when the claim for the drug is paid for by Medicare Part B and the beneficiary's cost sharing is covered by Medicaid. To determine unit counts for rebate calculations, at this time, in § 427.303(b)(2), CMS proposes codifying our policy described in revised Medicare Part B Drug Inflation Rebate Guidance in section 50.8.2 to exclude billing units from claims with dates of service during a month within a calendar quarter when the Medicare beneficiary has Medicaid coverage that may provide cost-sharing assistance. These are Qualified Medicare Beneficiary (QMB) Plus, Specified Low-Income Medicare Beneficiary (SLMB) Plus, QMB-only beneficiaries, and other full dually eligible beneficiaries. CMS further proposes codifying the policy in revised guidance that billing units for Part B rebatable drugs furnished to Medicare beneficiaries with Medicaid coverage that does not include cost-sharing assistance (that is, SLMB Only, Qualified Disabled and Working Individuals (QDWI), and Qualifying Individuals (QI) beneficiaries) be included in rebate calculations. CMS would identify the months for which a beneficiary has Medicaid coverage with cost-sharing assistance using available information (for example the State MMA File of dually eligible beneficiaries) at the time the rebate amount is being calculated for a calendar quarter. CMS proposes codifying this policy as manufacturers pay rebates through the Medicaid Drug Rebate Program on units of covered outpatient drugs that are furnished to dually eligible beneficiaries when the claim for the drug is paid for by Medicare Part B and the beneficiary's cost sharing is covered by Medicaid.

CMS also considered excluding all units furnished to dually eligible individuals but is not proposing this alternative as it would result in the over exclusion of units.

(3) Units That Are Packaged Into the Payment Amount for an Item or Service and Are Not Separately Payable

As described earlier in this section, CMS proposes codifying our policy in section 50.8.3 of revised Medicare Part B Drug Inflation Rebate Guidance and only include claim lines with a Medicare allowed amount greater than zero. Because CMS proposes in § 427.303(b)(3) identifying billing units for separately payable claim lines for Part B rebatable drugs only, no further action would be necessary to exclude billing units that are packaged into the payment amount for an item or service and are not separately payable, such as drugs for which payment is packaged under the OPPS, or the Ambulatory Surgical Center (ASC) payment system, or those furnished in the Federally qualified health centers (FQHC) or rural health clinics (RHC) setting. CMS notes that claim lines for drugs for which payment is bundled under the End-Stage Renal Disease (ESRD) prospective payment system would not have a Medicare allowed amount that is greater than zero and such units would therefore be excluded.

In accordance with policies established in the CY 2024 OPPS/ASC final rule and codified in regulatory text at 88 FR 81540, CMS would except biosimilar biological products from the OPPS threshold packaging policy when their reference biological products are separately paid. This means that CMS would pay separately for these biosimilar biological products even if their per-day cost is below the threshold packaging policy. Because units of these biosimilar biological products are not packaged into the payment amount for an item or service and are separately payable, they would be included in the Part B inflation rebate calculation if they are not qualifying biosimilar biological products.

(4) Units When a Drug Is No Longer a Part B Rebatable Drug

As described in section 1847A(i)(2) of the Act, multiple source drugs are not Part B rebatable drugs. A single source drug that is a Part B rebatable drug could become a multiple source drug at the start of or during a calendar quarter. In such cases, in § 427.303(b)(4), CMS proposes codifying policy in section 50.8.4 of the revised Medicare Part B Drug Inflation Rebate Guidance to identify the first marketed date, as described in § 427.20, of a drug product that is rated as therapeutically equivalent to such a drug under FDA's most recent publication of Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the FDA Orange Book [571]) and determine whether the drug is no longer a Part B rebatable drug. In § 427.303(b)(4), CMS proposes to exclude billing units of such drug furnished on and after the first day of the calendar month in which the therapeutically equivalent drug was first sold or marketed during the applicable calendar quarter. CMS further proposes codifying policy that it may consult with the FDA for technical assistance in instances where there is ambiguity as to whether a new product is therapeutically equivalent. Units furnished on or after the calendar month of the first marketed date would be excluded from the units identified in accordance with § 427.303(b)(4)(iii).

(5) Operational Considerations Related to the Inclusion of Units Furnished to Beneficiaries Who Are Enrolled in Medicare Advantage (MA) Plans

Section 1847A(i) of the Act requires the manufacturer of a Part B rebatable drug to pay a rebate that, generally, is calculated based on the total number of billing units of that drug that were furnished in a calendar quarter, multiplied by the excess specified amount for the drug over a statutorily defined inflation-adjusted payment amount. The inclusion in this

[571] Accessible via *https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.*

calculation of billing units of drugs that are furnished to Medicare beneficiaries who are enrolled in MA plans poses significant operational complexities. At this time, CMS is not proposing to establish a policy on treatment of MA units in the calculation of Part B inflation rebates due to operational considerations, but may establish policy on this issue in future rulemaking. CMS solicits comments on this approach.

(6) Units Subject to Discarded Drug Refunds

In § 427.303(b)(5), CMS proposes a policy addressing the interaction between Part B inflation rebates and billing units of discarded drugs. Under the Infrastructure Investment and Jobs Act of 2021, section 90004, manufacturers are required to provide a refund to CMS for certain discarded amounts from separately payable single-dose container or single-use package drugs beginning January 1, 2023. To implement the discarded drugs refund provision of the Infrastructure Investment and Jobs Act of 2021, in the CY 2023 PFS final rule (87 FR 69711 through 69719), CMS finalized the requirement that providers and suppliers use the ''JW'' claim modifier for all separately payable drugs with discarded amounts of drugs from a single-dose container or from a single-use package Part B claims that bill for drugs and biological products to report discarded amounts. CMS also finalized a requirement for providers and suppliers to use the ''JZ'' modifier on claims that bill for drugs from single-dose containers that are separately payable under Medicare Part B when there are no discarded amounts to attest that no amount of drug was discarded and eligible for payment.[572] As of October 1, 2023, claims for drugs from single-dose containers that do not use the modifiers as appropriate may be returned until claims are properly resubmitted.

Although section 1847A(i)(3)(B)(ii) of the Act does not require that billing units of discarded drugs be excluded from Part B inflation rebates, CMS is proposing to exclude billing units of discarded drugs that are subject to discarded drug refunds from Part B inflation rebates. CMS believes not applying Part B inflation rebates to billing units of discarded drugs for which a refund is owed would balance fairness for manufacturers that owe refunds for billing units of discarded drugs with the need to fulfill the requirements of section 11101 of the IRA.

As new policy not established in section 50.8.6 of the revised Medicare Part B Drug Inflation Rebate Guidance, CMS proposes to exclude billing units of a refundable single-dose container or single-use package drug as defined in § 414.902 (hereinafter referred to as ''refundable drug'') subject to discarded drug refunds, from the calculation of rebate amounts during the reconciliation process except for calendar quarters in calendar year 2023. In the CY 2024 PFS final rule (codified in § 414.940), CMS finalized policy to send annual refund reports for discarded drug refunds for the 4 quarters of a calendar year at or around the time it sends Part B Inflation Rebate Reports for the first quarter of the following calendar year. Therefore, CMS invoices manufacturers for discarded drug refunds on an annual basis but CMS is required to invoice manufacturers for Part B inflation rebates on a quarterly basis.

Under the timeline for processing discarded drug refunds, data to determine which billing units of discarded drugs are subject to discarded drug refunds will generally not be available until after CMS issues the Rebate Report to the manufacturer. Due to these data limitations, CMS proposes to include all discarded billing units, including units of a refundable drug subject to the discarded drug refund (as defined in § 414.940), in the calculation of billing units for the Preliminary Rebate Report and the Rebate Report. CMS proposes to use data available during the reconciliation process to exclude billing units of discarded drugs that are subject to discarded drug refunds from the calculation of the rebate amount.

For calendar quarters in calendar year 2023, CMS proposes to exclude billing units of a refundable drug subject to discarded drug refunds from the calculation of the rebate amount before CMS issues the Rebate Report to the manufacturer. As permitted by section 1847A(i)(1)(C) of the Act, CMS is delaying reporting of rebate information required by section 1847A(i)(1)(A) for calendar quarters in calendar years 2023 and 2024 until no later than September 30, 2025. Under this timeline for calendar quarters in calendar year 2023, CMS will have data available regarding which billing units are subject to discarded drug refunds when CMS sends the Preliminary Rebate Report and Rebate Report in 2025 for calendar quarters in calendar year 2023 and can exclude these billing units from the calculation of the rebate amount in these reports.

CMS solicits comments on the proposed approach to excluding billing units of a refundable drug subject to discarded drug refunds, from the calculation of Part B inflation rebate amounts during the reconciliation process, except for calendar quarters in calendar year 2023.

v. Adjustments for Changes to Billing and Payment Codes

Changes to billing and payment codes, including new code assignments and dose description changes, may occur.

When a new billing and payment code is assigned for a Part B rebatable drug and the code dose description, which determines that amount of drug in each billing unit, remains the same, CMS proposes to codify in § 427.304(b) the existing policy set forth in revised Medicare Part B Drug Inflation Rebate Guidance to use the benchmark quarter's payment amount, the payment amount benchmark quarter, and the benchmark quarter CPI–U of the prior billing and payment code to calculate the per unit Part B rebate amount. For example, a single source drug or biological product may be assigned a new billing and payment code if it was initially assigned to a billing and payment code with other products and then later assigned a unique billing and payment code. In this situation, a multiple source drug in an NDA may become a single source drug if all its other therapeutically equivalent drugs are discontinued and the now-single source NDA is later shifted into a separately payable code.

When a Part B rebatable drug's code dose description changes, CMS proposes to codify in § 427.304(a) policies established in section 50.9 of the revised Medicare Part B Drug Inflation Rebate Guidance and apply a conversion factor within the rebate calculation, when applicable. For example, a billing and payment code dose description that determines the amount of drug in each billing unit could be changed from 10mg to 5mg. If a billing and payment code dose description changes from 10mg to 5mg, the payment amount in the payment amount benchmark quarter for such drug was $200 based on 10mg, and the rebate period payment amount is based on 5mg, then CMS would apply a conversion factor of 0.5 to the payment amount in the payment amount benchmark quarter (yielding $100). In this example, the conversion factor would be based on the ratio of the current billing unit description to the

[572] See 87 FR 2512, November 18, 2022 (*https://www.federalregister.gov/d/2022-23873/p-2512*).

prior billing unit description (5mg/10mg = 0.5). In addition, to ensure consistency in how CMS is calculating a rebate when a billing and payment code's dose description changes, CMS proposes to apply a conversion factor before applying the percentage by which the rebate period CPI–U for the calendar quarter exceeds the benchmark period CPI–U to determine the inflation-adjusted payment amount.

In situations where a new billing and payment code is assigned for a Part B rebatable drug and the code dose description changes, CMS would apply a conversion factor, as appropriate, and use the benchmark quarter's payment amount, the payment amount benchmark quarter, and the benchmark quarter CPI–U of the prior billing and payment code to calculate the per unit Part B rebate amount—consistent with the policy in revised guidance that CMS is proposing to codify in § 427.304(a) and (b).

To apply the provisions in section 1847A(i) of the Act appropriately, CMS also proposes in § 427.304(c) to codify existing policy to maintain a crosswalk between such changes or codes.

CMS solicits comment on these proposals.

e. Reducing the Rebate Amount for Part B Rebatable Drugs in Shortage and When There Is a Severe Supply Chain Disruption (§§ 427.400 Through 427.402)

Section 1847A(i)(3)(G) of the Act requires the Secretary to reduce or waive the rebate amount owed by a manufacturer for a Part B rebatable drug with respect to a calendar quarter in two cases: (1) when a Part B rebatable drug is described as currently in shortage on a shortage list in effect under section 506E of the FD&C Act at any point during the applicable period; and (2) when CMS determines there is a severe supply chain disruption during the applicable quarter for a Part B rebatable biosimilar biological product, such as a disruption caused by a natural disaster or other unique or unexpected event. The statute does not describe how CMS should reduce or waive inflation rebates in each of these cases.

To implement the statutory requirement under section 1847A(i)(3)(G), CMS proposes to codify in subpart E of part 427 existing policies described in sections 50.10, 50.11, and 50.12 of the revised Medicare Part B Drug Inflation Rebate Guidance to reduce the total rebate amount owed by a manufacturer in each of these cases, as summarized in Table 50 and discussed later in this section.

	Drug Shortage		Severe Supply Chain Disruption
Duration of Reduction	Indefinite for as long as drug is "currently in shortage"		Four calendar quarters; manufacturer may request an extension for four additional quarters for up to eight calendar quarters total
Percent Reduction	Part B rebatable drug other than a plasma-derived product	Part B rebatable plasma-derived product	Part B rebatable biosimilar biological product
First four consecutive calendar quarters	25%	75%	75%
Second four consecutive calendar quarters	10%	50%	75%
Subsequent calendar quarters	2%	25%	Not applicable

TABLE 50: Determination of Rebate Reduction Amount for Part B Rebatable Drugs

As proposed, the rebate amount owed would not be fully waived in either of the cases previously described. CMS believes the proposed rebate reduction policies balance providing appropriate financial relief for manufacturers in certain circumstances, including when there is a severe supply disruption resulting from exogenous circumstances outside of a manufacturer's control, while not incentivizing manufacturers to delay taking appropriate steps to resolve a drug shortage or severe supply chain disruption to avoid an obligation to pay rebates. CMS will continue to evaluate these policies and may update them in future years. CMS underscores that most shortages involve multiple source generic drugs,[573] which are not Part B rebatable drugs and thus are not subject to Part B drug inflation rebates. CMS solicits comments on the proposed approach.

i. Definitions

CMS proposes in § 427.400 to define the following terms applicable to proposed subpart E (§§ 427.400 through 427.402)—

- ''Drug shortage'' or ''shortage''.
- ''Plasma-derived product''.

Proposed § 427.400 also would codify definitions established in the revised Medicare Part B Drug Inflation Rebate Guidance for the following terms:

- ''Currently in shortage''.
- ''Natural disaster''.
- ''Other unique or unexpected event''.
- ''Severe supply chain disruption''.

ii. Reducing the Rebate Amount for Part B Rebatable Drugs Currently in Shortage

In proposed § 427.401, CMS proposes to codify the policy established in section 50.11 of the revised Medicare Part B Drug Inflation Rebate Guidance whereby CMS would reduce the total rebate amount for a Part B rebatable drug that is currently in shortage based on the length of time the drug is in shortage during a calendar quarter and decrease the amount of the reduction over time. CMS intends to use the shortage lists maintained by the FDA Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) to determine whether a Part B rebatable drug is currently in shortage[574] during

[573] See: *https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-shortages-in-the-us2023.*

[574] For the purposes of this proposed rule, CMS uses the term ''currently in shortage'' to refer to Part

Continued

a calendar quarter. CMS will not consider an NDC–10 in the status of ''to be discontinued,'' ''discontinued,'' or ''resolved'' to be ''currently in shortage.'' At this time, CMS intends to provide the same reduction in the rebate amount for Part B rebatable drugs currently in shortage regardless of the cause of the shortage.

CMS will not provide a full waiver of the rebate amount for drugs currently in shortage on an FDA shortage list, as providing a full waiver of the rebate amount could further incentivize manufacturers to delay taking appropriate steps that may resolve a shortage more expeditiously simply to maintain having the drug listed on FDA's drug shortage list to avoid an obligation to pay rebates for an extended period. Further, in a report analyzing the root causes of drug shortages between 2013 and 2017, FDA found that more than 60 percent of drug shortages were the result of manufacturing or product quality issues, and providing a full waiver of the rebate amount in situations that may be within a manufacturer's control could be perceived as rewarding manufacturers for poor quality management.[575]

CMS would be responsible for monitoring the status of a Part B rebatable drug on an FDA shortage list, and manufacturers would not need to submit any information to CMS to be eligible for a reduction of the rebate amount for a Part B rebatable drug that is currently in shortage.

To calculate the reduced total rebate amount for a Part B rebatable drug, in § 427.401(b), CMS proposes the following formula:

Reduced *Total* Rebate Amount = total rebate amount *multiplied by* (1 *minus* applicable percent reduction) *multiplied by* (percentage of time drug was currently in shortage during the calendar quarter) *added to* the total rebate amount *multiplied by* (1 *minus* percentage of time drug was currently in shortage during the calendar quarter)

For the purpose of this formula, for a Part B rebatable drug that is a plasma-derived product, in § 427.401(b)(2)(i), CMS proposes an applicable percent reduction of 75 percent for the first 4 consecutive calendar quarters such Part B rebatable drug is currently in shortage, 50 percent for the second 4 consecutive calendar quarters, and 25 percent for each subsequent calendar quarter. For a Part B rebatable drug (including a biosimilar biological product) that is not a plasma-derived product, in § 427.401(b)(2)(ii), CMS proposes an applicable percent reduction of 25 percent for the first 4 consecutive calendar quarters such Part B rebatable drug is currently in shortage, 10 percent for the second 4 consecutive calendar quarters, and 2 percent for each subsequent calendar quarter.

Because drugs and biologicals on the FDA shortage lists are maintained at the NDC–10 level, and Part B drug inflation rebates are calculated at the HCPCS level, CMS proposes in § 427.401(c) that if any NDC–10 assigned to the HCPCS code(s) is currently in shortage, CMS would apply the rebate reduction to all of the NDCs under the relevant HCPCS code(s). CMS will closely monitor market data for the Part B rebatable drugs for which the rebate is reduced to ensure the integrity of the application of the rebate reduction policy.

CMS intends to provide a reduction in the rebate amount for as long as a Part B rebatable drug is currently in shortage. CMS believes the rebate reduction should be proportional to the time the drug is currently in shortage and decrease over time to balance providing financial relief to manufacturers experiencing a drug shortage while not incentivizing manufacturers to delay taking appropriate steps to resolve a shortage simply to maintain having the drug listed on an FDA shortage list to avoid an obligation to pay rebates for an extended period.

To determine the percentage of time a Part B rebatable drug was currently in shortage during the calendar quarter, as proposed in § 427.401(b)(3), CMS would count the number of days such drug is currently in shortage in a calendar quarter and divide by the total number of days in that calendar quarter.

In § 427.401(b)(2), CMS proposes codifying the policy set forth in section 50.11 of the revised Medicare Part B Drug Inflation Rebate Guidance to apply a greater applicable percent reduction for plasma-derived products than non-plasma derived products because the former rely on a variable supply of donated blood plasma that can impact downstream production and therefore hamper the ability to promptly resolve a shortage.

When the status of a Part B rebatable drug changes from currently in shortage to resolved during a calendar quarter and then changes to currently in shortage during one or more of the subsequent three calendar quarters, CMS would apply the shortage reduction as if there was a continuous shortage beginning with the quarter in which the drug has re-entered a shortage and move to the percent reduction applicable for the second four consecutive quarters. (In this scenario, once this drug enters its fifth quarter of shortage from the first quarter in which it was listed as currently in shortage, the applicable percent reduction would be 50 percent for the fifth through eighth calendar quarters for a Part B rebatable drug that is a plasma-derived product and 10 percent for a Part B rebatable drug that is not a plasma-derived product.) When the status of a Part B rebatable drug changes from currently in shortage to resolved and either remains in the status of resolved or is removed from the list for at least 4 full consecutive calendar quarters and then subsequently reemerges on a shortage list, CMS would treat the subsequent shortage as a new shortage and would apply the applicable percent reduction for the first 4 consecutive calendar quarters.

iii. Reducing the Rebate Amount for Part B Rebatable Biosimilar Biological Products When There Is a Severe Supply Chain Disruption

In § 427.402 of this proposed rule, CMS proposes to codify the policy established in section 50.12 of the revised Medicare Part B Drug Inflation Rebate Guidance for rebate reductions when CMS determines there is a severe supply chain disruption during a calendar quarter. As proposed in § 427.402(b)(1), CMS would provide a time-limited standard reduction of 75 percent in the total rebate amount for a Part B rebatable biosimilar biological product when CMS determines there is a severe supply chain disruption during the calendar quarter, such as that caused by a natural disaster or other unique or unexpected event. To receive a rebate reduction in accordance with proposed § 427.402(b)(1), the manufacturer would have to submit to CMS a rebate reduction request[576] that meets the eligibility requirements in proposed § 427.402(c). A rebate reduction request should specify each NDC–11 and HCPCS code to which the request applies and if CMS grants a manufacturer's request for an NDC–11, CMS proposes in § 427.402(b)(3) that the rebate reduction would apply to all the NDC–11s under the relevant HCPCS code. CMS has proposed additional

B rebatable drugs that are in the status of ''currently in shortage'' on the CDER shortage list, as well as biological products listed on CBER's current shortages list.

[575] See: *https://www.fda.gov/media/131130/download?attachment#page=33.*

[576] The rebate reduction request forms are currently going through the Paperwork Reduction Act approval process under the document identifier CMS–10858. The proposed collection was published for a 30-day comment period in the June 3, 2024 **Federal Register** (89 FR 47563).

submission requirements for rebate reduction requests in the information collection request under OMB control number: 0938–NEW (CMS–10858).

As proposed in § 427.402(c)(4), CMS would grant a reduction in the rebate amount owed if a manufacturer of an eligible drug submits to CMS a request in writing demonstrating supply chain disruption has occurred during the calendar quarter, (2) the severe supply chain disruption directly affects the manufacturer itself, a supplier of an ingredient or packaging, a contract manufacturer,[577] or a method of shipping or distribution that the manufacturer uses in a significant capacity to make or distribute the Part B rebatable biosimilar biological product, and (3) the severe supply chain disruption was caused by a natural disaster or other unique or unexpected event. As proposed in § 427.402(c)(2), for a natural disaster or other unique or unexpected event occurring on or after August 2, 2024, that the manufacturer believes caused a severe supply chain disruption, the manufacturer must submit the rebate reduction request within 60 calendar days from the first day that the natural disaster or other unique or unexpected event occurred or began in order for CMS to consider a rebate reduction.

CMS believes that severe supply chain disruptions generally take time to resolve and for purposes of this proposed rule, CMS proposes in § 427.402(a) to codify the policy established in section 50.12 of the revised Medicare Part B Drug Inflation Rebate Guidance whereby a determination that a severe supply chain disruption has occurred would be deemed to disrupt the supply chain for the quarter in which the event occurred and the three subsequent calendar quarters. If the manufacturer makes a timely request that includes all the supporting documentation and CMS determines, based on its review of the reduction request and supporting documentation, that a reduction should be granted, CMS would reduce the total rebate amount owed by a manufacturer by 75 percent for the calendar quarter in which the event that caused the severe supply chain disruption occurred or began, or the following calendar quarter if the request is submitted less than 60 calendar days before the end of a calendar quarter, and the three calendar quarters thereafter.

CMS proposes in § 427.402(c)(5) that if the manufacturer believes a severe supply chain disruption continues into a fifth consecutive calendar quarter after the start of the natural disaster or other unique or unexpected event, the manufacturer may request a reduction of the rebate amount for the fifth through eighth calendar quarters by submitting a rebate reduction extension request to CMS along with any new supporting documentation. CMS has proposed additional submission requirements for rebate reduction extension requests in the information collection request under OMB control number: 0938–NEW (CMS–10858). As proposed in § 427.402(c)(5)(ii), a rebate reduction extension request and any new supporting documentation must be submitted at least 60 calendar days before the start of the fifth calendar quarter in order for CMS to consider a rebate reduction extension.

If the manufacturer submits a complete and timely extension request, and CMS determines that the information submitted warrants an extension of the rebate reduction, the total rebate amount would be reduced by 75 percent for the fifth through eighth calendar quarters for that manufacturer's Part B rebatable biosimilar biological product, in accordance with proposed § 427.402(b)(2).

Consistent with the policy established in section 50.12 of the revised Medicare Part B Drug Inflation Rebate Guidance, a manufacturer may receive only one extension of the rebate reduction per Part B rebatable biosimilar biological product per CMS determination of a severe supply chain disruption, as proposed in § 427.402(c)(5). Said differently, the severe supply chain disruption rebate reduction would be limited to 8 consecutive calendar quarters total per Part B rebatable biosimilar biological product per CMS determination of a severe supply chain disruption.

As proposed in § 427.402(b)(4)(i), if the manufacturer believes there are multiple events causing severe supply chain disruptions during the same four calendar quarters for the same Part B rebatable biosimilar biological product and submits multiple rebate reduction requests for the same product, CMS will grant no more than one rebate reduction for that Part B rebatable biosimilar biological product for those 4 consecutive calendar quarters. For example, if the manufacturer of a Part B rebatable biosimilar biological product is granted a severe supply chain disruption rebate reduction request for its product due to a natural disaster that occurred in January 2025 and then experiences a second severe supply chain disruption caused by a second, distinct natural disaster in July 2025, CMS would not grant the second rebate reduction request. That is, the manufacturer would receive the 75 percent reduction for four calendar quarters for the severe supply chain disruption caused by the first natural disaster but would not receive a reduction for the second natural disaster. However, if the second natural disaster exacerbated the severe supply chain disruption caused by the first natural disaster, the manufacturer may reflect such circumstances in its request for an extension of the rebate reduction for the fifth through eighth calendar quarters.

As proposed in § 427.402(b)(4)(ii), if CMS grants a severe supply chain disruption rebate reduction request for a Part B rebatable biosimilar biological product, and the product appears as currently in shortage during one of the same four calendar quarter(s) as for which the severe supply chain disruption reduction was granted, CMS would apply the 75 percent reduction to the four calendar quarters for which the severe supply disruption request was granted and would not grant any additional reduction for the shortage status during those quarters. For any subsequent calendar quarters that the Part B rebatable biosimilar biological product appears as currently in shortage, CMS would reduce the rebate amount in accordance with the drug shortages reduction proposed in § 427.401, starting with the highest reduction (that is, 75 percent for a plasma-derived product and 25 percent for a Part B rebatable drug that is not a plasma-derived product). For example, if CMS grants a severe supply chain disruption rebate reduction request for a Part B rebatable biosimilar biological product that was submitted on February 15, 2024, and that product is currently in shortage from December 15, 2024 until May 15, 2025, CMS would apply a 75 percent reduction in the total rebate amount to all four calendar quarters in 2024, and then would apply the shortages reduction as proposed in § 427.401, beginning with a reduction of 25 percent for a Part B rebatable biosimilar biological product or 75 percent in the case of a plasma-derived product that is a Part B rebatable biosimilar biological product for the first two calendar quarters of 2025.

As proposed in § 427.402(b)(4)(iii), if a Part B rebatable biosimilar biological

[577] A contract manufacturer is a party that performs one or more manufacturing operations on behalf of a manufacturer(s) of active pharmaceutical ingredients (APIs), drug substances, in-process materials, finished drug products, including biological products, and combination products. See ''Contract Manufacturing Arrangements for Drugs: Quality Agreements Guidance for Industry,'' November 2016: *https://www.fda.gov/media/86193/download*.

product that is currently in shortage experiences a severe supply chain disruption, the manufacturer may submit a request for a severe supply chain disruption rebate reduction. If CMS grants the rebate reduction request, the rebate amount would be reduced by 75 percent for the duration of 4 consecutive calendar quarters (that is, the calendar quarter in which the event that caused the severe supply chain disruption occurred and the three calendar quarters thereafter), and CMS would not grant any additional reduction under § 427.401 for the currently in shortage status during those 4 calendar quarters. If CMS receives the request and all supporting documentation describing the natural disaster or other unique or unexpected event causing the severe supply chain disruption less than 60 days before the end of a calendar quarter, CMS would apply the 75 percent rebate reduction to the next calendar quarter and to the three subsequent calendar quarters thereafter. For example, if a Part B rebatable biosimilar biological product that is currently in shortage in the calendar quarter beginning October 1, 2024, is granted a severe supply chain disruption rebate reduction request as a result of a natural disaster that occurs on October 20, 2024, CMS would apply a 75 percent reduction in the rebate amount for the duration of the calendar quarter in which the natural disaster occurred and the three subsequent calendar quarters thereafter (that is, October 1, 2024, to September 30, 2025). In this same example, if the natural disaster instead occurs on November 20, 2024, CMS would apply the shortages reduction proposed in § 427.401 for the calendar quarter beginning October 1, 2024, and ending on December 31, 2024, and then a 75 percent reduction under the severe supply chain disruptions policy to the next calendar quarter and the three subsequent calendar quarters thereafter (that is, January 1, 2025 to December 31, 2025).

In proposed § 427.402(c)(6), CMS proposes to review rebate reduction requests and rebate reduction extension requests within 60 calendar days of receipt of all documentation, if feasible, beginning with the calendar quarter that begins on October 1, 2024. CMS will begin accepting rebate reduction requests and rebate reduction extension requests upon completion of the Paperwork Reduction Act (PRA) process, including for severe supply chain disruptions caused by a natural disaster or other unique or unexpected event that occurred on or after January 1, 2023, prior to completion of the PRA process. If a manufacturer's rebate reduction request does not meet the criteria in proposed § 427.402(c)(4) or if the rebate reduction request is incomplete or untimely based on the requirements in proposed § 427.402(c), CMS would deny the request. CMS also proposes that if a manufacturer's rebate reduction extension request does not meet the criteria in proposed § 427.402(c)(5), is incomplete or untimely based on the requirements in proposed § 427.402(c)(5), or if a reduction under proposed § 427.402(b)(1) was not provided for such Part B rebatable biosimilar biological product, CMS would deny the rebate reduction extension request. As proposed in § 427.402(c)(6)(iii), CMS' decisions to deny a request would be final and not be subject to an appeals process.

As proposed at § 427.402(c)(7), CMS would keep confidential, to the extent allowable under law, any requests for a rebate reduction, including supporting documentation. CMS proposes that information provided as part of a severe supply chain disruption rebate reduction request that the submitter indicates is a trade secret or confidential commercial or financial information would be protected from disclosure if CMS determines the information meets the requirements set forth under Exemptions 3 and/or 4 of the Freedom of Information Act (FOIA). In addition to the protections under the FOIA for trade secrets and commercial or financial information obtained from a person that is privileged or confidential, the Trade Secrets Act at 18 U.S.C. 1905 requires executive branch employees to protect such information. CMS would protect confidential and proprietary information as required by applicable law.

f. Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments (§§ 427.500 Through 427.505)

Section 1847A(i)(1)(A) of the Act requires the Secretary to provide a report to each manufacturer of a Part B rebatable drug with the following information not later than 6 months after the end of an applicable calendar quarter: (1) the total number of billing units for each Part B rebatable drug; (2) the amount, if any, of the excess average sales price increase (the amount by which the specified amount exceeds the inflation-adjusted payment amount as calculated in proposed § 427.301(g)) for an applicable calendar quarter; and (3) the rebate amount for the Part B rebatable drug. In compliance with section 1847A(i)(1)(B) of the Act, manufacturers of a Part B rebatable drug must provide a rebate for each Part B rebatable drug no later than 30 calendar days after the receipt of the information provided by the Secretary in section 1847A(i)(1)(A) of the Act.

To fulfill this statutory requirement, CMS is proposing to provide a Preliminary Rebate Report followed by a Rebate Report, as described in proposed § 427.501(b) and (c), to all manufacturers of a Part B rebatable drug, even if the amount due is $0; all rebate amounts would be subject to reconciliation as proposed in § 427.501(d). As proposed in § 427.501(d)(4), CMS does not intend to send notice to manufacturers for drugs that are not considered rebatable pursuant to proposed § 427.20.

Additionally, to address the completeness and accuracy of the rebate amount, CMS proposes to conduct one regular reconciliation to determine whether the rebate amount should be adjusted due to updated claims and payment data used in the calculation of such rebate amount (specified in proposed § 427.501(b)(1)) to occur 12 months after the issuance of the Rebate Report. The reporting process for reconciliation will be the same process described for the original Rebate Report, with payment due for any outstanding rebate amount 30 days after receipt of a report with a reconciled rebate amount. In addition to regular reconciliation, CMS proposes a process to conduct reconciliation of the rebate amount as needed to correct agency error and when CMS determines that the information used by CMS to calculate a rebate amount was inaccurate due to manufacturer misreporting.

CMS believes conducting a reconciliation for the Part B Rebate Program is important in ensuring the accuracy of the rebate amount and for programmatic alignment with the Part D Rebate Program.

i. Definitions

In proposed § 427.500, CMS proposes the following term applicable to proposed subpart F (§§ 427.500 through 427.505):

- ''Date of receipt''.

For example, if CMS issues a Rebate Report through the method and process described in § 427.504 on June 30, 2026, then July 1, 2026, will be the date of receipt and day one of the 30-calendar-day payment period.

ii. Reports of Rebate Amounts and Suggestion of Error

Consistent with the process specified in section 60 of the revised Medicare Part B Drug Inflation Rebate Guidance involving preliminary and final reports,

CMS proposes to codify a multi-step process to provide a manufacturer as defined in § 427.20 with the rebate information specified in section 1847A(i)(1)(A) of the Act. CMS considered the following factors in determining a method and process for providing the rebate information: meeting statutorily provided deadlines in section 1847A(i) of the Act (for example, dates by which to provide the rebate amount to the manufacturer); the operational time to acquire the relevant information specified in the proposed part 427; the operational time to calculate the rebate amount specified in subpart D of the proposed part 427; clarity of the information provided as well as potential burden on manufacturers; and how to ensure accuracy of the rebate amount.

CMS proposes at proposed § 427.501 the use of an initial Preliminary Rebate Report and a subsequent Rebate Report, with an opportunity for manufacturers to identify certain mathematical errors (see proposed § 427.503 and discussed in further detail later in this section) and one regular reconciliation of the rebate amount to account for data revisions 12 months after the Rebate Report is provided. CMS proposes at proposed § 427.501(d)(1), to conduct a reconciliation 12 months after issuance of the subsequent Rebate Report specified in § 427.501(c) to include any restatements that have occurred in the drug pricing data and claims billing data reported to CMS and used in the rebate calculation specified in subpart D of the part.

CMS proposes in proposed § 427.501 that the multi-step reporting process for providing rebate information to a manufacturer would include: (1) an initial report, which CMS proposes to entitle the ''Preliminary Rebate Report'' in proposed § 427.501(b) and (2) a second report, which CMS proposes to entitle the ''Rebate Report'' in proposed § 427.501(c). The Rebate Report would serve as the invoice for the rebate amount due, if any, for each NDC that has been assigned to a billing and payment code for a product determined to be a Part B rebatable drug for the applicable calendar quarter, as specified in proposed § 427.101. Manufacturers of Part B rebatable drugs would receive a Rebate Report for their rebatable drugs even if the amount due is $0. CMS proposes at proposed § 427.501(d)(1) a regular reconciliation of the rebate amount to occur 12 months after issuance of the subsequent Rebate Report specified in proposed § 427.501(c).

As the first step in the reporting process, as proposed in proposed § 427.501(b) and consistent with section 60 of the revised Medicare Part B Drug Inflation Rebate Guidance, CMS would provide the manufacturer of a Part B rebatable drug with the preliminary rebate amount through a Preliminary Rebate Report that is provided to each manufacturer of a Part B rebatable drug at least 1 month prior to the issuance of the Rebate Report specified in proposed § 427.501(c) for an applicable calendar quarter (that is, at least 5 months after the end of the applicable calendar quarter). To facilitate manufacturer understanding of the Preliminary Rebate Report, CMS is proposing in proposed § 427.501(b)(1) that the Preliminary Rebate Report would include the following information: the NDC(s) and billing and payment code for the Part B rebatable drug as specified in proposed § 427.20, the total number of billing units as specified in proposed § 427.303; the payment amount in the payment amount benchmark quarter as specified in proposed § 427.302(d); the applicable calendar quarter specified amount as specified in proposed § 427.302(b); the applicable benchmark period and rebate period CPI-Us as specified in proposed § 427.302(e) and (f); the inflation-adjusted payment amount as specified in proposed § 427.302(g); the amount, if any, by which the specified amount as described in proposed § 427.302(b) exceeds the inflation-adjusted payment amount as described in proposed § 427.302(g) for the Part B rebatable drug for the applicable calendar quarter as determined under proposed § 427.302; any applied reduction as described in proposed §§ 427.401 and 427.402; and the rebate amount due as specified in proposed § 427.301(a).

When determining what information should be included on rebate reports, CMS considered the statutory requirements outlined in section 1847A(i)(1)(A) of the Act to determine which data elements are necessary to review the Preliminary Rebate Report for error (described later in this section) and to protect proprietary information. In response to comments on the initial Medicare Part B Drug Inflation Rebate Guidance, CMS has proposed to disclose data elements as suggested by interested parties that are not enumerated in the statute, such as the applicable benchmark period and rebate period CPI-Us. CMS acknowledges requests from interested parties to provide additional data elements such as claims-level data at the NDC–11 level, that are not included in this proposal. CMS considered these requests in development of this proposed rule but does not believe it necessary to provide further information to fulfill its statutory obligation and believes that the potential benefit to manufacturers of additional data are outweighed by the administrative burdens additional reporting would impose to the agency. The elements listed above provide sufficient information for a manufacturer review the Preliminary Rebate Report for mathematical error, while protecting proprietary information, and these elements are operationally feasible for CMS to provide. CMS believes the elements listed in proposed § 427.501(b)(1) satisfy these considerations.

By structuring the Rebate Report process to include a Preliminary Rebate Report before the Rebate Report, CMS is able to provide manufacturers with an opportunity to review the Preliminary Rebate Report before the rebate amount is invoiced via the Rebate Report. While CMS is not required to provide a preliminary report, CMS seeks to facilitate manufacturer understanding of the report and believes it would be beneficial for manufacturers to review the report for mathematical errors that can be corrected before invoicing via the Rebate Report. Further, a Preliminary Rebate Report would provide additional notice to manufacturers regarding whether they may owe a rebate amount.

In proposed § 427.503, CMS proposes a process in which a manufacturer may suggest to CMS that the manufacturer believes the Preliminary Rebate Report includes a mathematical error within 10 calendar days after the date of receipt of the Preliminary Rebate Report. For example, if the Preliminary Rebate Report is provided on May 31, 2026, then June 1, 2026, would be the date of receipt and, therefore, day one of the 10-calendar-day period to submit a Suggestion of Error. In this example, Suggestions of Error would be due by 11:59 p.m. PT on June 10, 2026. CMS reviewed comments on the 10-day Suggestion of Error period submitted in response to the initial Medicare Part B Drug Inflation Rebate Guidance, many of which suggested that manufacturers receive at least 30 days to review the Preliminary Rebate Report. CMS considered a 10-day, 15-day, and 30-day Suggestion of Error period and believes a 10-calendar-day period (see proposed § 427.503(c)) is sufficient after considering the volume of the data to be provided to manufacturers, the narrow scope of items that may be identified as a Suggestion of Error, and the operational time necessary for CMS to provide a Rebate Report within 6 months of the end of the applicable calendar quarter as required under

section 1847A(i)(1)(A) of the Act. However, CMS proposes in proposed § 427.502(c)(1)(ii) to expand the Suggestion of Error period to 30 calendar days for the Preliminary Rebate Report for calendar year 2023 and calendar year 2024. This extended Suggestion of Error period will provide additional time and flexibility during the first invoicing cycle of the Part B Rebate Program.

Section 1847A(i)(8) of the Act precludes administrative or judicial review on the determination of units, whether a drug is a Part B rebatable drug, and the calculation of the rebate amount (see proposed § 427.503(a)(1)). Therefore, the Suggestion of Error process will be limited to mathematical steps involved in determining the rebate amount and the elements precluded from administrative or judicial review will not be considered in-scope for the Suggestion of Error process. Additionally, CMS is not providing an administrative dispute resolution process. CMS intends to consider all in-scope submissions under the Suggestion of Error process as specified in proposed § 427.503(a) (for example, suggestions regarding a mathematical error). CMS does not intend to review suggestions of error that are out-of-scope or submissions for a rebatable drug with an amount due of $0.

As the second step in the reporting process, CMS proposes in proposed § 427.501(c) to provide the rebate amount to the manufacturer through the Rebate Report no later than 6 months after the end of the applicable calendar quarter. As proposed in § 427.501(c)(1), the Rebate Report would include the same data elements as the Preliminary Rebate Report (specified in § 427.501(b)(1)) and include any recalculations based on CMS acceptance of a manufacturer's Suggestion of Error from proposed § 427.503, or any CMS-determined recalculations from proposed § 427.501(d)(2), if applicable. Manufacturers must pay the rebate amount within 30 calendar days from the date of receipt of the Rebate Report (see proposed § 427.505(a)). For example, if the Rebate Report is provided on June 30, 2026, then July 1, 2026, would be the date of receipt and therefore day one of the 30-calendar-day payment period; payment would be due no later than 11:59 p.m. PT on July 30, 2026.

In proposed §§ 427.504 and 427.505, CMS proposes that it will establish a standard method and process to issue Rebate Reports and accept manufacturer rebate payments. This method and process may include an online portal administered by a CMS contractor which would provide manufacturers with access to their Rebate Reports, submit Suggestions of Error, and pay a rebate amount due. CMS intends to provide technical instructions separate from this rulemaking to manufacturers of Part B rebatable drugs regarding how to access Rebate Reports and how to receive notifications alerting the manufacturer when information is available. CMS also intends to issue reminder notices to manufacturers regarding the due date of rebate payments. In proposed § 427.504(a), CMS notes that the manufacturer that may access Rebate Reports and make applicable rebate amount payments is the manufacturer responsible for paying a rebate and, as stated above, CMS proposes to identify the manufacturer that is responsible for paying a rebate using the same approach used for reporting ASP and Medicaid Drug Rebate Program data.

iii. Reconciliation of a Rebate Amount

As discussed in section 60 of the revised Medicare Part B Drug Inflation Rebate Guidance, CMS considered options for establishing a standardized method and process at regular intervals to determinate any appropriate adjustments to the rebate amount for a Part B rebatable drug for an applicable calendar quarter to account for revised information as well as options for recalculation based on CMS identifying an agency error or determining manufacturer data was misreported. While the provisions in 1847A(i) of the Act do not expressly provide for reconciliation in the Medicare Part B Drug Inflation Rebate Program, CMS has determined that a process for reconciling the rebate amount for updated information is necessary and appropriate to promote the accuracy of the rebate amount for each drug for each applicable calendar quarter. CMS is proposing policies for reconciliation, including with respect to enforcement of payment of any reconciled rebate amount, consistent with both the statutory framework for the Part B Inflation Rebate Program and the express authority in sections 1102 and 1871 of the Act to adopt regulations for the proper administration of the Medicare Prescription Drug Inflation Rebate Program.

As proposed at § 427.501(d), CMS believes that it is necessary and appropriate for CMS to recalculate the rebate amount for an applicable calendar quarter at a regular interval to include updated information about key data elements included in the calculation of the rebate amount. These data elements as set forth in proposed § 427.501(d)(1)(i) include: total units; the payment amount in the payment amount quarter; and any applied reductions as described in proposed §§ 427.401 and 427.402. Updating these calculation inputs at a regular reconciliation interval will result in a rebate amount that more fully reflects the majority of shifts in the underlying data following additional time for claims run-out, which refers to the maturation of claims in the claims processing system. Because the information accessed represents the claims' status in the claims processing system at that moment in time, additional claims run-out may yield different information, either because more claims with dates of service during the applicable calendar quarter were finalized and added to the claims processing system or because the status of the existing claims changed. CMS refers to ''X months of run-out'' as the period between the end of the applicable calendar quarter and the date when CMS accesses information about the claims; for example, ''3 months of run-out'' means that claims data are accessed for claims with service dates during an applicable calendar quarter 3 months after the end of such applicable calendar quarter. Conducting a reconciliation of the rebate amount with additional claims run-out will improve the accuracy of the rebate amount. Additionally, reconciliation of payment amounts is consistent with the approach to the calculation of payment amounts in other CMS programs (such as the Coverage Gap Discount Program) that provide for a reconciliation period.

CMS notes that the reconciliation of a rebate amount, whether the regular reconciliation proposed at § 427.501(d)(1) or a discretionary reconciliation proposed at § 427.501(d)(2) discussed further below, will not create a separately payable and distinct rebate amount. Rather, reconciliation updates the prior rebate amount owed to CMS, if any, by a manufacturer of a Part B rebatable drug so that the rebate amount ultimately reflects a more precise calculation of the rebate amount, as required by section 1847A(i) of the Act, to account for shifts in the underlying data following additional time for claims run-out after the Rebate Report is issued as well as subsequently identified data integrity issues. Moreover, because the reconciled rebate amount is an adjustment to the prior rebate amount, CMS proposes at § 427.501(d)(1)(i)(F) for the report of a reconciled rebate amount to also identify the difference between the rebate amount due as specified on

the Rebate Report set forth in § 427.501(c) and the reconciled rebate amount. CMS would only collect the net rebate amount due, if any, upon reconciliation, so as to prevent any duplicate payments. CMS also proposes to refund any overpayment made by a manufacturer, as determined during reconciliation, as discussed in proposed § 427.505(c).

Additionally, as CMS suggested in section 60 of the revised Medicare Part B Drug Inflation Rebate Guidance, CMS considered multiple options for establishing a standardized method and process to occur at regular intervals to determine any appropriate adjustment to the rebate amount for a Part B rebatable drug for an applicable calendar quarter to account for revised information prior to adopting the proposal described here with for reconciliation of the Part B inflation rebate amount at 12 months. CMS considerations included the length of time needed to capture relevant changes to data inputs for recalculation, whether the timing should align with the reconciliation of Part D rebate amounts, and manufacturer burden. Specifically, CMS considered the average time span needed to ensure submission of the majority of revisions from claims run-out periods for Part B,[578] and how such unit revisions compare to the Part D plan unit revisions specified in section 1860D–14B(b)(6) of the Act. CMS also considered the average time span needed to ensure the majority of Part B claims submitted would already be adjudicated and determined to be final action claims, CMS' policies related to the frequency of ASP restatements, the reporting timeline for refunds on discarded drug units, and reporting timelines for 340B claims and claims for beneficiaries dually eligible for Medicare and Medicaid. Without a reconciliation process, the Part B rebate amount would include units of discarded drugs on which manufacturers potentially owe a refund, thereby potentially requiring manufacturers to pay both a discarded drug refund and a rebate amount on certain units of a Part B rebatable drug due to the timing of revisions to discarded drug units discussed in further detail in section II.2.c.iv of this proposed rule.

CMS believes a longer period of claims run-out (at least 12 months of run-out time in the proposed approach) would ensure that CMS more fully accounts for capturing of revised units. CMS considered that penalties associated with failure to submit timely and accurate ASP data (specified in § 414.806(b)) encourage timely submission of ASP data with the submission timeline in accordance with § 414.804(a)(5) when considering the completeness of 12 months of claims run-out. While CMS considered a longer period until a revision is completed, such as the 36-month period provided by the Medicaid Drug Rebate Program (MDRP) for AMP restatements in § 447.510(d)(3), CMS believes that a 12-month reconciliation period is appropriate for the Part B rebate program because of requirements to submit timely and accurate ASP data (specified in § 414.806(b)), and it provides sufficient time to capture the majority of updates to the data specified in proposed § 427.301 while closing out (except for the proposed circumstances in proposed § 427.501(d)(2) regarding CMS' identification of mathematical errors or manufacturer misreporting) the calculation of the rebate amount for a Part B rebatable drug for an applicable calendar quarter within a reasonable time period after the Rebate Report is issued. While CMS proposes a 12- and 36-month reconciliation period in the Medicare Part D Drug Inflation Rebate Program, due largely to the 36-month restatement period provided for MDRP AMP restatements (specified in § 447.510(d)(3)), CMS does not believe a second or longer restatement process is needed for Part B rebatable drugs because, as described previously, the ASP and claims run-out periods correspond with sufficient claims run-out and ASP restatement timing for Part B (particularly when considering penalties associated with failure to submit timely and accurate ASP data (specified in § 414.806(b)).

Further, in considering whether consistency across CMS programs is critical, CMS believes that consideration for the completeness of data, as discussed above, should be prioritized over consistency across program timelines. That is, when examining timelines from other CMS programs that collect data contributing to calculation of the rebate amount, CMS prioritized that, to the extent feasible, completeness and accuracy of the data elements contributing to the calculation of the rebate amount rather than prioritizing consistency among the data collection and reconciliation timelines themselves. Finally, CMS believes that a restatement of each data element included in proposed § 427.501(d) to reconcile the rebate amount provided in the Rebate Report in proposed § 427.501(c) and drugs acquired through the 340B Program as proposed in § 427.303(b)(1)(i) is appropriate to capture an updated rebate amount and is in line with other CMS programs that provide for a reconciliation period, including ASP restatements (see § 414.806). While some data points may not change, CMS would review the data to determine if there are any updates in the data and use the updated data in the reconciliation to provide a reconciled rebate amount to the manufacturer.

Based on these considerations, similar to the multi-step process for the Rebate Report proposed in § 427.501(b) and (c), in summary, CMS proposes a multi-step process to provide each manufacturer of a Part B rebatable drug with a reconciled rebate amount on a regular basis. At the 12 month reconciliation, CMS proposes a reconciliation process will include: (1) a preliminary reconciliation of the rebate amount, which CMS would provide to manufacturers of Part B rebatable drugs as proposed in § 427.501(d)(1) and (2) a reconciled rebate amount, which CMS would provide to manufacturers of a Part B rebatable drug as proposed in § 427.501(d)(1)(ii). CMS also proposes to apply the Suggestion of Error process specified in proposed § 427.503 to the preliminary reconciliation.

In detail, first, as specified in proposed § 427.501(d)(1) and similar to the Preliminary Rebate Report process proposed in § 427.501(b), CMS proposes to provide the manufacturer with information about the preliminary reconciliation of the rebate amount at least 1 month prior to the issuance of the reconciled rebate amount (see proposed § 427.501(d)(1)) to each manufacturer of a Part B rebatable drug for an applicable calendar quarter. CMS proposes in § 427.501(d)(1) that the preliminary reconciliation would include, at a minimum, the same information outlined for the Rebate Report and the following updated information, if applicable: updated total number of rebatable units as specified in proposed § 427.303; the payment amount in the payment amount benchmark quarter, if any inputs are restated within the reconciliation run-out period, as specified in proposed § 427.302(d); applicable calendar quarter specified amount (defined in § 427.302(b)), if any inputs are restated within the reconciliation run-out period; the excess amount by which the specified amount exceeds the inflation-adjusted payment amount, if any inputs are restated within the reconciliation run-out period, as specified in § 427.302; the reconciled total rebate amount calculated in accordance with

[578] See the CCW White Paper: Medicare Claims Maturity, *https://www2.ccwdata.org/documents/10280/19002256/medicare-claims-maturity.pdf.*

§ 427.301; and the difference between the total rebate amount due as specified on the Rebate Report set forth in proposed § 427.501(d)(1)(i)).

In proposed § 427.503(a), similar to the Suggestion of Error process proposed for the Preliminary Rebate Report in proposed § 427.501(a), within 10 calendar days after date of receipt of the information about the preliminary reconciliation of the rebate amount, CMS proposes that a manufacturer may suggest to CMS that the manufacturer believes the preliminary reconciled rebate amount contains a mathematical error. CMS believes a 10-calendar-day period is sufficient due to the same considerations of data volume, the narrow set of reviewable items, and the operational time period necessary for CMS to complete the process to publish the reconciled rebate amount. The preclusions in section 1847A(i)(8) of the Act on administrative and judicial review apply to the reconciliation process.

Second, in detail, CMS proposes in § 427.501(d) to provide the reconciled rebate amount to the manufacturer 12 months after the Rebate Report was issued for an applicable calendar quarter. As proposed in § 427.501(d)(1)(i), the information in the report for the reconciled rebate amount would include the same data elements as provided in the information provided to the manufacturer of a Part B rebatable drug regarding the preliminary reconciliation of a rebate amount (specified in proposed § 427.501(d)(1)) and include any recalculations based on CMS acceptance of a manufacturer's Suggestion of Error from proposed § 427.503. A reconciliation of the rebate amount may result in an increase, decrease, or no change to the rebate amount, compared to the Rebate Report for an applicable calendar quarter (see proposed § 427.501(d)(3)).

Additionally, as CMS suggested in section 60 of the revised Medicare Part B Drug Inflation Rebate Guidance, CMS considered options for establishing circumstances where a recalculation of the rebate amount may be appropriate for an applicable calendar quarter after issuing the Rebate Report and/or a reconciled rebate amount based on CMS identifying an error or CMS determining that the information used by CMS to calculate a rebate amount was inaccurate due to false reporting or similar fault by the manufacturer (for example, manufacturer pricing or product data under section 1927(b)(3) of the Act). CMS also considered potential time limits for revisions and whether certain circumstances, such as instances of false reporting, should be exempt from such time limits.

Based on these considerations, CMS believes that, to capture an accurate rebate amount and consistent with reconciliations of pricing data otherwise submitted to CMS that provide for revisions when necessary due to errors, including mathematical errors, and manufacturer misreporting, certain circumstances may merit a recalculation of the rebate amount separate from the 12-month reconciliation proposed in § 427.501(d)(1). Specifically, CMS proposes in § 427.501(d)(2) that CMS may recalculate a rebate amount, when CMS identifies either: (1) an agency error such as a mathematical error or an error in the information specified in a Rebate Report as described in proposed § 427.501(c) or report of a reconciled rebate amount as described in proposed § 427.501(d)(1) including reporting system or coding errors, or (2) CMS determining that information used to calculate the rebate amount was inaccurate due to manufacturer misreporting. Examples of agency errors could include CMS incorrectly assigning a billing or payment code or incorrectly calculating the billing units per package, or the mechanism that provides a Rebate Report to the manufacturer or the Rebate Report incorrectly displays a rebate amount. Examples of manufacturer misreporting could include instances in which the manufacturer has made a correction to previously submitted data as well as instances in which the individual or entity reporting data or information to CMS on behalf of the manufacturer knows or should know is inaccurate or misleading (for example, inaccurate ASP data as specified in § 414.806). This does not include standard restatements to ASP or other data outside of the standard process of issuing the reconciled rebate amount. In addition to manufacturer-initiated corrections, CMS may become aware of manufacturer misreporting based on fact finding and conclusions of enforcement authorities, for example, the HHS Office of Inspector General, the CMS Center for Program Integrity, or the Department of Justice. In a situation where an error or manufacturer misreporting is identified prior to the 12-month reconciliation of the rebate amount proposed in § 427.501(d)(1), CMS may choose to include a correction based on the circumstances proposed in § 427.501(d)(2) concurrently with the 12-month reconciliation. When CMS reconciles data due to an instance of agency error or manufacturer misreporting, CMS proposes that the agency would limit the scope of the reconciliation to the specific information that is the basis for the reconciliation and not update or otherwise revise any other data elements in the Rebate Report (specified in proposed § 427.501(c)) or the report of the reconciled rebate amount (specified in proposed § 427.501(d)(1)) unless the correction directly impacts additional data fields. For example, CMS believes corrections to an ASP quarterly file may not change the specified amount for the applicable calendar quarter.

In addition, because reconciling a rebate amount imposes substantial administrative burden on CMS to reprocess the rebate amount, retest the reporting system, and reissue a rebate report, CMS proposes in § 427.501(d)(2) that it may exercise discretion not to initiate recalculate the rebate amount in these situations which are outside of the regular reconciliation process proposed in § 427.501(d)(1).

CMS proposes that for a recalculation due to agency error, the error must be identified within 3 years of the date of receipt of the reconciled rebate amount for the applicable calendar quarter (see proposed § 427.501(d)(2)(i)). Identification means that CMS has knowledge of the error; CMS does not need to have completed its revision of the impacted data or determined if the revision impacts the rebate amount within the 3-year period. CMS would timely complete these steps and determine, when the reconciliation does impact the rebate amount, whether the reconciliation must be included in a discretionary revision or within an upcoming reconciled rebate amount for an applicable calendar quarter. CMS believes that a 3-year period dating from the issuance of a reconciliation aligns broadly with the timeframe in which most manufacturers provide Part B ASP restatements.

CMS proposes in § 427.501(d)(2)(ii) that for a circumstance in which a manufacturer misreports data, CMS is not bound by the 3-year time limit for revision of the rebate amount. For example, if a determination is made that a manufacturer misreported ASP data, then CMS may recalculate the rebate amount owed for a Part B rebatable drug. CMS requests comments on the proposals related to manufacturer misreporting.

CMS proposes in § 427.505(a)(1) that upon receipt of the reconciled rebate amount manufacturers must pay the rebate within 30 calendar days from the date of receipt of the reconciled rebate amount. A 30-day payment deadline aligns with the payment period set forth

in statute at section 1847A(i)(1)(B) of the Act. As specified in proposed § 427.504, CMS would use the same method and process for issuing Rebate Reports and submission of payments for reports with a reconciled rebate amount. CMS would provide notice to manufacturers when a report with a reconciled rebate amount, which will include the information proposed in § 427.501(d), is available for the manufacturer's Part B rebatable drugs. CMS proposes in § 427.505(c) that if a refund is owed to a manufacturer based on a reconciled rebate amount, CMS would initiate the process to issue such a refund within 60 days from the date of receipt of the reconciled rebate amount (proposed in § 427.501(d)). CMS will issue additional information on this method and process through additional program communications.

iv. Rebate Report for Applicable Calendar Quarters in CY 2023 and CY 2024

Section 1847A(i)(1)(C) of the Act provides the CMS with the option to delay sending the information required by section 1847A(i)(1)(A) for applicable calendar quarters in calendar years 2023 and 2024 until not later than September 30, 2025. In § 427.502, consistent with section 60.2 of the revised Medicare Part B Drug Inflation Rebate Guidance, CMS proposes consolidating the Preliminary Rebate Reports and Rebate Reports for CYs 2023 and 2024 into two reports: one report for the four applicable calendar quarters in CY 2023 and one report for the four applicable calendar quarters in CY 2024. This approach allows for 12 months of claims run-out for each applicable calendar quarter in CY 2023 and at least 3 months of claims run-out for each applicable calendar quarter in CY 2024. For these combined reports, CMS proposes in § 427.502 to provide an extended 30 calendar day Suggestion of Error period for the Preliminary Rebate Report.

CMS intends to send a reconciled rebate amount for the four applicable calendar quarters in CY 2024 9 months after the Rebate Report, to allow for 12 months of claims run-out for each applicable calendar quarter; CMS does not intend to conduct reconciliation for the four applicable calendar quarters in CY 2023 since the Rebate Report would already reflect 12 months of claims run-out (see proposed § 427.502(b)). This approach aligns claims and payment data run-out with the run-out used during a regular reconciliation cycle. The Suggestion of Error period for the report containing the reconciled rebate amount for applicable calendar quarters in CY 2024 would be 10 calendar days.

This approach also minimizes the number of reports issued to manufacturers as a result of the delay in reporting and simplifies payment procedures, thereby minimizing manufacturer burden. Starting with the first applicable calendar quarter of CY 2025, reporting would begin a standard cadence and follow the procedures otherwise proposed in subpart F of this part 427.

CMS proposes that manufacturers that do not pay the Medicare Part B inflation rebate amount owed for a Part B rebatable drug within 30 calendar days of receiving a Rebate Report, including reports containing a reconciled rebate amount, may be subject to a civil money penalty of 125 percent of the rebate amount, as applicable, for such drug for the applicable calendar quarter. The civil money penalty is in addition to the rebate amount.

g. Enforcement of Manufacturer Payment of Rebate Amounts (§ 427.600)

Section 1847A(i)(7) of the Act gives CMS the authority to impose a civil money penalty equal to at least 125 percent of the rebate amount for each drug for each applicable calendar quarter on a manufacturer that fails to pay the rebate amount for each rebatable Part B drug. Subpart G would implement this section of the Act and establish the procedures for determining and collecting a civil money penalty.

In accordance with section 1847A(i)(1)(B) and proposed § 427.505(a), manufacturers must provide to CMS a rebate amount owed within 30 calendar days of receipt of the Rebate Report containing the rebate amount due. As described in proposed § 427.600(a), CMS is proposing that it may impose a civil money penalty when a manufacturer fails to pay the rebate amount in full by the payment deadlines proposed in § 427.505(a). This means a manufacturer may be subject to a civil money penalty if the manufacturer fails to pay the full the rebate amount as invoiced in the Rebate Report or any reconciled rebate amount that is greater than the amount invoiced in the Rebate Report. More specifically, a manufacturer could be subject to a civil money penalty when a manufacturer fails to pay a rebate amount due by any payment deadline proposed in § 427.505(a)(1) and (2) for: (1) a Rebate Report specified in proposed § 427.501(c); (2) a reconciled rebate amount greater than the rebate amount reflected in the Rebate Report specified in proposed § 427.501(d); or (3) a Rebate Report and a reconciled rebate amount greater than the amount reflected in the Rebate Report, if applicable, for the applicable calendar quarters in calendar years 2023 and 2024 as specified in proposed § 427.502. As discussed earlier in subpart e.iii, CMS notes that the reconciled rebate amount is not a separately payable and distinct rebate amount. Rather, the reconciled rebate amount is an update to the rebate amount owed to CMS by a manufacturer of a Part B rebatable drug.

Civil money penalties are a point-in-time penalty tied to the rebate amount due at the applicable payment deadline, which occurs 30 days after the date of receipt of a Rebate Report. In proposed § 427.600(b), CMS proposes to establish the methodology for determining the amount of the civil money penalty as equal to 125 percent of the rebate amount for such drug for such applicable calendar quarter, and that this penalty would be due in addition to the rebate amount due. That is, a manufacturer would be responsible for paying the full rebate amount due in addition to any civil money penalty imposed because of late payment. While CMS has the statutory authority to impose a civil money penalty greater than 125 percent of the rebate amount in the Part B Rebate Program under section 1847(A)(i)(7), CMS is proposing a penalty amount of 125 percent of the rebate amount to align with the penalty amount in the Part D Inflation Rebate Program. CMS is proposing this approach to civil money penalties based on section 1847A(i)(1)(B) of the Act, which establishes a requirement by the manufacturer to provide CMS with a rebate not later than 30 days after receipt from CMS of the report on the amount of the excess average sales price increase. CMS believes that the ability to assess civil money penalties is necessary in all circumstances where a payment is due for a rebate amount to CMS to ensure compliance with the rebate program's requirements. The civil money penalty would be calculated based on the outstanding rebate amount due at the payment deadline, which is defined in proposed § 427.505(a) as 30 calendar days after the date of receipt of a Rebate Report containing any rebate amount due; once a civil money penalty is assessed due to a late payment, the penalty would remain in effect even if the manufacturer pays the outstanding amount as the penalty is initiated due to a missed payment deadline. Because the payment deadline is clearly defined in section 1847A(i)(1)(B) of the Act, any late payments of a rebate amount due, including late payment of any reconciled rebate amounts greater than the amount reflected in the Rebate

Report, would be considered a violation potentially subject to a civil money penalty. Any civil money penalty would be assessed before the next reconciliation process.

CMS is proposing in § 427.600(b)(2) that civil money penalties may be calculated at several points in time associated with missing a payment deadline for the rebate amount due reflected in the Rebate Report or missing a payment deadline associated with any rebate amount determined after a reconciliation to be greater than the amount invoiced in the Rebate Report. As these separate events can result in distinct assessments of civil money penalties, this means that CMS would not modify a civil money penalty from a prior missed payment deadline based on changes to the rebate amount due following reconciliation, including scenarios where the rebate amount is reduced following reconciliation. However, in the event that the rebate amount due on a Rebate Report was not paid and a civil money penalty was issued for violation of the payment deadline, CMS would not issue a second civil money penalty on a reconciled rebate amount if reconciliation decreased the rebate amount stated on the Rebate Report. CMS believes that enforcing this requirement after each payment deadline, regardless of what rebate amount a manufacturer may or may not owe at a future payment deadline, is necessary to maintain the integrity of the program and consistency of the implementation of the program. Further, CMS is proposing this approach to ensure an enforcement approach that is operationally feasible and applied consistently in all cases.

As an example of this approach in practice, CMS presents a scenario where the rebate amount due on the Rebate Report is $100. Following reconciliation 12 months after the Rebate Report was issued, CMS calculates a reconciled rebate amount for the applicable calendar quarter of $120 (an increase of $20 from the rebate amount identified in the Rebate Report due to updated claims run-out and payment data). Under this scenario, in the event the manufacturer does not pay the $100 rebate amount owed within the 30-day deadline following receipt of the Rebate Report, a civil money penalty for $125 ($100 × 1.25) could be assessed against the manufacturer due to their failure to meet the payment deadline. If the manufacturer pays the $100 before the reconciliation is completed, and then timely pays the $20 due within the 30-day payment deadline following the reconciliation 12 months after the Rebate Report or does not pay the $100 before the reconciliation is completed but timely pays the $120 due within the 30 day payment deadline following reconciliation 12 months after the Rebate Report, no further civil money penalty would be assessed.

Alternatively, in the event the manufacturer pays the $100 rebate amount due within the 30-day deadline following receipt of the Rebate Report but fails to meet the payment deadline for the net $20 rebate amount due following reconciliation, a civil money penalty of $25 ($20 × 1.25) could be assessed against the manufacturer due to their failure to meet the payment deadline for the updated rebate amount due following reconciliation. Finally, under this scenario in the event the manufacturer fails to meet any payment deadline throughout the full reconciliation cycle of this rebate amount; that is, the deadline is missed for the $100 amount due stated in the Rebate Report, and the $20 net rebate amount due following reconciliation, CMS may assess a separate civil money penalty on the rebate amount due at each of these missed deadlines. In this example, violations of each of these payment deadlines would result in a penalty of $125 ($100 × 1.25), followed by a penalty of $25 ($20 × 1.25), each of which would be assessed following the manufacturer's failure to meet the related payment deadline for the outstanding rebate amount due.

In an alternative possible scenario, consider the following. The rebate amount due on the Rebate Report is $100. Following reconciliation 12 months after the Rebate Report was issued, CMS calculates a reconciled rebate amount owed for the applicable period of $80 (a decrease of $20 from the rebate amount identified in the Rebate Report). In this scenario, if a manufacturer does not pay the $100 by the payment deadline for the rebate amount due in the Rebate Report, a civil money penalty for $125 ($100 × 1.25) may be assessed against the manufacturer due to its failure to meet the payment deadline for the rebate amount due identified in the Rebate Report. This civil money penalty is not affected if the manufacturer pays the rebate amount once it is past the deadline, nor is it impacted by the reconciled rebate amount, because at the payment deadline missed by the manufacturer, the manufacturer owed a rebate of $100 to CMS and that rebate amount was not paid timely. As noted previously, under this scenario, given that there is no additional rebate amount due upon reconciliation compared to the rebate amount stated on the Rebate Report, there would not be a civil money penalty assessed on the reconciled rebate amount.

Further, note that payment of any civil money penalty does not obviate the requirement for the manufacturer to pay any outstanding rebate amount due, including any rebate amount due following a reconciliation. Therefore, paying a civil money penalty does not satisfy the obligation to pay the underlying rebate amount on which the civil money penalty is calculated. In addition, CMS is evaluating all available options to ensure manufacturers' timely compliance with their rebate payment obligations, including, without limitation, potential recovery approaches and enforcement actions. For example, CMS may refer manufacturers to the Department of Justice, Department of the Treasury, and/or the Department of Health and Human Services Office of Inspector General for further review and investigation.

In proposed § 427.600(c), CMS proposes that if CMS makes a determination to impose a civil money penalty on a manufacturer for violation of a payment deadline, CMS would send a written notice of the decision to impose a civil money penalty that includes a description of the basis for the determination, the basis for the penalty, the amount of the penalty, the date the penalty is due, the manufacturer's right to a hearing, and information about where to file the request for a hearing. To ensure a consistent approach to civil money penalties, CMS proposes applying existing appeal procedures for civil money penalties in 42 CFR 423, subpart T of this title to manufacturers appealing a civil money penalty imposed under the Medicare Part B Drug Inflation Rebate Program. CMS has utilized this appeals process many years for civil money penalty determinations affecting MA organizations and Part D sponsors. CMS therefore proposes to use this well-established process for civil money penalty appeals from manufacturers that do not make inflation rebate payments by the payment deadline. CMS also proposes in § 427.600(e)(1) that the scope of appeals is limited to: (1) CMS determinations relating to whether the rebate payment was made by the payment deadline; and (2) the calculation of the penalty amount. Section 1847A(i)(8) of the Act precludes judicial review of specific data inputs or calculations related to the underlying Rebate Report and reconciliation; therefore, such data and calculations are not appealable through this process.

Section 1847A(i)(7) of the Act states that the provisions of section 1128A of the Act (except subsections (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a civil money penalty or procedure under section 1128A(a) of the Act. CMS proposes to codify this requirement in proposed § 427.600(f). In alignment with the procedure outlined in section 1128A of the Act, CMS proposes in § 427.600(d) that collection of the civil money penalty would follow expiration of the timeframe for requesting an appeal, which is 60 calendar days from the civil money penalty determination in cases where the manufacturer did not request an appeal. In cases where a manufacturer requests a hearing and the decision to impose the civil money penalty is upheld, CMS would initiate collection of the civil money penalty once the administrative decision is final. CMS is seeking comment on proposals related to the violations of payment deadlines and issuance of a civil money penalty.

CMS proposes in § 427.600(g) that in the event that a manufacturer declares bankruptcy, as described in title 11 of the United States Code, and as a result of the bankruptcy, fails to pay either the full rebate amount owed or the total sum of civil money penalties imposed, the government reserves the right to file a proof of claim with the bankruptcy court to recover the unpaid rebate amount and/or civil monetary penalties owed by the manufacturer.

h. Severability (§ 427.10)

In proposed § 427.10, we propose that, were any provision of part 427 to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, such provisions would be severable from part 427 and the invalidity or unenforceability would not affect the remainder thereof or any other part of this subchapter or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances. While the provisions in part 427 are intended to present a comprehensive approach to implementing the Medicare Part B Drug Inflation Rebate Program, we intend that each of them is a distinct, severable provision, as proposed, and would not affect similar provisions in the Medicare Part D Drug Inflation Rebate Program. Through this rulemaking, the Part B drug inflation rebate proposals are intended to operate independently of each other, even if each serves the same general purpose or policy goal. For example, CMS intends that the proposed policies related to reducing the rebate amount for Part B rebatable drugs currently in shortage and when there is a severe supply chain disruption (§§ 427.401 and 427.402) are distinct and severable from the proposals related to the determination of Part B rebatable drugs subject to rebates (§ 427.101). As another example, CMS intends that the proposed policy for using the payment limit for purposes of calculating the beneficiary coinsurance adjustment (§ 427.201(b)) is distinct and severable from the proposals to use the specified amount for purposes of the Part B rebate calculation (§ 427.301). Even where one provision makes reference to a second provision, the preamble and the regulatory text clarify the intent of the agency that the two provisions would be severable if one provision were to be invalidated in whole or in part. For example, CMS would still be able to calculate drugs and biological products with average total allowed charges below the applicable threshold as described in § 427.101(c)(1), for exclusion from inflation rebate calculations, even if the provision to apply the applicable threshold at the billing and payment code level is deemed invalid (§ 427.101(c)(3)). We welcome comments on this severability policy.

3. Medicare Part D Drug Rebates for Drugs, Biologicals, and Sole Source Generic Drugs With Prices That Increase Faster Than the Rate of Inflation

a. Definitions (§ 428.20)

In this proposed rule, CMS proposes to codify definitions of terms with meanings given in section 1860D–14B of the Act and established in the revised Medicare Part D Drug Inflation Rebate Guidance, as well as new definitions based on policies detailed in this proposed rule.

At proposed § 428.20, CMS is proposing that the following terms in section 1860D–14B of the Act are defined:

- ''Annual manufacturer price (AnMP)''.
- ''Applicable period''.
- ''Applicable period Consumer Price Index for All Urban Consumers (CPI–U)''.
- ''Benchmark period CPI–U''.
- ''Part D rebatable drug''.
- ''Payment amount benchmark period''.
- ''Unit''.

Further, in § 428.20 of this proposed rule, CMS proposes to codify definitions established in the revised Medicare Part D Drug Inflation Rebate Guidance and new definitions based on policies detailed in this proposed rule for the following terms:

- ''Applicable threshold''.
- ''Average manufacturer price (AMP)''.
- ''Benchmark period manufacturer price''.
- ''Covered Part D drug''.
- ''CPI–U''.[579]
- ''First marketed date''.
- ''Inflation-adjusted payment amount''.
- ''Manufacturer''. CMS intends that manufacturer identification in the Medicare Prescription Drug Inflation Rebate Program, inclusive of communications and rebate liability, will be consistent with the policies and practices adopted under § 447.502 for purposes of manufacturer obligations under the Medicaid Drug Rebate Program. We believe this approach will provide clarity and allow for consistency in the agency's treatment of financial transactions, including in the contexts of debt collection, bankruptcy, and changes in ownership. We welcome feedback on this proposed approach and whether there are alternative approaches that may better achieve the agency's goals for application of rebate liability and collection of rebate amount, including whether additional policies and/or a Medicare Prescription Drug Inflation Rebate Program agreement are needed to clarify financial accountability for rebate amounts in situations where there are changes in ownership of a manufacturer or of a rebatable drug.
- ''National Drug Code (NDC)''.
- ''Subsequently approved drug''.

b. Determination of Part D Rebatable Drugs (§§ 428.100 Through 428.101)

i. Definitions

In proposed § 428.100, CMS proposes to define the following terms applicable to subpart B (§§ 428.100 through 428.101):

- ''Individual who uses such a drug or biological''.
- ''Gross covered prescription drug costs''.

ii. Identification of Part D Rebatable Drugs

Section 1860D–14B(g)(1)(A) of the Act defines a ''Part D rebatable drug,'' in part, as a drug or biological described at section 1860D–14B(g)(1)(C) that is a ''covered Part D drug'' as that term is defined in section 1860D–2(e) of the Act. A drug or biological described in section 1860D–14B(g)(1)(C) means a

[579] These data are referenced to 1982 − 84 = 100—that is, the average of pricing data for the 36 months from 1982 through 1984 serve as the basis for the index and are assigned a value of 100. These data are not seasonally adjusted.

drug or biological that, as of the first day of the applicable period involved, is: (1) a drug approved under an NDA under section 505(c) of the FD&C Act (that is, a brand name drug); (2) a drug approved under an ANDA under section 505(j) of the FD&C Act that meets the criteria in section 1860D–14B(g)(1)(C)(ii) (that is, a generic drug that meets certain sole source criteria); or (3) a biological licensed under section 351 of the PHS Act (that is, a biological product, including a biosimilar).

In § 428.101(a), CMS proposes to identify a Part D rebatable drug [580] for each applicable period by determining which covered Part D drugs, as defined in section 1860D–2(e) of the Act, meet the requirements in section 1860D–14B(g)(1)(C) of the Act (that is, are brand name drugs approved under an NDA, biologicals licensed under a biologics license application (BLA), or generic drugs approved under an ANDA). As noted, a Part D rebatable drug must meet the requirements in section 1860D–14B(g)(1)(C) of the Act as of the first day of the applicable period.

To evaluate whether a generic drug approved under an ANDA meets all the criteria in section 1860D–14B(g)(1)(C)(ii) of the Act, CMS proposes in § 428.101(a)(3) to codify the policy established in section 30 of the revised Medicare Part D Drug Inflation Rebate Guidance whereby CMS would use specified FDA resources such as the ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (commonly known as the Orange Book) [581] and NDC Directory to determine whether a generic drug meets the definition of a Part D rebatable drug. In § 428.101(a)(3)(i) and (ii), CMS proposes to clarify the policy established in revised Medicare Part D Drug Inflation Rebate Guidance by adding that, for purposes of § 428.101, CMS considers historical information from NDC Directory files, such as discontinued, delisted, and expired listings, provided by FDA to CMS or published by FDA on its website to be included in the NDC Directory. As proposed in § 428.101(a)(3)(iii), to determine whether the manufacturer of the generic drug is a first applicant during the 180-day exclusivity period, or whether the manufacturer of the generic drug is a first approved applicant for a competitive generic drug therapy, CMS will refer to FDA website resources such as the Orange Book and may consult with FDA for technical assistance as needed. CMS will determine whether a generic drug that is a covered Part D drug meets the definition of a Part D rebatable drug based on the status of the drug on the first day of the applicable period.

While generic drugs that do not meet the sole source criteria in section 1860D–14B(g)(1)(C)(ii) of the Act (that is, multiple source generic drugs) are excluded from the definition of a Part D rebatable drug, CMS understands that a generic drug may meet the definition of a Part D rebatable drug on the first day of an applicable period and then cease to meet such definition later in the applicable period if, for example, the FDA approves another therapeutically equivalent generic drug under a 505(j) ANDA and that drug is marketed during such applicable period.

iii. Drugs and Biologicals With Average Annual Total Cost Under Part D Below the Applicable Threshold

Under section 1860D–14B(g)(1)(B) of the Act, a drug or biological is excluded from the definition of a Part D rebatable drug if the ''average annual total cost'' under Part D for such period per individual who uses such a drug or biological product is less than $100 per year, as determined by the Secretary using the most recent data available, or, if data are not available, as estimated by the Secretary. The statute provides that the $100 annual amount for the applicable period beginning October 1, 2022, is to be increased by percentage changes in the CPI–U for subsequent applicable periods. In § 428.101(b), CMS proposes to codify the policy established in section 30.2 of the revised Medicare Part D Drug Inflation Rebate Guidance for determining the applicable threshold and excluding from the definition of a Part D rebatable drug, and thus Part D drug inflation rebates, drugs and biologicals for which the average annual total cost under Part D for such applicable period per individual who uses such drug or biological product is below that applicable threshold.

As described in the revised Medicare Part D Drug Inflation Rebate Guidance, CMS intends to calculate the average annual total cost based on gross covered drug costs for the Part D rebatable drug at the NDC–9 level. CMS will divide the gross covered drug costs for the drug by the number of unique Part D beneficiaries as described above that were dispensed the drug in that applicable period. For this calculation, CMS will use PDE data with gross covered drug costs greater than zero that are available for the drug with dates of service during that applicable period. Drugs that are determined to have average annual total costs under Part D of less than $100 per individual using such drug per year, adjusted by changes in the CPI–U, will be excluded from Part D drug inflation rebate calculations for the applicable period in question.

c. Determination of the Rebate Amount for Part D Rebatable Drugs (§§ 428.200 Through 428.204)

i. Definitions

In proposed § 428.200, CMS proposes to define the following terms applicable to subpart C (§§ 428.200 through 428.204):

- ''340B Program''.
- ''Line extension''.
- ''New formulation''.
- ''Oral solid dosage form''.

ii. Calculation of the Total Rebate Amount To Be Paid by Manufacturers

Under section 1860D–14B(b)(1) of the Act, the Part D drug inflation rebate for each Part D rebatable drug and applicable period, subject to certain considerations, is the estimated amount that is equal to the product of: (1) the amount, if any, by which the annual manufacturer price (AnMP) for such Part D rebatable drug for the applicable period exceeds the inflation-adjusted payment amount for the Part D rebatable drug for the applicable period, and (2) the total number of units of the Part D rebatable drug dispensed under Part D and covered and paid by Part D plan sponsors during the applicable period. To calculate the Part D drug inflation rebate consistent with section 1860D–14B(b)(1) of the Act, CMS proposes in § 428.201(a)(1) to codify the calculation methodology described in section 40 of the revised Medicare Part D Drug Inflation Rebate Guidance, which provides that the total Part D drug inflation rebate amount is equal to the per unit Part D drug inflation rebate amount, as determined under proposed § 428.202(a), multiplied by the total number of units of a Part D rebatable drug dispensed under Part D and covered by Part D plan sponsors, as determined in accordance with proposed § 428.203. CMS proposes in § 428.201(a)(2) that the total Part D drug inflation rebate amount for a Part D rebatable drug that is a line extension of a Part D rebatable drug that is an oral solid dosage form is equal to the amount specified in proposed § 428.204. The Part D drug inflation rebate amount calculated in accordance with this

[580] For purposes of this proposed rule, CMS uses the term ''Part D rebatable drug'' to refer to the dosage form and strength with respect to such drug for which Part D drug inflation rebates are calculated.

[581] FDA Orange Book: *https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeuticequivalence-evaluations-orange-book.*

subpart is subject to adjustment based on any reductions in accordance with subpart D of this part or any reconciliations in accordance with subpart E of the part.

In § 428.201(b), CMS proposes to exclude from the calculation performed under subpart C drugs and biologicals that meet the definition of a Part D rebatable drug, but which are missing AMP data for the entire duration of the applicable period because, for the reasons specified below, there were no quarters during that period in which their manufacturers were required to report AMP data under section 1927(b)(3) of the Act. The calculations for the rebate amount set forth in section 1860D–14B(b) of the Act contemplate use of AMP and unit data reported by manufacturers under section 1927 of the Act. Similarly, section 1860D–14B(d) of the Act indicates CMS should use, for purposes of carrying out the Medicare Part D Drug Inflation Rebate Program, information submitted by manufacturers under section 1927(b)(3) of the Act. Section 1927 requires manufacturers that participate in the Medicaid Drug Rebate Program (MDRP) to enter into agreements with the HHS Secretary and submit price and drug product information to CMS for each covered outpatient drug (COD), as defined in sections 1927(k)(2)–(4) of the Act and in § 447.502.

Not every drug that satisfies the definition of a Part D rebatable drug may be marketed by a manufacturer that has an MDRP agreement in effect with the Secretary during the applicable period. Similarly, there may be limited instances in which a drug or biological satisfies the definition of a Part D rebatable drug but is not a COD under the MDRP. As a result, information may not be reported under section 1927(b)(3) of the Act for all Part D rebatable drugs, and thus may not be available to CMS for purposes of calculating Part D drug inflation rebates under section 1860D–14B of the Act. Said differently, in limited cases where a Part D rebatable drug is marketed by a manufacturer that does not have an obligation to report pricing and drug product data under section 1927(b)(3) of the Act for the reasons noted, the manufacturer does not currently report information needed for CMS to be able to calculate Part D drug inflation rebates.

Due to this operational issue, CMS proposes in § 428.201(b) to codify the policy established in section 30.1 of the revised Medicare Part D Drug Inflation Rebate Guidance whereby CMS would exclude from Part D drug inflation rebate calculations drugs and biologicals that meet the definition of a Part D rebatable drug but for which the manufacturer does not have an MDRP agreement in effect with the HHS Secretary under section 1927 of the Act at any point during the applicable period, or the Part D rebatable drug is one that does not meet the definition of a COD. This would effectively exclude from rebate calculations Part D rebatable drugs for which there is missing AMP data for the entire duration of the applicable period for the sole reason that there were no quarters during that period in which the manufacturer was required to report AMP data under section 1927(b)(3) of the Act. In either of these situations, a manufacturer does not have an obligation to report pricing and drug product data under section 1927(b)(3) of the Act and thus the information required to calculate Part D drug inflation rebates for these drugs is not available to CMS. If a manufacturer is required to report AMP under section 1927(b)(3) of the Act for any part of the applicable period for a drug or biological that meets the definition of a Part D rebatable drug, CMS would not exclude such drug or biological from Part D drug inflation rebate calculations. We also clarify that the proposed exclusion at § 428.201(b) relates only to the calculation of the rebate amount and does not affect the determination of whether a drug or biological meets the definition of a Part D rebatable drug. When performing the reconciliation described at § 428.401(d), CMS would reexamine whether the manufacturer was required to report AMP for any part of the applicable period for the Part D rebatable drug; if at reconciliation the manufacturer was required to report AMP for any part of the applicable period, CMS would calculate a Part D rebate amount for this Part D rebatable drug. CMS intends to monitor how these exclusions from the Part D drug inflation rebate calculation may impact manufacturer behavior and may revisit this exclusion in the future.

In the initial Medicare Part D Drug Inflation Rebate Guidance, CMS solicited comments on the proposed approach and alternative approaches. CMS continues to be interested in comments on this topic and welcomes additional comments on this approach and alternative approaches—specifically, how CMS should address the situations in which the manufacturer of a Part D rebatable drug does not have an MDRP agreement in effect for any part of the applicable period or when a Part D rebatable drug may be excluded from the definition of a COD and manufacturers may not be required to report pricing and drug product information under section 1927(b)(3) of the Act.

iii. Calculation of the Per Unit Part D Drug Rebate Amount

To calculate the total rebate amount in accordance with proposed § 428.201(a), CMS will first calculate the per unit Part D drug rebate amount as proposed in § 428.202. As described in the revised Medicare Part D Drug Inflation Rebate Guidance and provided in proposed § 428.202(a), CMS will calculate the per unit Part D drug inflation rebate amount by determining the amount by which the AnMP for a Part D rebatable drug exceeds the inflation-adjusted payment amount for such drug for the applicable period. To determine the per unit Part D inflation rebate amount for a Part D rebatable drug, CMS must calculate the AnMP for the drug, identify the payment amount benchmark period and calculate the benchmark period manufacturer price for the drug, identify the benchmark period CPI–U, and calculate the inflation-adjusted payment amount for the drug.

(1) Calculation of the AnMP for the Applicable Period

To determine the AnMP for a Part D rebatable drug and applicable period, CMS proposes in § 428.202(b) to codify the policy described in the revised Medicare Part D Drug Inflation Rebate Guidance whereby CMS would use the AMP reported by a manufacturer to the Medicaid Drug Programs system under sections 1927(b)(3)(A)(i) and (ii) of the Act for each calendar quarter of the applicable period, as well as the units reported by a manufacturer under section 1927(b)(3)(A)(iv) of the Act for each month of the applicable period. The manufacturer-reported AMP units represent the total units of a drug sold by the manufacturer each month to retail community pharmacy and wholesaler purchasers as described under section 1927(k)(1)(A) of the Act. Manufacturers may include under certain circumstances non-retail community pharmacy sales units in the calculation of their AMPs for 5i drugs.[582]

[582] 5i drugs are CODs that are inhaled, infused, instilled, implanted, or injected. Manufacturers are instructed to calculate the AMP for 5i drugs that are not generally dispensed through a retail community pharmacy using the methodology described at § 447.504(d) and (e). Section 447.507(b)(1) provides that a 5i drug is not generally dispensed through a retail community pharmacy if 70 percent or more of the sales (based on units at the NDC–9 level) of the 5i drug, were to entities other than retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies.

As specified in section 1860D–14B(b)(2) of the Act, the AnMP for a Part D rebatable drug for an applicable period is equal to the sum of the products of (1) the AMP for the Part D rebatable drug reported for each calendar quarter of the applicable period, and (2) the total units of the Part D rebatable drug reported for each of the corresponding calendar quarters of the applicable period divided by the total units of the Part D rebatable drug reported for the 4 calendar quarters in the applicable period. The following formula illustrates how CMS would calculate the AnMP for a Part D rebatable drug as proposed in § 428.202(b):

(AMP for calendar quarter beginning October) *multiplied by* (sum of monthly units for October calendar quarter *divided by* total units for 12-month applicable period) +
(AMP for calendar quarter beginning January) *multiplied by* (sum of monthly units for January calendar quarter *divided by* total units for 12-month applicable period) +
(AMP for calendar quarter beginning April) *multiplied by* (sum of monthly units for April calendar quarter *divided by* total units for 12-month applicable period) +
(AMP for calendar quarter beginning July) *multiplied by* (sum of monthly units for July calendar quarter *divided by* total units for 12-month applicable period)

In § 428.202(b)(2), CMS proposes that the first applicable period for a Part D rebatable drug will be the earliest applicable period that follows the payment amount benchmark period identified in proposed § 428.202(c)(1) through (4). For a Part D rebatable drug first approved or licensed on or before October 1, 2021, with a payment amount benchmark period identified in § 428.202(c)(1), the first applicable period would begin on October 1, 2022 and end on September 30, 2023. For a Part D rebatable drug first approved or licensed on or before October 1, 2021 with a payment amount benchmark period identified in § 428.202(c)(3), or a subsequently approved drug with a payment amount benchmark period identified in § 428.202(c)(2) or (4), the first applicable period would begin on October 1 of the year following the payment amount benchmark period identified in proposed § 428.202(c)(2) through (4). As described below, CMS is soliciting comments on alternative policies for determining the payment amount benchmark period in certain instances of missing AMP. In the case of a Part D rebatable drug that was previously a selected drug as described in proposed § 428.202(c)(5) for which the payment amount benchmark period is reset as the last calendar year of the price applicability period for such drug, the earliest applicable period that follows the reset payment amount benchmark period would begin on October 1 of the year following the payment amount benchmark period identified in proposed § 428.202(c)(5). The date that CMS will use to determine when a drug is first approved or licensed is the FDA approval date that the manufacturer reports to the Medicaid Drug Programs system under section 1927(b)(3)(A)(v) of the Act.

(2) Identification of the Payment Amount Benchmark Period

Consistent with section 1860D–14B(g)(3) of the Act and as described in sections 40.2.2 and 40.3 of the revised Medicare Part D Drug Inflation Rebate Guidance, CMS proposes in § 428.202(c)(1) that for a drug first approved or licensed by the FDA on or before October 1, 2021, the payment amount benchmark period is the period beginning on January 1, 2021 and ending on September 30, 2021. For a subsequently approved drug, CMS proposes in § 428.202(c)(2) that the payment amount benchmark period would be the first calendar year beginning after the drug's first marketed date, as specified under section 1860D–14B(b)(5)(A) of the Act. To identify the payment amount benchmark period for a Part D rebatable drug, CMS would use the FDA approval date or the first marketed date reported under section 1927(b)(3)(A)(v) of the Act, as applicable.

(a) Proposal To Establish a Payment Amount Benchmark Period in Certain Instances of Missing AMP

Section 1860D–14B of the Act does not expressly address how CMS should calculate the benchmark period manufacturer price for a Part D rebatable drug when a manufacturer has not reported AMP during the payment amount benchmark period identified by statute. For example, as described in the revised Medicare Part D Drug Inflation Rebate Guidance, while section 1860D–14B(g)(3) of the Act contemplates that drugs first approved or licensed by the FDA on or before October 1, 2021, would have a payment amount benchmark period of January 1, 2021, through September 30, 2021, the statute does not address circumstances in which such drugs are not marketed until after October 1, 2021, and thus lack AMP from January 1, 2021, through September 30, 2021, to calculate the benchmark period manufacturer price. In response to comments, CMS stated in section 40.1.2 of the revised Medicare Part D Drug Inflation Rebate Guidance that Part D rebatable drugs first approved or licensed on or before October 1, 2021, that were not marketed until after that date and thus did not have AMP in the statutorily defined payment amount benchmark period (that is, January 1, 2021, through September 30, 2021) would be treated in the same manner as subsequently approved drugs for purposes of establishing the payment amount benchmark period, benchmark period CPI–U, first applicable period, and first applicable period CPI–U. In the revised guidance, CMS also stated that it intended to address this policy in future rulemaking and would solicit comments on this policy at that time.

Based on further review, CMS has observed that a number of NDC–9s of Part D rebatable drugs approved on or before October 1, 2021, do not have AMP reported in the period of January 1, 2021, through September 30, 2021, and a number of NDC–9s of subsequently approved drugs do not have AMP reported in the first calendar year beginning after the drug's first marketed date. To enable CMS to calculate the benchmark period manufacturer price and inflation rebate amounts for these NDC–9s, CMS is proposing in § 428.202(c)(3) that for a Part D rebatable drug first approved or licensed on or before October 1, 2021, for which there are no quarters during the period beginning on January 1, 2021, and ending on September 30, 2021, for which AMP has been reported under section 1927(b)(3) of the Act, CMS would identify the payment amount benchmark period as the first calendar year, which would be no earlier than calendar year 2021, in which such drug has at least 1 quarter of AMP reported. Said differently, to identify the payment amount benchmark period for the purpose of calculating the benchmark period manufacturer price for a Part D rebatable drug first approved or licensed on or before October 1, 2021, CMS would first look to the period from January 1, 2021, to September 30, 2021 and if no AMP was reported to the MDRP for that 3-quarter period, CMS would then identify the payment amount benchmark period as the first calendar year no earlier than calendar year 2021 in which such drug has at least 1 quarter of AMP reported. Similarly, in proposed § 428.202(c)(4), CMS proposes that for a subsequently approved drug for which there are no quarters during the first calendar year

beginning after the drug's first marketed date for which AMP has been reported under section 1927(b)(3), the payment amount benchmark period would be the first calendar year in which such drug has at least 1 quarter of AMP reported. To identify the payment amount benchmark period for the purpose of calculating the benchmark period manufacturer price for a subsequently approved drug, CMS would look to the first calendar year beginning after the drug's first marketed date and if no AMP was reported to the MDRP for such NDC–9 for that 4-quarter period, CMS would then identify the payment amount benchmark period as the first calendar year in which such drug has at least 1 quarter of AMP reported. This approach (or the alternative approaches described below), if finalized, would replace the policy in the revised Medicare Part D Drug Inflation Rebate Guidance to treat Part D rebatable drugs first approved or licensed on or before October 1, 2021, that were not marketed until after that date in the same manner as subsequently approved drugs. As proposed in § 428.202(b)(2), the first applicable period for such drug would begin on October 1 of the year following the payment amount benchmark period. This policy would apply to Part D rebatable drugs first approved or licensed on or before October 1, 2021, drugs first approved or licensed on or before October 1, 2021, but not marketed until after that date, as well as subsequently approved drugs.

As an example of how CMS would identify the payment amount benchmark period as proposed under § 428.202(c)(3), if a Part D rebatable drug that was first approved or licensed by the FDA on July 7, 2021, and has a first marketed date of September 15, 2021, does not have AMP reported in the period beginning January 1, 2021 and ending September 30, 2021, but does have AMP reported for the second calendar quarter of 2022, CMS would identify the payment amount benchmark period for such drug as calendar year 2022 (that is, January 1, 2022, through December 31, 2022). In this example, the benchmark period CPI–U would be the CPI–U for January 2022, the first applicable period would be the applicable period beginning October 1, 2023, and ending September 30, 2024, and the applicable period CPI–U would be the CPI–U for October 2023. Similarly, as an example of how CMS would identify the payment amount benchmark period as proposed under § 428.202(c)(4), if a subsequently approved drug with a first marketed date of December 15, 2021, does not have AMP reported for any quarters in calendar year 2022 (that is, the first calendar year after the drug's first marketed date) but does have AMP reported for the first calendar quarter of 2023, CMS would identify the payment amount benchmark period as calendar year 2023 (that is, January 1, 2023, through December 31, 2023). In this example, the benchmark period CPI–U would be the CPI–U for January 2023, the first applicable period for this drug would be the applicable period beginning October 1, 2024, and ending September 30, 2025, and the applicable period CPI–U would be the CPI–U for October 2024.

CMS is soliciting comments on this approach, as well as the alternatives described below.

(b) Comment Solicitation on Alternatives Considered for Calculating the Benchmark Period Manufacturer Price When AMP Is Missing

CMS is aware that one reason why a manufacturer may not report AMP for any quarters of a payment amount benchmark period described in § 428.202(c)(1) or (2), as applicable, is that a manufacturer may acquire a Part D rebatable drug from another manufacturer and, due to that acquisition and the use of a new labeler code, obtain a new NDC–9 for that Part D rebatable drug. In this instance, the NDC–9 of the selling manufacturer and the NDC–9 of the buying manufacturer belong to the same dosage form and strength and therefore the same Part D rebatable drug. Although the buying manufacturer may not have AMP for the new NDC–9 to report to the Medicaid Drug Programs system for the Part D rebatable drug's payment amount benchmark period described in § 428.202(c)(1) or (c)(2), the buying manufacturer is required by the MDRP to report for the new NDC–9 the base date AMP associated with the dosage form and strength to which the new NDC–9 belongs.[583] This base date AMP is equal to the quarterly AMP that a manufacturer reports as described in § 447.509(a)(7)(ii)(B). There also may be instances outside of the acquisition context in which a new NDC–9 for an existing dosage form and strength is reported to the MDRP. To prevent a manufacturer from resetting the payment amount benchmark period and therefore the benchmark period manufacturer price by obtaining a new NDC–9 for the Part D rebatable drug, CMS stated in section 40.2.2 of the revised Medicare Part D Drug Inflation Rebate Guidance that it will use the benchmark period manufacturer price of the earliest NDC–9 of the Part D rebatable drug.

After further consideration of this policy and the data that are available to CMS in the Medicaid Drug Programs system, CMS does not believe that calculating the benchmark period manufacturer price using the three or four quarters, as applicable, of AMP reported in the payment amount benchmark period described in proposed § 428.202(c)(1) or (2) of the earliest NDC–9 of the Part D rebatable drug is operationally feasible at this time. Although the buying manufacturer is required by the MDRP to report for the new NDC–9 the base date AMP associated with the earliest NDC–9 of the dosage form and strength, and to report the first marketed date associated with the earliest NDC–9 of the dosage form and strength as the first marketed date for the new NDC–9,[584] the buying manufacturer is not required to report which NDC–9 was used to determine the base date AMP and first marketed date. CMS may therefore lack the information necessary to identify the earliest NDC–9 of the Part D rebatable drug for purposes of determining the benchmark period manufacturer price to be used in calculating the inflation rebate amount.

CMS understands that statutory provisions at section 1860D–14B of the Act require that CMS establish the payment amount benchmark period at the dosage form and strength level, and that resetting the payment amount benchmark period for a new NDC–9 of an existing Part D rebatable drug may not fully align with this directive. Simultaneously, and as described above in this section III.I.3.c.2.b, CMS understands there may be a gap in the AMP data available to calculate the benchmark period manufacturer price at the dosage form and strength level for certain drugs. To enable CMS to calculate the benchmark period manufacturer price when a new NDC–

[583] Medicaid Drug Rebate Program Notice, Release No. 90 (April 18, 2014). *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-090.pdf.*

[584] See 88 FR 34238, 34257 (May 26, 2023). Section 1927(c)(2)(A)(ii)(II) of the Act expressly provides that the base date AMP quarter, with respect to a dosage form and strength of a drug, is established ''without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer . . .'' See also the data field definition of market date: ''For S, I, and N drugs marketed under an FDA-approved application (for example, BLA, NDA, ANDA), the earliest date the drug was first marketed under the application number by any labeler.'' *https://www.medicaid.gov/sites/default/files/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/recordspecficationanddefinitions.pdf.*

9 of an existing Part D rebatable drug is reported to the MDRP and that NDC–9 lacks AMP data for the time period described in proposed § 428.202(c)(1) or (2), CMS is soliciting comments on alternative policy options that are described in more detail below.

First, CMS is soliciting comments on a modified version of the policy described in section 40.1.2 of the revised Medicare Part D Drug Inflation Rebate Guidance. Under this modified policy, if a new NDC–9 of an existing Part D rebatable drug is reported to the MDRP, CMS would calculate the benchmark period manufacturer price for such NDC–9 using the base date AMP reported by a manufacturer under section 1927(b)(3) of the Act for such Part D rebatable drug, if such base date AMP was reported for a calendar quarter that overlaps with the time period described in proposed § 428.202(c)(1) or (2), as applicable for that Part D rebatable drug. CMS believes this modified policy would be operationally feasible because CMS would calculate the benchmark period manufacturer price using the base date AMP that is reported with the new NDC–9; CMS therefore would not need to identify the earliest NDC–9 of the Part D rebatable drug. Under this policy, CMS would only use the base date AMP to calculate the benchmark period manufacturer price if the base date AMP was associated with a calendar quarter that overlapped with the time period described in proposed § 428.202(c)(1) or (2), as applicable for that Part D rebatable drug. If CMS were to adopt this alternative approach, CMS would expect to operationalize it through conforming changes to proposed § 428.202(c) and other applicable proposed regulatory text.

CMS notes that, if CMS were to finalize this alternative approach, CMS would be unable to use this approach to calculate the benchmark period manufacturer price in the case of a new NDC–9 of an existing Part D rebatable drug with base date AMP that does not overlap with the time period described in proposed § 428.202(c)(1) or (2). In such instances, CMS would either establish a future payment amount benchmark period using an approach similar to that described in proposed § 428.202(c)(3) and (4) or apply one of the other alternative policies described below.

Another alternative CMS is considering is to require manufacturers of Part D rebatable drugs to submit to CMS AMP data for the time period identified under proposed § 428.202(c)(1) or (2) in cases where the manufacturer did not report AMP to the MDRP under section 1927(b)(3) of the Act for such period but AMP data are available either for the NDC–9 or for another NDC–9 within the same dosage form and strength. For example, if the quarter for which a manufacturer reports base date AMP for a new NDC–9 of an existing dosage form and strength does not overlap with the time period identified under proposed § 428.202(c)(1) or (2), but the earliest NDC–9 of the dosage form and strength that served as the basis for the base date AMP has AMP data available during any quarter of that time period, CMS would require manufacturers to report such AMP data. For a Part D rebatable drug with a payment amount benchmark period identified under proposed § 428.202(c)(1), a manufacturer would be required to submit to CMS AMP data for the calendar quarters in the period beginning January 1, 2021, and ending on September 30, 2021, to the extent such drug was first marketed before September 30, 2021. For a subsequently approved drug with a payment amount benchmark period identified under proposed § 428.202(c)(2), a manufacturer would be required to submit to CMS AMP data for the first calendar year beginning after the drug's first marketed date. CMS acknowledges the intersection between a potential reporting requirement under the Medicare Part D Drug Inflation Rebate Program for manufacturers to provide AMP data and existing AMP data reporting requirements for manufacturers under the MDRP. Should CMS pursue this option, CMS would explore using existing AMP reporting processes for the MDRP to operationalize any new AMP reporting requirement. This approach of requiring manufacturers to report such information would be consistent with CMS' understanding of the provisions of section 1860D–14B of the Act requiring CMS to establish the payment amount benchmark period at the dosage form and strength level, and with CMS' authority under sections 1102(a) and 1871(a)(1) of the Act to make rules and regulations as necessary for the efficient administration of programs, including the Medicare Part D Drug Inflation Rebate Program. CMS welcomes comments on the method by which CMS could collect such information, the timing of the potential collection and deadlines, and whether information reported by manufacturers should be taken into account for purposes of compiling the Rebate Reports for a Part D rebatable drug or instead only be included in the reconciliation processes specified in proposed § 428.401(d) and described later in this proposed rule.

CMS is also considering an alternative policy whereby CMS would calculate the benchmark period manufacturer price for a new NDC–9 of an existing Part D rebatable drug that lacks AMP data for the time period described in § 428.202(c)(1) or (2) using a reasonable proxy metric. CMS welcomes comments on potential proxy metrics CMS could use to calculate the benchmark period manufacturer price for a new NDC–9 of an existing dosage form and strength for which no AMP data are reported for such periods.

These alternative policy options are intended to achieve the same goal as the policy described in section 40.2.2 of the revised Medicare Part D Drug Inflation Rebate Guidance (that is, to disincentivize a manufacturer from resetting its payment amount benchmark period by obtaining a new NDC–9 for an existing Part D rebatable drug). CMS also welcomes comments on the alternative policy described in the revised Medicare Part D Drug Inflation Rebate Guidance whereby CMS would treat drugs first approved or licensed on or before October 1, 2021, that were not marketed until after that date in the same manner as subsequently approved drugs for purposes of establishing the payment amount benchmark period, benchmark period CPI–U, first applicable period, and first applicable period CPI–U. CMS is soliciting comments on these alternatives and may adopt one or more of such alternatives in the final rule based on comments received. Additionally, CMS is seeking comments on other policies that CMS should consider to prevent manufacturers from inappropriately resetting the payment amount benchmark period by obtaining a new NDC–9 for an existing Part D rebatable drug.

Under CMS' proposed policy to identify a payment amount benchmark period in certain instances of missing AMP as proposed in § 428.202(c)(3) and (4) and each of these alternatives considered, CMS would consider any restatements to the AMP data used to calculate the benchmark period manufacturer price during reconciliation, as specified in proposed § 428.401(d) and described later in this proposed rule. Furthermore, CMS would also monitor the extent to which manufacturers obtain a new NDC–9 for the same Part D rebatable drug in a manner that could result in inappropriately resetting the payment amount benchmark period or otherwise affect the calculation of the benchmark period manufacturer price. CMS

reminds manufacturers of their reporting obligations under section 1927(b) of the Act and § 447.510 of this title and that failure to provide timely information may result in penalties as detailed in section 1927(b)(3)(C)(i) of the Act.

If finalized, CMS would apply the policies described above to rebate calculations beginning with the applicable period that began on October 1, 2022. CMS has determined that, consistent with the policy described in section III.I.1, in order to calculate inflation rebates for Part D rebatable drugs that do not have AMP or other pricing data available under section 1927(b)(3) on which to base the benchmark period manufacturer price, CMS' proposed policy must apply for applicable periods beginning with the applicable period that began on October 1, 2022.

(c) Identification of the Payment Amount Benchmark Period for a Part D Rebatable Drug No Longer Considered To Be a Selected Drug

In proposed § 428.202(c)(5), CMS proposes to codify policies described in section 40.2.2 of the revised Medicare Part D Drug Inflation Rebate Guidance relating to the identification of the payment amount benchmark period for a selected drug (as defined in section 1192(c) of the Act) with respect to a price applicability period (as defined in section 1191(b)(2) of the Act) in the case such Part D rebatable drug is no longer considered to be a selected drug. The Medicare Part D Drug Inflation Rebate Program applies to selected drugs notwithstanding the status of the drug as a selected drug. However, the calculation of certain components of the rebate amount formula for selected drugs depends upon whether the selected drug has reached the end of its price applicability period and is no longer considered to be a selected drug under section 1192(c) of the Act. Specifically, section 1860D–14B(b)(5)(C) of the Act specifies a different payment amount benchmark period and benchmark period CPI–U for a Part D rebatable drug in the case such drug is no longer considered to be a selected drug under section 1192(c) of the Act, for each applicable period beginning after the price applicability period with respect to such drug. Accordingly, in such a case where a Part D rebatable drug is no longer a selected drug, CMS proposes in § 428.202(c)(5) that the payment amount benchmark period will be reset as the last calendar year of such price applicability period for such selected drug.

(3) Calculation of the Benchmark Period Manufacturer Price

CMS proposes in § 428.202(d) that, subject to proposed § 428.202(g), to determine the benchmark period manufacturer price for a Part D rebatable drug, CMS would use the AMP reported by a manufacturer to the Medicaid Drug Programs system under sections 1927(b)(3)(A)(i) and (ii) of the Act for each calendar quarter of the payment amount benchmark period, as identified in accordance with proposed § 428.202(c), as well as the units reported by a manufacturer under section 1927(b)(3)(A)(iv) of the Act for each month of such payment amount benchmark period. For a Part D rebatable drug first approved or licensed on or before October 1, 2021, section 1860D–14B(b)(4) of the Act specifies that the benchmark period manufacturer price is the sum of the products of (1) the AMP for the Part D rebatable drug reported for each calendar quarter of the payment amount benchmark period (that is, January 1, 2021, through September 30, 2021), and (2) the total units reported for each of the corresponding calendar quarters of the payment amount benchmark period divided by the total units of the Part D rebatable drug reported for the 3 calendar quarters in the payment amount benchmark period. The following formula illustrates how CMS would calculate the benchmark period manufacturer price for a Part D rebatable drug with a payment amount benchmark period identified under proposed § 428.202(c)(1), as proposed in § 428.202(d)(1):

(AMP for calendar quarter beginning January 2021) *multiplied by* (sum of monthly AMP units for January 2021 calendar quarter *divided by* sum of the units reported for the 3 quarters of the payment amount benchmark period) +

(AMP for calendar quarter beginning April 2021) *multiplied by* (sum of monthly AMP units for April 2021 calendar quarter *divided by* sum of the units reported for the 3 quarters of the payment amount benchmark period) +

(AMP for calendar quarter beginning July 2021) *multiplied by* (sum of monthly AMP units for July 2021 calendar quarter *divided by* sum of the units reported for the 3 quarters of the payment amount benchmark period)

For a Part D rebatable drug with a payment amount benchmark period identified under proposed § 428.202(c)(2) through (5), the following formula illustrates how CMS would calculate the benchmark period manufacturer price for a Part D rebatable drug as proposed in § 428.202(d)(2):

(AMP for calendar quarter beginning January) *multiplied by* (sum of monthly AMP units for January calendar quarter *divided by* sum of the monthly units reported for the 4 quarters of the payment amount benchmark period) +

(AMP for calendar quarter beginning April) *multiplied by* (sum of monthly AMP units for April calendar quarter *divided by* sum of the monthly units reported for the 4 quarters of the payment amount benchmark period) +

(AMP for calendar quarter beginning July) *multiplied by* (sum of monthly AMP units for July calendar quarter *divided by* sum of the monthly units reported for the 4 quarters of the payment amount benchmark period) +

(AMP for calendar quarter beginning October) *multiplied by* (sum of monthly AMP units for October calendar quarter *divided by* sum of the monthly units reported for the 4 quarters of the payment amount benchmark period)

(4) Identification of the Benchmark Period CPI–U

To calculate the inflation-adjusted payment amount in accordance with section 1860D–14B(b)(3), CMS must identify the benchmark period CPI–U. As described in the revised Medicare Part D Drug Inflation Rebate Guidance and in accordance with section 1860D–14B(g)(4), CMS proposes in § 428.202(e)(1) that the benchmark period CPI–U for a Part D rebatable drug first approved or licensed by the FDA on or before October 1, 2021, would be the CPI–U for January 2021. For a subsequently approved drug, CMS proposes in § 428.202(e)(2) that the benchmark period CPI–U would be the CPI–U for January of the first calendar year beginning after the drug's first marketed date, as required under section 1860D–14B(b)(5)(A).

As described earlier in this proposed rule, CMS has observed that a number of NDC–9s of Part D rebatable drugs approved or licensed on or before October 1, 2021, do not have AMP reported in the period beginning January 1, 2021, and ending September 30, 2021, and a number of NDC–9s of subsequently approved drugs do not have AMP reported in the first calendar year following the drug's first marketed date. To enable CMS to calculate the benchmark period manufacturer price and inflation rebate amounts for these NDC–9s, CMS is proposing in

§ 428.202(c)(3) and (4) to identify the payment amount benchmark period for such NDC–9s as the first calendar year, which would be no earlier than calendar year 2021, in which such drug has at least 1 quarter of AMP data reported. As previously discussed, CMS is soliciting comments on alternative methodologies to identify the payment amount benchmark period and calculate the benchmark period manufacturer price to address certain instances in which AMP has not been reported and, if any such alternatives are adopted, CMS may adopt conforming modifications to proposed § 428.202(e). To identify the benchmark period CPI–U for an NDC–9 described in proposed § 428.202(c)(3), CMS further proposes in § 428.202(e)(3) that for a Part D rebatable drug first approved on or before October 1, 2021, for which there are no quarters during the period beginning on January 1, 2021, and ending on September 30, 2021, for which AMP has been reported to the MDRP, the benchmark period CPI–U would be the CPI–U for January of the calendar year in which such drug has at least 1 quarter of AMP reported. CMS proposes in § 428.202(e)(4) that for a subsequently approved drug for which there are no quarters during the first calendar year beginning after the drug's first marketed date for which AMP has been reported to the MDRP, the benchmark period CPI–U is the CPI–U for January of the calendar year in which such drug has at least 1 quarter of AMP reported.

As discussed previously, the Medicare Part D Drug Inflation Rebate Program applies to selected drugs notwithstanding the status of the drug as a selected drug. However, the calculation of certain components of the applicable rebate amount formula for selected drugs depends upon whether the selected drug has reached the end of its price applicability period and is no longer considered to be a selected drug under section 1192(c) of the Act. In accordance with section 1860D–14B(b)(5)(C) of the Act, in such a case where a Part D rebatable drug is no longer a selected drug, CMS proposes in § 428.202(e)(5) that the benchmark period CPI–U will be the CPI–U for January of the last calendar year of such price applicability period.

(5) Calculation of the Inflation-Adjusted Payment Amount

As specified in section 1860D–14B(b)(3) of the Act and described in section 40.2.3 of the revised Medicare Part D Drug Inflation Rebate Guidance, the inflation-adjusted payment amount with respect to a Part D rebatable drug and applicable period is the benchmark period manufacturer price increased by the percentage by which the applicable period CPI–U exceeds the benchmark period CPI–U. CMS proposes in § 428.202(f) to calculate the inflation-adjusted payment amount for a Part D rebatable drug by dividing the applicable period CPI–U by the benchmark period CPI–U and then multiplying the quotient by the benchmark period manufacturer price. The following formula illustrates how CMS would calculate the inflation-adjusted payment amount for a Part D rebatable drug as proposed in § 428.202(f):

(Benchmark period manufacturer price) *multiplied by* (applicable period CPI–U *divided by* benchmark period CPI–U)

As described earlier in this proposed rule and proposed in § 428.202(a), CMS will use the inflation-adjusted payment amount to calculate the per unit Part D drug inflation rebate amount by determining the amount by which the AnMP for a Part D rebatable drug exceeds the inflation-adjusted payment amount for a Part D rebatable drug for an applicable period.

(6) Situations in Which Manufacturers Do Not Report Units Under Section 1927(b)(3)(A)(iv)

Section 1860D–14B of the Act generally requires CMS to determine the per unit Part D drug inflation rebate amount using the monthly units reported by manufacturers to the Medicaid Drug Programs system under section 1927(b)(3)(A)(iv) of the Act. CMS understands it is possible that a manufacturer may not have sales or monthly units of a COD to report to the Medicaid Drug Programs system for a calendar quarter because, for example, there may be a temporary interruption in sales of the COD, or there may be no sales immediately after the drug is first approved or licensed by the FDA. CMS proposes in § 428.202(g)(1) to codify the policy described in section 40.1.2 of the revised Medicare Part D Drug Inflation Rebate Guidance, whereby in cases where there are 1 or more quarter(s) in the payment amount benchmark period or applicable period for which a manufacturer has not reported units under section 1927(b)(3)(A)(iv) of the Act but has reported AMP under sections 1927(b)(3)(A)(i) and (ii) of the Act, CMS would calculate the benchmark period manufacturer price or AnMP, as applicable, using data only from quarter(s) with units. That is, quarter(s) in the payment amount benchmark period or applicable period for which a manufacturer has not reported units under section 1927(b)(3)(A)(iv) of the Act would be excluded from the calculation. CMS proposes in § 428.202(g)(2) to codify the policy described in section 40.1.2 of the revised guidance whereby if there are no quarters of the payment amount benchmark period or applicable period for which a manufacturer has reported units under section 1927(b)(3)(A)(iv) of the Act, but the manufacturer has reported AMP under sections 1927(b)(3)(A)(i) and (ii) of the Act for at least 1 quarter of such period, CMS would use the average of the AMP over the calendar quarters of the payment amount benchmark period or applicable period for which AMP is reported to calculate the benchmark period manufacturer price or AnMP, respectively.

iv. Determination of the Total Number of Units Dispensed Under Part D

In § 428.203(a), CMS proposes to codify the existing policy established in the revised Medicare Part D Drug Inflation Rebate Guidance whereby CMS would determine the total number of units of each Part D rebatable drug dispensed under Part D and covered by Part D sponsors based on information reported to CMS by Part D plan sponsors on the Part D PDE records for the 12-month applicable period. More specifically, CMS would determine the total number of units from the Quantity Dispensed field on the PDE record for each Part D rebatable drug with gross covered prescription drug costs greater than zero. Because the PDE record does not provide the unit type used to determine Quantity Dispensed, CMS proposes in § 428.203(a)(2) that CMS would crosswalk the information from the PDE record to a drug database that provides the unit type for an NDC, such as Medi-Span or the FDA's Comprehensive NDC Structured Product Labeling (SPL) Data Element (NSDE) file, matching on the NDC of the Part D rebatable drug. CMS understands that in limited instances, the unit type obtained from such drug databases may not match the AMP unit type reported by manufacturers to the Medicaid Drug Programs system, and in these cases, CMS would convert the total units reported on the PDE record to the AMP units reported to the Medicaid Drug Program system.

CMS conducts a thorough review of PDE records, which includes the identification of outliers in the quantity dispensed field of PDE records, as part of the Part D payment reconciliation process that occurs between CMS and

plan sponsors each year.[585] CMS intends to rely on this payment reconciliation process, through which Part D plan sponsors have an opportunity to correct PDE records flagged by CMS as containing potential outliers, to resolve outliers that would otherwise impact the Part D drug inflation rebate amount calculated under proposed § 428.201(a). Because PDE records are not updated to reflect the resolution of outliers identified through the Part D payment reconciliation process for a given calendar year until after CMS plans to send Rebate Reports for the applicable period (capturing data that include the first three quarters of that calendar year), the Rebate Report will not reflect the resolution of unit outliers identified through the Part D payment reconciliation process. However, because CMS intends to conduct a reconciliation of the rebate amount with additional PDE run-out (as proposed in § 428.401(d) and described later in this proposed rule), the reconciled rebate amounts will reflect the resolution of any unit outliers corrected by Part D plan sponsors through the Part D payment reconciliation process. CMS does not intend to conduct separate outlier analysis of PDE for the purposes of the Medicare Part D Drug Inflation Rebate Program, but CMS did consider several adjustments to reduce the effect of outliers not resolved through the Part D payment reconciliation process, including removal of PDE records that were identified by CMS as having potential outlier quantity dispensed fields but were neither corrected nor verified by Part D plan sponsors, removal of the quantity dispensed field for certain records at or above a certain statistically derived threshold, and imputing quantity dispensed values for such records. CMS is soliciting comments on this proposed approach to rely on CMS' existing review of PDE records, as well as on the adjustments considered to reduce the effect of outliers not resolved through the Part D payment reconciliation process.

As proposed in § 428.203(b), CMS would remove from the total number of units any units of a generic drug dispensed on or after the date that such generic drug no longer meets the definition of a Part D rebatable drug, as well as units acquired through the 340B Program, as described in section III.I.3.c of this proposed rule. CMS invites comments on any additional units that should be excluded from the rebate amount calculation.

(1) Removal of Units When a Generic Drug Is No Longer a Part D Rebatable Drug

In § 428.203(b)(1), CMS proposes to codify the policy established in section 40.2.8 of the revised Medicare Part D Drug Inflation Rebate Guidance to exclude from the rebate calculation any units of a generic drug dispensed on or after the date that such generic drug no longer meets the definition of a Part D rebatable drug. To determine whether a generic drug that meets the definition of a Part D rebatable drug on the first day of an applicable period ceases to meet such definition later in the applicable period, CMS will use the most recent version of the downloadable FDA Orange Book to identify whether FDA has approved a 505(j) ANDA for a drug that is rated as therapeutically equivalent to such generic drug. If CMS determines that FDA has approved such a therapeutically equivalent drug under a 505(j) ANDA, CMS will then use the NDC Directory, including historical information from NDC Directory files such as discontinued, delisted, and expired listings provided by FDA or published on the FDA website to determine the marketing status of such therapeutically equivalent drug and to determine whether, during the applicable period, the therapeutically equivalent drug was marketed. Similarly, CMS will use the NDC Directory to identify whether the reference listed drug, or an authorized generic of the reference listed drug was marketed during the applicable period. CMS will exclude from the rebate calculation any units dispensed on or after the first day of the calendar month that a generic drug no longer meets the definition of a Part D rebatable drug. CMS intends to apply this unit exclusion at the month level and would exclude all units of a generic drug that ceases to meet the definition of a Part D rebatable drug beginning with the first day of the first month when a therapeutically equivalent drug approved under a 505(j) ANDA is marketed based on the marketing start date in the NDC Directory or when the reference listed drug, or an authorized generic of the reference listed drug is marketed based on the marketing start date in the NDC Directory. CMS proposes to apply this exclusion each calendar month because the Orange Book downloadable data files are updated monthly.

(2) Exclusion of 340B Acquired Units From Part D Rebatable Drug Requirements

Section 1860D–14B(b)(1)(B) of the Act requires that beginning with plan year 2026, CMS shall exclude from the total number of units for a Part D rebatable drug, with respect to an applicable period, those units for which a manufacturer provides a discount under the 340B Program. Because this requirement starts after the first quarter of the applicable period that begins on October 1, 2025, the exclusion of 340B units would only apply for the last three quarters of this applicable period. That is, CMS would exclude 340B units starting on January 1, 2026.

Data on which units dispensed under Part D and covered by Part D plan sponsors were purchased under the 340B Program is unavailable under the data sources specified at section 1860D–14B(d) of the Act (that is, information submitted by manufacturers, States, and Part D plan sponsors), and CMS does not currently have access to this data through other means. CMS understands that the 340B status of a Part D drug is usually not known by the dispenser at the point-of-sale, and that 340B covered entities (hereinafter ''covered entities'') typically identify the 340B status of a Part D drug retrospectively. Because the covered entity and CMS do not exchange dispensed Part D drug information confirming the 340B status of a Part D rebatable drug, CMS is unable to identify 340B units at the claim-level at this time. For these reasons, CMS believes it necessary to establish an estimation methodology to remove 340B units from the total number of units for a Part D rebatable drug, as described in this section.

(a) Estimation Methodology To Remove 340B Units From Rebate Calculations

To fulfill the statutory requirement to remove 340B units from rebate calculations beginning on January 1, 2026, CMS is proposing in § 428.203(b)(2) a new policy to remove units from the total number of units dispensed of a Part D rebatable drug for each applicable period based on a calculated percentage that reflects the portion of 340B purchasing relative to total sales. CMS proposes the percentage (hereinafter, ''estimation percentage'') to equal the total number of units purchased by covered entities under the 340B Program for an NDC–9, divided by the total units sold of that NDC–9. An example calculation for a Part D rebatable drug for a given applicable period is shown below for illustrative purposes:

[585] See *https://www.hhs.gov/guidance/document/pde-analysis-process-withheld-and-invoiced-outlier-pdes.*

Total number of units dispensed under Part D determined under § 428.203(a), minus the units determined under § 428.203(b)(1): 1,000
Estimation percentage:
Total number of units purchased by covered entities under the 340B Program: 5,000
Total units sold: 50,000
5,000 *divided by* 50,000 = 10 percent
340B units excluded under § 428.204(b)(2): 10 percent
multiplied by 1,000 = 100

The proposed estimation policy is consistent with CMS' authority under section 1860D–14B(b)(1)(B) of the Act and sections 1102(a) and 1871(a)(1) of the Act, the latter of which provide the authority to make rules and regulations as necessary for the efficient administration of programs, including the Medicare Part D Drug Inflation Rebate Program. Because the statutory requirement to remove 340B units from rebate calculations does not begin until January 1, 2026, for the applicable year that begins on October 1, 2025, CMS proposes to apply the estimation percentage only to those units associated with claims with dates of service in the last three quarters of the applicable period (that is, January 1, 2026, through September 30, 2026).

To identify the numerator of the estimation percentage (that is, the total number of units purchased under the 340B Program for an NDC–9), CMS proposes to use data from HRSA's Prime Vendor Program (PVP). Certain supply chain entities report 340B unit data to the PVP at the NDC–11 level, and based on the data received, CMS would aggregate these data at the NDC–9 level [586] to identify the total number of 340B units of a Part D rebatable drug that covered entities purchased in a given time period. CMS proposes to work with HRSA to obtain the necessary data from the PVP. CMS understands that there are limitations of using the PVP data, including that some covered entities may choose not to participate in the PVP, and CMS would not have access to 340B purchases reported by supply chain entities for this share of covered entities. Further, certain 340B purchases may not be reported to the PVP if those purchases were made through alternative distribution models such as a covered entity purchasing directly from a manufacturer, certain specialty distribution channel purchases, or drugs that receive a 340B rebate under the Ryan White HIV/AIDS Program's AIDS Drug Assistance Program. CMS is soliciting comments on what other data sources may be available to calculate the numerator of the estimation percentage. CMS is also soliciting comments on how it could account for potential underreporting of 340B units if data are not available on certain 340B purchases, such as those described above, that may not be reported to the PVP.

To identify the denominator of the estimation percentage (that is, the total units sold of an NDC–9), CMS proposes to use existing manufacturer reporting under the Medicaid Drug Rebate Program (MDRP) of unit sales. Specifically, CMS proposes to use the total number of units that are used to calculate the monthly AMP and which manufacturers are required to report to CMS for each covered outpatient drug (COD) in accordance with section 1927(b)(3)(A)(iv) of the Act. CMS believes that using these unit data to calculate an estimation percentage is consistent with the use of these same data to calculate the AnMP in proposed § 428.202(b) and the benchmark period manufacturer price in proposed § 428.202(d).

CMS recognizes the importance of ensuring that the numerator and denominator of the proposed estimation percentage reflect the same time period of sales for units dispensed in the same settings. CMS acknowledges that the proposed data source for the numerator (PVP data) reflects purchases by covered entities that dispense or administer 340B-eligible drugs in retail community pharmacies and in outpatient settings. The proposed data source for the denominator (unit sales used to calculate AMP) represents, in accordance with the definition of AMP at section 1927(k)(1) of the Act, (1) manufacturer sales to wholesalers for drugs distributed to retail community pharmacies, and (2) manufacturer sales to retail community pharmacies that purchase drugs directly from the manufacturer. Therefore, the numerator of the proposed estimation percentage represents 340B units dispensed in multiple settings, whereas the denominator represents units typically dispensed only in the retail community pharmacy setting. CMS welcomes evidence demonstrating how 340B dispensing rates differ between the retail community pharmacy setting versus multiple settings and may consider adjusting the estimation percentage to reflect variation between the percentage of 340B units dispensed in multiple settings (that is, retail community pharmacies and outpatient settings) and the percentage of 340B units dispensed in only the retail community pharmacy setting. The proposed regulatory text at § 428.203(b)(2) would be subject to any such adjustment factor that may be adopted.

CMS also recognizes that the proposed estimation percentage represents the total number of 340B units dispensed as a proportion of total units dispensed, irrespective of insurance/payor type. CMS is soliciting comments on whether the agency should further adjust the percentage of 340B units dispensed to the general population to estimate the percentage of 340B units dispensed to Part D beneficiaries for claims with dates of service on or after January 1, 2026, including comments on how the percentage of 340B units dispensed to the general population compares with the percentage of 340B units dispensed to Part D beneficiaries. CMS welcomes evidence that demonstrates how these percentages differ. CMS will consider this information in developing its final policies and may consider adjusting the estimation percentage to reflect variation between the percentage of 340B units dispensed to Part D beneficiaries and the percentage of 340B units dispensed to the general population. The proposed regulatory text at § 428.203(b)(2) would be subject to any such adjustment factor that may be adopted. CMS is also soliciting comments on whether there are other circumstances for which CMS should apply an adjustment factor to the estimation percentage.

CMS considered using alternative data sources to calculate the estimation percentage. To identify the total number of units purchased under the 340B Program to use in the numerator of the estimation percentage, CMS considered requiring other entities throughout the pharmaceutical supply chain, including manufacturers, to report these data to CMS. An advantage of this approach is that manufacturers could provide data directly on total 340B units sold; in other words, this data would capture the limited 340B sales that the PVP data does not capture. A disadvantage of this approach is that not all manufacturers of Part D rebatable drugs may have existing mechanisms for tracking 340B sales for Medicare Part D, which could necessitate that new tracking and reporting mechanisms be created. At this time, CMS is not proposing this alternative because CMS would prefer to rely on data that are already reported to the PVP, as using these data would help to minimize reporting burdens and may

[586] NDC–9 and NDC–11 numbers are identical except for two numbers in NDC–11s that indicate package size. Because of this, NDC–11 is more granular than NDC–9, and multiple NDC–11 numbers can aggregate under a single NDC–9 number.

result in cleaner and more accurate data due to the quality checks performed on the PVP data for purposes of compliance with the 340B Program. For example, audit and price integrity checks are performed on the PVP data to ensure the distributors submit and code the data correctly.

To identify the total units sold to use in the denominator of the estimation percentage, CMS similarly considered establishing a new requirement for other entities throughout the pharmaceutical supply chain, including manufacturers, to report these data to CMS. An advantage of this approach is that the denominator would represent sales that are ultimately dispensed in retail community pharmacy settings and in outpatient settings (whereas, as mentioned previously, unit reporting under the MDRP represents units typically dispensed only in the retail community pharmacy setting). A disadvantage of this approach is that it could necessitate that new tracking and reporting mechanisms be created. At this time, CMS is not proposing this alternative as CMS believes that relying upon existing manufacturer reporting of unit sales reported with AMP under the MDRP would be preferable to a new reporting option and would help minimize reporting burden. Further, the use of unit sales reported with AMP may provide cleaner and more accurate data than establishing a new manufacturer reporting requirement since manufacturers must certify their AMP reporting, in accordance with § 447.510(e), and are subject to civil money penalties for false or inaccurate reporting, in accordance with section 1927(b)(3)(B) of the Act. CMS also considered using data on unit sales available in a nationally representative and commercially available database but one disadvantage of this option would be that CMS would be unable to audit the quality of data available through such a database.

(b) Comment Solicitation on a Medicare Part D Claims Data Repository

In the initial Medicare Part D Drug Inflation Rebate Guidance, CMS solicited comments on the best mechanism to identify 340B units dispensed under Part D.[587] CMS discussed requiring the dispensing entity to include a 340B claims indicator on the Part D drug claim to be included in PDE records. Many commenters disagreed that the PDE record was the most accurate way to identify 340B discounts for Part D drugs. A few commenters highlighted the operational challenges, administrative burden, and potential for increased dispensing fees and reimbursement issues with both point-of-sale modifiers and retrospective 340B identifiers. In addition, a wide array of interested parties recommended that CMS create a mechanism through which covered entities would retrospectively submit data to CMS identifying 340B claims dispensed under Part D. Interested parties urged that this mechanism allow covered entities to submit these data directly to CMS, rather than through claims that dispensers submit via Part D plan sponsors.

In response to this feedback from interested parties, CMS is soliciting comments on establishing a Medicare Part D claims data repository (hereinafter, ''repository'') in a future year of the Medicare Part D Drug Inflation Rebate Program to comply with the requirement under section 1860D–14B(1)(B) of the Act that CMS shall exclude from the total number of units for a Part D rebatable drug those units for which a manufacturer provides a discount under the 340B Program. This approach would require that covered entities submit certain data elements from 340B-identified Part D claims to the repository. CMS solicits comments on such a requirement later in this section.

As described later in this section, a repository could receive data elements submitted by covered entities from 340B-identified claims for all drugs covered under Medicare Part D billed to Medicare. As requested by interested parties in comments on the initial Medicare Part D Drug Inflation Rebate Guidance, the repository could allow covered entities to submit these data directly to CMS (or a contractor), rather than through claims that dispensers submit to Part D plan sponsors. CMS could consider all data elements received by the repository to be associated with 340B-identified claims; that is, the repository would not further verify the 340B status of a claim but rather would serve solely to store these data. Under this process, CMS could require an attestation from covered entities that the data elements from all claims submitted to the repository are from verified 340B claims. CMS is exploring approaches to confirming completeness and accuracy of the submission, and CMS is soliciting comments on methods to review and ensure the accuracy of reported data. CMS could then match the stored data elements to PDE records for each Part D rebatable drug dispensed during the applicable period. Units associated with PDE records that match to data elements stored in the repository could be considered those for which the manufacturer provides a discount under the 340B Program and therefore removed from the total number of units used to calculate the total rebate amount.

(c) Comment Solicitation on Requiring Covered Entities To Submit 340B Claims Data to the Repository

CMS is soliciting comments on using its authority under section 1860D–14B(b)(1)(B) of the Act, as well as its authorities under sections 1102(a) and 1871(a)(1) of the Act, to require covered entities to enroll in a repository and submit certain data elements from 340B-identified claims for all covered Part D drugs billed to Medicare to this repository. CMS understands covered entities typically contract with 340B third-party administrators (340B TPAs) to determine 340B eligibility of claims using data submitted by covered entities and their contract pharmacies.[588] CMS welcomes comments on whether or how, to the extent a covered entity uses a 340B TPA, CMS could require or encourage TPAs to submit certain data elements to the repository on behalf of that covered entity.

Requiring covered entities to submit data elements from 340B-identified Part D claims to the repository could allow CMS to receive data directly from the entities that participate in the 340B Program to identify 340B units to exclude from Part D drug inflation rebate calculations without intermediary entities needing to develop processes to capture these data and relay it to CMS. CMS is considering requiring covered entities to submit the following data elements from Part D claims for covered Part D drugs that are purchased under the 340B Program and dispensed to Medicare Part D beneficiaries: (1) Date of Service (that is, the date the prescription was filled by the pharmacy); (2) Prescription or Service Reference Number; (3) Fill Number (that is, the code indicating whether the prescription is an original or a refill; if a refill, the code indicates the refill number); and (4) Dispensing Pharmacy NPI. CMS believes that these would be the minimum data elements required to match claims and remove 340B units from Part D drug inflation rebate calculations. CMS is soliciting

[587] See: *https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-initial-guidance.pdf*.

[588] Covered entities may elect to dispense 340B drugs to patients through contract pharmacy services, an arrangement in which the covered entity enters a contract with the pharmacy to provide pharmacy services.

comments from interested parties on this list of data elements and whether these data elements would be accessible to covered entities to submit to CMS.

(d) Comment Solicitation on Timing Requirements for Potential Submissions to a Medicare Part D Claims Data Repository

CMS is soliciting comments on requiring covered entities to submit the fields specified by CMS to the repository within 3 months of the end of a given calendar quarter. For example, for claims with dates of service between October 1, 2027, through December 31, 2027, covered entities would be required to submit data elements from 340B-identified claims to CMS no later than March 31, 2028. The 340B units identified from these quarterly submissions could be removed from the total number of units and total rebate amount specified in the Preliminary Rebate Report and Rebate Report detailed in proposed § 428.401(b) and (c), respectively.

In accordance with the proposed regulation at § 428.401(d) to reconcile the rebate amount in the case of revised information, including a reconciliation of the total number of units detailed at proposed § 428.401, CMS is soliciting comments on providing covered entities with additional time to submit data to reflect a revision to the 340B determination of claims with dates of service throughout an applicable period. A revision could come in one of two forms: (1) resubmission of data for a claim that the covered entity previously submitted to a repository in error or with errors in the requested data fields, or (2) new submission of data for a claim that the covered entity had previously determined was not purchased under the 340B Program, but later identified was purchased under such program. For the first type of revision, CMS is soliciting comments on requiring that the covered entity resubmit the data from such claim using a field to indicate that such data should be removed from the repository's dataset of 340B-identified claims; if applicable, the covered entity could resubmit the claim with the correct information. CMS is soliciting comments on the process and timing for covered entities to submit this revised data to the repository after the end of the applicable period. Updates to the total number of units and total rebate amount based on this revised information from covered entities would be reflected in the reconciliation process detailed at proposed § 428.401(d).

CMS is soliciting comments from interested parties on the feasibility of the proposed quarterly reporting timeline for covered entities to submit data elements from Part D 340B claims, as well as the additional time to submit data to reflect a revision to the 340B determination of claims.

(e) Alternative Policy Considered: 340B Claims Identifier

As described in section 40.2.7 of the initial Medicare Part D Drug Inflation Rebate Guidance, CMS considered requiring that a 340B indicator be included on the PDE record at the time of dispense to identify drugs purchased under the 340B Program that were dispensed under Medicare Part D. As described in the ''Summary of Public Comments on the Initial Medicare Part D Drug Inflation Rebates Memorandum and CMS' Responses'' in the revised Medicare Part D Drug Inflation Rebate Guidance, many commenters—including covered entities, pharmacies, Part D plan sponsors, and pharmacy benefit managers—disagreed that the PDE record would be the most accurate way to identify 340B discounts for Part D drugs. A few commenters highlighted the operational challenges, administrative burden, and potential for increased dispensing fees and reimbursement issues with 340B claim identifiers. After further consideration of comments received in response to the initial guidance and of the process through which a claim is determined to have 340B status, CMS is no longer pursuing this policy at this time but may consider it in future rulemaking.

v. Treatment of New Formulations of Part D Rebatable Drugs

Section 1860D–14B(b)(5)(B)(i) of the Act requires CMS to determine a formula for the rebate amount and the inflation-adjusted payment amount for a Part D rebatable drug that is a line extension of a Part D rebatable drug that is an oral solid dosage form for an applicable period that is consistent with the formula applied under section 1927(c)(2)(C) of the Act for determining a rebate obligation for a rebate period under such section. Section 1927(c)(2)(C) of the Act provides for an alternative rebate calculation for line extension drugs under the MDRP, and CMS issued guidance on how this calculation is performed for these purposes.[589]

Section 1860D–14B(b)(5)(B)(ii) of the Act further states that for a Part D rebatable drug, the term line extension means, ''a new formulation of the drug, such as extended release formulation, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation.'' This language is identical to the definition of ''line extension'' in section 1927(c)(2)(C) of the Act. Regulatory definitions of ''line extension'' and ''new formulation'' for the MDRP were adopted through rulemaking[590] and can be found at § 447.502. In alignment with CMS' policy in section 40.4 of the revised Medicare Part D Drug Inflation Rebate Guidance, CMS proposes in § 428.200 to adopt the definitions of ''line extension'' and ''new formulation'' at § 447.502 of this title for the purposes of identifying new formulations of Part D rebatable drugs.

In proposed § 428.204, CMS would determine the total rebate amount to be paid by manufacturers by taking the greater of (1) the total rebate amount calculated in proposed § 428.201(a) for the applicable period for the Part D rebatable drug that is a line extension, or (2) the alternative total rebate amount. This proposal is a modification to policy established in revised Medicare Part D Drug Inflation Rebate Guidance. While the revised guidance stated that CMS would compare the *per unit* rebate amount to the alternative *per unit* rebate amount, as proposed in § 428.204, CMS would compare the *total* rebate amount calculated in proposed § 428.201(a) to the alternative *total* rebate amount, which CMS believes is consistent with the existing regulations for new formulations at § 447.509(a)(4). CMS further proposes in § 428.204 to codify the policy described in section 40.4 of the revised guidance to calculate the alternative inflation rebate amount for a Part D rebatable drug that is a line extension consistent with the formula applied under section 1927(c)(2)(C) of the Act. That is, CMS would determine an inflation rebate amount ratio for the initial drug identified by the manufacturer in accordance with § 447.509(a)(4)(i)(B) by dividing the inflation rebate amount for that initial drug for the applicable period by the AnMP for that initial drug for the applicable period, as calculated under proposed § 428.202(b).

To identify the initial drug for the line extension, CMS would use information from the Medicaid Drug Program system and identify line extensions based on manufacturer reporting of drugs as line extensions and related pricing and product data in that system. CMS notes

[589] See: *https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/unit-rebate-calculation/unit-rebate-amount-calculation-for-line-extension-drugs-with-example/index.html.*

[590] See: 85 FR 87000, 87101 (December 31, 2020).

that Medicaid rebates are calculated quarterly, and a different initial drug may be identified in different quarters by the manufacturer for a particular line extension drug. Part D drug inflation rebates are calculated based on a 12-month applicable period, meaning there may be instances where a Part D rebatable line extension drug has multiple potential initial drugs during the applicable period that could be used for the alternative inflation rebate amount calculation. In such situations, for consistency, CMS will use the initial drug identified by the manufacturer in the last quarter of the Part D inflation rebate applicable period to identify the initial drug for the line extension drug alternative inflation rebate calculation. If an initial drug was not identified in the last quarter for a drug that is a line extension, CMS will use the initial drug identified for a quarter most recently in that applicable period to identify the initial drug for the line extension drug alternative inflation rebate calculation.

d. Reducing the Rebate Amount for Part D Rebatable Drugs in Shortage and When There Is a Severe Supply Chain Disruption or Likely Shortage (§§ 428.300 Through 428.303)

Section 1860D–14B(b)(1)(C) of the Act requires the Secretary to reduce or waive the rebate amount owed by a manufacturer for a Part D rebatable drug with respect to an applicable period in three distinct cases: (1) when a Part D rebatable drug is described as currently in shortage on a shortage list in effect under section 506E of the FD&C Act at any point during the applicable period; (2) when CMS determines there is a severe supply chain disruption during the applicable period for a generic Part D rebatable drug or biosimilar, such as a disruption caused by a natural disaster or other unique or unexpected event; and (3) when CMS determines that without such a reduction or waiver, a generic Part D rebatable drug is likely to be described as in shortage on such shortage list during a subsequent applicable period. The statute does not describe how CMS should reduce or waive inflation rebates.

To implement the statutory requirement under section 1860D–14B(b)(1)(C), CMS proposes to codify in subpart D of part 428 existing policies described in sections 40.5, 40.5.1, 40.5.2, and 40.5.3 of the revised Medicare Part D Drug Inflation Rebate Guidance to reduce the total rebate amount owed by a manufacturer in each of these three cases, as summarized in Table 51 and discussed later in this section.

	Drug Shortage		Severe Supply Chain Disruption	Likely to be in Shortage
Duration of Reduction	Indefinite for as long as drug is "currently in shortage"		One applicable period; manufacturer may request an extension for an additional applicable period for up to two applicable periods total	
Percent Reduction	Part D rebatable drug other than a plasma-derived product or generic Part D rebatable drug	Part D rebatable plasma-derived product or generic Part D rebatable drug	Part D rebatable biosimilar or generic Part D rebatable drug	Generic Part D rebatable drug
First applicable period	25%	75%	75%	75%
Second applicable period	10%	50%	75%	75%
Subsequent applicable periods	2%	25%	Not applicable	Not applicable

TABLE 51: Determination of Rebate Reduction Amount for Part D Rebatable Drugs

As proposed, CMS would not fully waive the rebate amount owed in any case. CMS believes the proposed rebate reduction policies balance providing appropriate financial relief for manufacturers in certain circumstances, including when there is a severe supply disruption resulting from exogenous circumstances outside of a manufacturer's control, while not incentivizing manufacturers to delay taking appropriate steps to resolve a drug shortage or severe supply chain disruption, or maintain a situation in which a generic would be at risk of shortage to avoid an obligation to pay rebates. CMS will continue to evaluate these policies and may update them in future years. CMS underscores that most shortages involve multiple source generic drugs,[591] which are not Part D rebatable drugs and thus are not subject to Part D drug inflation rebates. CMS solicits comments on the proposed approach.

i. Definitions

CMS proposes in § 428.300 to define the following terms applicable to subpart D (§§ 428.300 through 428.303):

- ''Biosimilar''.
- ''Drug shortage'' or ''shortage''.
- ''Generic Part D rebatable drug''.
- ''Likely to be in shortage''.
- ''Plasma-derived product''.

Proposed § 428.300 also would codify definitions established in the revised Medicare Part D Drug Inflation Rebate Guidance for the following terms:

- ''Currently in shortage''.
- ''Natural disaster''.
- ''Other unique or unexpected event''.
- ''Severe supply chain disruption''.

ii. Reducing the Rebate Amount for Part D Rebatable Drugs Currently in Shortage

In proposed § 428.301, CMS proposes to codify the policy established in section 40.5.1 of the revised Medicare Part D Drug Inflation Rebate Guidance

[591] See: *https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-shortages-in-the-us2023.*

whereby CMS would reduce the total rebate amount for a Part D rebatable drug that is currently in shortage based on the length of time the drug is in shortage during an applicable period and decrease the amount of the reduction over time. CMS intends to use the shortage lists maintained by the FDA Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) to determine whether a Part D rebatable drug is currently in shortage [592] during an applicable period. CMS will not consider an NDC–10 in the status of ''to be discontinued,'' ''discontinued,'' or ''resolved'' to be ''currently in shortage.'' At this time, CMS intends to provide the same reduction in the rebate amount for Part D rebatable drugs currently in shortage regardless of the cause of the shortage.

CMS will not provide a full waiver of the rebate amount for drugs currently in shortage on an FDA shortage list, as providing a full waiver of the rebate amount could further incentivize manufacturers to delay taking appropriate steps that may resolve a shortage more expeditiously simply to maintain having the drug listed on FDA's drug shortage list to avoid an obligation to pay rebates for an extended period. Further, in a report analyzing the root causes of drug shortages between 2013 and 2017, FDA found that more than 60 percent of drug shortages were the result of manufacturing or product quality issues, and providing a full waiver of the rebate amount in situations that may be within a manufacturer's control could be perceived as rewarding manufacturers for poor quality management.[593]

CMS would be responsible for monitoring the status of a Part D rebatable drug on an FDA shortage list, and manufacturers would not need to submit any information to CMS to be eligible for a reduction of the rebate amount for a Part D rebatable drug that is currently in shortage.

To calculate the reduced total rebate amount for a Part D rebatable drug, in § 428.301(b)(1), CMS proposes the following formula:

Reduced *Total* Rebate Amount = the total rebate amount *multiplied by* (1 *minus* applicable percent reduction) *multiplied by* (percentage of time drug was currently in shortage during the applicable period) *added to* the total rebate amount *multiplied by* (1 *minus* percentage of time drug was currently in shortage during the applicable period)

For the purpose of this formula, for a Part D rebatable drug that is a generic drug or a plasma-derived product, in § 428.301(b)(2)(i), CMS proposes an applicable percent reduction of 75 percent for the first applicable period such Part D rebatable drug is currently in shortage, 50 percent for the second applicable period, and 25 percent for each subsequent applicable period. For a Part D rebatable drug (including a biosimilar) that is not a generic drug or a plasma-derived product, in § 428.301(b)(2)(ii), CMS proposes an applicable percent reduction of 25 percent for the first applicable period such Part D rebatable drug is currently in shortage, 10 percent for the second applicable period, and 2 percent for each subsequent applicable period.

Because drugs and biologicals on the FDA shortage lists are maintained at the NDC–10 level, and Part D drug inflation rebates are calculated at the NDC–9 level, CMS proposes in § 428.301(c) that if any NDC–10 for a Part D rebatable drug is currently in shortage, CMS would apply the rebate reduction to the entire Part D rebatable drug at the NDC–9 level. CMS will closely monitor market data for the Part D rebatable drugs for which the rebate is reduced to ensure the integrity of the application of the rebate reduction policy.

CMS intends to provide a reduction in the rebate amount for as long as a Part D rebatable drug is currently in shortage. CMS believes the rebate reduction should be proportional to the time the drug is currently in shortage and decrease over time to balance providing financial relief to manufacturers experiencing a drug shortage while not incentivizing manufacturers to delay taking appropriate steps to resolve a shortage simply to maintain having the drug listed on an FDA shortage list to avoid an obligation to pay rebates for an extended period.

To determine the percentage of time a Part D rebatable drug was currently in shortage during the applicable period, as proposed in § 428.301(b)(3), CMS would count the number of days such drug is currently in shortage in an applicable period and divide by the total number of days in that applicable period.

In proposed § 428.301(b)(2), CMS proposes codifying the policy set forth in section 40.5.1 of the revised Medicare Part D Drug Inflation Rebate Guidance to apply a greater applicable percent reduction for generic Part D rebatable drugs, which, by definition, are sole source generic drugs, compared to brand-name drugs and biologicals, including biosimilars. CMS understands that generic drugs are often low-margin products whose prices are tied to the marginal cost of production and thus are vulnerable to potential market exit and shortage when input costs increase. CMS notes that the Medicare Part D Drug Inflation Rebate Program does not apply to multiple source generic drugs, which are the generic drugs most likely to be in shortage.[594] CMS proposes also applying a greater applicable percent reduction for plasma-derived products than non-plasma derived products because the former rely on a variable supply of donated blood plasma that can impact downstream production and therefore hamper the ability to promptly resolve a shortage.

When the status of a Part D rebatable drug changes from currently in shortage to ''resolved'' and either remains in the status of ''resolved'' or is removed from the list, and then reemerges on the list in the status of currently in shortage in the next applicable period, CMS would apply the shortage reduction as if there was a continuous shortage and move to the applicable percent reduction for the second applicable period. (In this scenario, the applicable percent reduction would be 50 percent for the second applicable period for a generic Part D rebatable drug or plasma-derived product and 10 percent for a Part D rebatable drug that is not a generic drug or plasma-derived product.) When the status of a Part D rebatable drug changes from currently in shortage to ''resolved'' and either remains in the status of ''resolved'' or is removed from the list for at least one applicable period, and then subsequently reemerges on a shortage list, the subsequent shortage would be treated as a new shortage. In such case, the applicable percent reduction for the first applicable period in which the drug reemerges on the shortage list would be 75 percent for a generic Part D rebatable drug or plasma-derived product and 50 percent for a Part D rebatable drug that is not a generic or plasma-derived product.

[592] For the purposes of this proposed rule, CMS uses the term ''currently in shortage'' to refer to Part D rebatable drugs that are in the status of ''currently in shortage'' on the CDER shortage list, as well as biological products listed on CBER's current shortages list.

[593] See: *https://www.fda.gov/media/131130/download?attachment#page=33.*

[594] See: *https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-shortages-in-the-us2023.*

iii. Reducing the Rebate Amount for Generic Part D Rebatable Drugs and Biosimilars When There Is a Severe Supply Chain Disruption

In § 428.302 of this proposed rule, CMS proposes to codify existing policy established in section 40.5.2 of the revised Medicare Part D Drug Inflation Rebate Guidance for rebate reductions when CMS determines there is a severe supply chain disruption during an applicable period. As proposed in § 428.302(b)(1), CMS would provide a time-limited standard reduction of 75 percent in the total rebate amount for a generic Part D rebatable drug or biosimilar when CMS determines there is a severe supply chain disruption during the applicable period, such as that caused by a natural disaster or other unique or unexpected event. To receive a rebate reduction in accordance with proposed § 428.302(b)(1), the manufacturer would have to submit to CMS a rebate reduction request [595] that meets the eligibility requirements proposed in § 428.302(c). A rebate reduction request should specify each NDC–11 to which the request applies, and if CMS grants a manufacturer's severe supply chain disruption rebate reduction request for an NDC–11, CMS proposes in § 428.302(b)(3) that the rebate reduction would apply to the entire generic Part D rebatable drug or biosimilar at the NDC–9 level. CMS has proposed additional submission requirements for rebate reduction requests in the information collection request under OMB control number: 0938–NEW (CMS–10858).

As proposed in § 428.302(c)(4), CMS would grant a reduction in the rebate amount owed if a manufacturer of an eligible drug submits to CMS a request in writing demonstrating that (1) a severe supply chain disruption has occurred during the applicable period, (2) the severe supply chain disruption directly affects the manufacturer itself, a supplier of an ingredient or packaging, a contract manufacturer,[596] or a method of shipping or distribution that the manufacturer uses in a significant capacity to make or distribute the generic Part D rebatable drug or biosimilar, and (3) the severe supply chain disruption was caused by a natural disaster or other unique or unexpected event. CMS will begin accepting rebate reduction requests and rebate reduction extension requests upon completion of the Paperwork Reduction Act (PRA) process, including for severe supply chain disruptions caused by a natural disaster or other unique or unexpected event that occurred on or after October 1, 2022, but before to completion of the PRA process. As proposed in § 428.302(c)(2), for a natural disaster or other unique or unexpected event occurring on or after August 2, 2024, that the manufacturer believes caused a severe supply chain disruption, the manufacturer must submit the rebate reduction request within 60 calendar days from the first day that the natural disaster or other unique or unexpected event occurred or began in order for CMS to consider a rebate reduction.

If the manufacturer makes a timely request that includes all the supporting documentation, and CMS determines, based on its review of the reduction request and supporting documentation, that a reduction should be granted, CMS would reduce the total rebate amount owed by a manufacturer by 75 percent for the manufacturer's generic Part D rebatable drug or biosimilar for the applicable period in which the event that caused the severe supply chain disruption occurred or began or, the following applicable period if the request is submitted less than 60 calendar days before the end of an applicable period. CMS acknowledges that the 60-day advance submission requirement may pose a challenge to timing of the rebate reduction when the severe supply chain disruption-causing event occurs late in one applicable period, and the request is not submitted until the next applicable period. In such circumstances, CMS would apply a rebate reduction to an applicable period based on the timing of the natural disaster or other unique or unexpected event causing a severe supply chain disruption and the timing of the submission of the request and may adjust the timing of the application of the rebate reduction as appropriate to meet the invoicing deadlines specified in statute and subpart E of proposed part 428.

CMS proposes in § 428.302(c)(5) that if a manufacturer believes severe supply chain disruption continues into a second, consecutive applicable period after the start of the natural disaster or other unique or unexpected event, the manufacturer may request a reduction of the total rebate amount for that second applicable period by submitting a rebate reduction extension request to CMS, along with any new supporting documentation. CMS has proposed additional submission requirements for rebate reduction extension requests in the information collection request under OMB control number: 0938–NEW (CMS–10858). As proposed in § 428.302(c)(5)(ii), a rebate reduction extension request and any new supporting documentation must be submitted at least 60 calendar days before the start of that second applicable period in order for CMS to consider a rebate reduction extension, except for when the initial request is made less than 60 calendar days before the end of an applicable period such that the initial rebate reduction applied to the next applicable period rather than the applicable period in which the event that caused the severe supply chain disruption occurred or began. In these cases, the rebate reduction extension request must be submitted at least 60 calendar days prior to the end of the applicable period in which the initial reduction applied.

If the manufacturer submits a complete and timely extension request, and CMS determines that the information submitted warrants an extension of the rebate reduction, the total rebate amount would be reduced by 75 percent for a second consecutive applicable period for that manufacturer's generic Part D rebatable drug or biosimilar in accordance with proposed § 428.302(b)(2).

Consistent with the policy established in section 40.5.2 of the revised Medicare Part D Drug Inflation Rebate Guidance, a manufacturer may receive only one extension of the rebate reduction per generic Part D rebatable drug or biosimilar per CMS determination of a severe supply chain disruption, as proposed in § 428.302(c)(5). Said differently, CMS would limit the severe supply chain disruption rebate reduction to two consecutive applicable periods total per generic Part D rebatable drug or biosimilar per CMS determination of a severe supply chain disruption.

As proposed in § 428.302(b)(4)(i), if the manufacturer believes there are multiple events causing severe supply chain disruptions during the same applicable period for the same generic Part D rebatable drug or biosimilar and submits multiple rebate reduction requests for the same generic drug or biosimilar, CMS will grant no more than one rebate reduction for that generic drug or biosimilar for the applicable

[595] The rebate reduction request forms are currently going through the Paperwork Reduction Act approval process under the document identifier CMS–10858. The proposed collection was published for a 30-day comment period in the June 3, 2024 **Federal Register** (89 FR 47563).

[596] A contract manufacturer is a party that performs one or more manufacturing operations on behalf of a manufacturer(s) of active pharmaceutical ingredients (APIs), drug substances, in-process materials, finished drug products, including biological products, and combination products. See ''Contract Manufacturing Arrangements for Drugs: Quality Agreements Guidance for Industry,'' November 2016: *https://www.fda.gov/media/86193/download*.

period. For example, if the manufacturer of a generic Part D rebatable drug or biosimilar is granted a severe supply chain disruption rebate reduction request for its product due to a natural disaster that occurred in January 2025 and then experiences a second severe supply chain disruption caused by a second, distinct natural disaster in July 2025, CMS would not grant the second rebate reduction request. That is, the manufacturer would receive the 75 percent reduction for one applicable period for the severe supply chain disruption caused by the first natural disaster but would not receive a rebate reduction for the second natural disaster. However, if the second natural disaster exacerbated the severe supply chain disruption caused by the first natural disaster, the manufacturer may reflect such circumstances in its request for an extension of the rebate reduction for a second applicable period.

As proposed in § 428.302(b)(4)(ii), if CMS grants a severe supply chain disruption rebate reduction request for a generic Part D rebatable drug or biosimilar, and the drug or biosimilar appears as currently in shortage during the same applicable period as the one for which the severe supply chain disruption reduction request was granted, CMS would apply the 75 percent reduction to the entire applicable period for which the severe supply disruption request was granted and would not grant any additional reduction for the shortage status during that applicable period. For any subsequent applicable periods that the generic Part D rebatable drug or biosimilar appears as currently in shortage, CMS would reduce the total rebate amount in accordance with the drug shortages reduction proposed in § 428.301, starting with the highest reduction (that is, 75 percent for a generic Part D rebatable drug or plasma-derived product and 25 percent for a Part D rebatable drug that is not a generic drug or plasma-derived product). For example, if CMS grants a severe supply chain disruption rebate reduction request for a generic Part D rebatable drug or biosimilar that was submitted on November 15, 2024, and that generic Part D rebatable drug or biosimilar is currently in shortage from September 15, 2025, until May 15, 2026, CMS would apply a 75 percent reduction in the total rebate amount for the duration of the applicable period for which the severe supply chain disruption rebate reduction request was granted (that is, October 1, 2024, to September 30, 2025), and then would apply the shortages reduction as proposed in § 428.301, beginning with a reduction of 25 percent for a biosimilar or 75 percent for a generic Part D rebatable drug or plasma-derived product that is a biosimilar for the applicable period beginning October 1, 2025.

As proposed in § 428.302(b)(4)(iii), if a generic Part D rebatable drug or biosimilar that is currently in shortage experiences a severe supply chain disruption, the manufacturer may submit a severe supply chain disruption rebate reduction request. If CMS grants the rebate reduction request, the rebate amount would be reduced by 75 percent for the applicable period, and CMS would not grant any additional reduction under proposed § 428.301 for the currently in shortage status during that applicable period. For example, if a generic Part D rebatable drug or biosimilar that is currently in shortage in the applicable period beginning October 1, 2024 is granted a severe supply chain disruption rebate reduction request as a result of a natural disaster that occurs on April 5, 2025, CMS would apply a 75 percent reduction in the rebate amount for the duration of the applicable period in which the natural disaster occurred (that is, October 1, 2024, to September 30, 2025). In this same example, if the natural disaster instead occurs on September 5, 2025, CMS would apply the shortages reduction proposed in § 428.301 for the duration of the applicable period beginning October 1, 2024 (that is, October 1, 2024, to September 30, 2025), and then a 75 percent reduction under the severe supply chain disruption policy to the next applicable period beginning October 1, 2025 (that is, October 1, 2025, to September 30, 2026).

In § 428.302(c)(6), CMS proposes to review rebate reduction requests and rebate reduction extension requests within 60 calendar days of receipt of all documentation, if feasible, beginning with the applicable period that begins on October 1, 2024. If a manufacturer's rebate reduction request does not meet the criteria in proposed § 428.302(c)(4) or if the rebate reduction request is incomplete or untimely based on the requirements in proposed § 428.302(c), CMS would deny the request. CMS also proposes that if a manufacturer's rebate reduction extension request does not meet the criteria in proposed § 428.302(c)(5), is incomplete or untimely based on the requirements in proposed § 428.302(c)(5), or if a reduction under proposed § 428.302(b)(1) was not provided for such generic Part D rebatable drug or biosimilar, CMS would deny the rebate reduction extension request. As proposed in § 428.302(c)(6)(iii), CMS' decisions to deny a request would be final and not be subject to an appeals process.

As proposed at § 428.302(c)(7), CMS would keep confidential, to the extent allowable under law, any requests for a rebate reduction, including supporting documentation. CMS proposes that information provided as part of a severe supply chain disruption rebate reduction request that the submitter indicates is a trade secret or confidential commercial or financial information would be protected from disclosure if CMS determines the information meets the requirements set forth under Exemptions 3 or 4 of the Freedom of Information Act (FOIA). In addition to the protections under the FOIA for trade secrets and commercial or financial information obtained from a person that is privileged or confidential, the Trade Secrets Act at 18 U.S.C. 1905 requires executive branch employees to protect such information. CMS would protect confidential and proprietary information as required by applicable law.

iv. Reducing the Rebate Amount for Generic Part D Rebatable Drugs Likely To Be in Shortage

In § 428.303 of this proposed rule, CMS proposes to codify existing policy established in section 40.5.3 of the revised Medicare Part D Drug Inflation Rebate Guidance for rebate reductions when a generic Part D rebatable drug is likely to be in shortage, as defined in proposed § 428.300. As proposed in § 428.303(b)(1), CMS would provide a time-limited standard reduction of 75 percent in the total rebate amount for a generic Part D rebatable drug when CMS determines that the generic Part D rebatable drug is likely to be in shortage. To receive a rebate reduction in accordance with proposed § 428.303(b)(1), the manufacturer would have to submit to CMS a rebate reduction request [597] that meets the eligibility requirements proposed in § 428.303(c). A rebate reduction request should specify each NDC–11 to which the request applies and if CMS grants a manufacturer's likely to be in shortage rebate reduction request for an NDC–11, CMS proposes in § 428.303(b)(3) that the rebate reduction would apply to the entire generic Part D rebatable drug at the NDC–9 level. CMS has proposed

[597] The rebate reduction request forms are currently going through the Paperwork Reduction Act approval process under the document identifier CMS–10858. The proposed collection was published for a 30-day comment period in the June 3, 2024 **Federal Register** (89 FR 47563).

additional submission requirements for rebate reduction requests in the information collection request under OMB control number: 0938–NEW (CMS–10858).

As proposed in § 428.303(c)(4), CMS would grant a reduction in the rebate amount owed if a manufacturer of an eligible drug submits to CMS a request in writing demonstrating that (1) the generic Part D rebatable drug is likely to be in shortage, (2) the manufacturer is taking actions to avoid the potential drug shortage, and (3) the reduction of the rebate amount would reduce the likelihood of the drug appearing on an FDA shortage list. As proposed in § 428.303(c)(2), a manufacturer must submit the rebate reduction request before the start of the next applicable period in which the manufacturer believes the generic Part D rebatable drug is likely to be in shortage in order for CMS to consider a rebate reduction.

If the manufacturer makes a timely request that includes all the supporting documentation, and CMS determines, based on its review of the reduction request and supporting documentation, that a reduction should be granted, CMS would reduce the total rebate amount owed by a manufacturer by 75 percent for the manufacturer's generic Part D rebatable drug for the applicable period in which the request was submitted or the following applicable period, depending on the timing of the submission of the request.

CMS proposes in § 428.303(c)(5) that if a manufacturer believes the potential drug shortage continues for a second, consecutive applicable period, the manufacturer may request a reduction of the total rebate amount for that second applicable period by submitting a rebate reduction extension request to CMS, along with any new supporting documentation. CMS has proposed additional submission requirements for rebate reduction extension requests in the information collection request under OMB control number: 0938–NEW (CMS–10858). As proposed in § 428.303(c)(5)(ii), a rebate reduction extension request and any new supporting documentation must be submitted at least 60 calendar days before the start of the second applicable period in which the manufacturer believes the generic Part D rebatable drug is likely to be in shortage in order for CMS to consider a rebate reduction extension.

If the manufacturer submits a complete and timely extension request, and CMS determines that the information submitted warrants an extension of the rebate reduction, the total rebate amount would be reduced by 75 percent for a second consecutive applicable period for that manufacturer's generic Part D rebatable drug in accordance with proposed § 428.303(b)(2).

Consistent with the policies established in section 40.5.3 of the revised Medicare Part D Drug Inflation Rebate Guidance, a manufacturer may receive only one extension of the rebate reduction per generic Part D rebatable drug per CMS determination of likelihood of shortage, as proposed in § 428.303(c)(5). Said differently, CMS would limit the likely to be in shortage rebate reduction to two consecutive applicable periods total per generic Part D rebatable drug per CMS determination of likelihood of shortage.

As proposed in § 428.303(b)(4), if CMS grants a rebate reduction request for a generic Part D rebatable drug that is likely to be in shortage, and the drug appears as currently in shortage during the same applicable period as the one for which the likely to be in shortage reduction request was granted, CMS would apply the 75 percent reduction to the entire applicable period for which the likely to be in shortage request was granted and would not grant any additional reduction for the shortage status during that applicable period. For any subsequent applicable periods that the generic Part D rebatable drug appears as currently in shortage, CMS would reduce the total rebate amount in accordance with the drug shortages reduction proposed in § 428.301, starting with the highest reduction (that is, 75 percent for a generic Part D rebatable drug). For example, if CMS grants a likely to be in shortage rebate reduction request for a generic Part D rebatable drug that was submitted on August 15, 2024, and that generic Part D rebatable drug is currently in shortage from September 15, 2025, until May 15, 2026, CMS would apply a 75 percent reduction in the total rebate amount for the duration of the applicable period for which the likely to be in shortage rebate reduction request was granted (that is, October 1, 2024, to September 30, 2025), and then would apply the shortages reduction as proposed in § 428.301, beginning with a reduction of 75 percent for a generic Part D rebatable drug for the applicable period beginning October 1, 2025.

If the manufacturer of a generic Part D rebatable drug that is currently in shortage believes such generic drug is likely to continue to be in shortage in the next applicable period, the manufacturer may submit a likely to be in shortage rebate reduction request to CMS. If the request meets the criteria described in proposed in § 428.303(c)(4), CMS would reduce the total rebate amount owed by a manufacturer by 75 percent for the manufacturer's generic Part D rebatable drug. Consistent with the evaluation criteria proposed in § 428.303(c)(4), CMS does not intend to consider a generic Part D rebatable drug as likely to be in shortage based solely upon the drug being currently in shortage. However, if the manufacturer believes there are circumstances that may exacerbate the current shortage such that without the reduction the generic Part D rebatable drug is likely to be in shortage in the next applicable period, the manufacturer may reflect such circumstances in its rebate reduction request. For example, if a generic Part D rebatable drug is currently in shortage during the applicable period beginning October 1, 2023 because the manufacturer had trouble meeting demand for the drug and then in August 2024, the manufacturer faces difficulties securing the API for such drug and believes this may worsen the shortage situation and result in the generic Part D rebatable drug being currently in shortage in the next applicable period, the manufacturer may submit a likely to be in shortage rebate reduction request to CMS providing information on the severity of the likely shortage. CMS welcomes comments on this approach. In § 428.303(c)(6), CMS proposes to review rebate reduction requests and rebate reduction extension requests within 60 calendar days of receipt of all documentation, if feasible, beginning with the applicable period that begins on October 1, 2024. If a manufacturer's rebate reduction request does not meet the criteria in proposed § 428.303(c)(4) or if the rebate reduction request is incomplete or untimely based on the requirements in proposed § 428.303(c), CMS would deny the request. CMS also proposes that if a manufacturer's rebate reduction extension request does not meet the criteria in proposed § 428.303(c)(5), is incomplete or untimely based on the requirements in proposed § 428.303(c)(5), or if a reduction under proposed § 428.303(b)(1) was not provided for such generic Part D rebatable drug, CMS would deny the rebate reduction extension request. As proposed in § 428.303(c)(6)(iii), CMS' decisions to deny a request would be final and not be subject to an appeals process.

As proposed at § 428.303(c)(7), CMS would keep confidential, to the extent allowable under law, any requests for a rebate reduction, including supporting documentation. CMS proposes that information provided as part of a likely

to be in shortage rebate reduction request that the submitter indicates is a trade secret or confidential commercial or financial information would be protected from disclosure if CMS determines the information meets the requirements set forth under Exemptions 3 or 4 of FOIA. In addition to the protections under the FOIA for trade secrets and commercial or financial information obtained from a person that is privileged or confidential, the Trade Secrets Act at 18 U.S.C. 1905 requires executive branch employees to protect such information. CMS would protect confidential and proprietary information as required by applicable law.

e. Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments (§§ 428.400 Through 428.405)

Section 1860D–14B(a)(1) of the Act requires the Secretary to report to each manufacturer of a Part D rebatable drug the following information not later than 9 months after the end of the applicable period: (1) the amount, if any, of the excess AnMP increase described in section 1860D–14B(b)(1)(A)(ii) for each Part D rebatable drug and (2) the rebate amount for each Part D rebatable drug. In compliance with section 1860D–14B(a)(2) of the Act, the manufacturer of a Part D rebatable drug must provide a rebate for each Part D rebatable drug no later than 30 calendar days after the receipt of the information provided by the Secretary in section 1860D–14B(a)(1) of the Act.

To fulfill this statutory requirement, CMS proposes to send a Preliminary Rebate Report followed by a Rebate Report, as described in proposed § 428.401(b) and (c), to all manufacturers of a Part D rebatable drug, even if the amount due is $0; all rebate amounts would be subject to reconciliation as proposed in § 428.401(d). As proposed in § 428.401(b), CMS does not intend to send notice to manufacturers for drugs that are not considered rebatable pursuant to proposed § 428.20.

Additionally, section 1860D–14B(b)(6) states that CMS shall provide a method and process under which CMS adjusts the calculation of the rebate amount for a Part D rebatable drug for an applicable period if CMS determines such an adjustment is necessary based on revisions to the number of units of a rebatable covered Part D drug dispensed submitted by a PDP sponsor of a prescription drug plan or an MA organization offering an MA–PD plan. The statute also specifies that CMS must reconcile any underpayments in the rebate amount paid by the manufacturer of the applicable Part D rebatable drug due to such an adjustment and underpayments must be paid no later than 30 days from the date of receipt of information from CMS about the adjustment. To fulfill this statutory obligation and to address the completeness and accuracy of the rebate amount, CMS proposes to conduct regular reconciliations at two points in time to determine whether the rebate amount must be adjusted due to updated claims and payment data used in the calculation of such rebate amount (specified in proposed § 428.401(d)(1)): (1) 12 months after the issuance of the Rebate Report, and (2) 36 months after the issuance of the Rebate Report. The reporting process for each reconciliation will be the same process described for the original Rebate Report, with payment due for any outstanding rebate amount 30 days after receipt of a report with a reconciled rebate amount. In addition to regular reconciliations, CMS proposes a process to conduct reconciliations of the rebate amount as needed to correct agency error and when CMS determines that the information used by CMS to calculate a rebate amount was inaccurate due to manufacturer misreporting.

i. Definitions

In proposed § 428.400, CMS proposes to define the following term applicable to subpart E (§§ 428.400 through 428.405):

- ''Date of receipt''.

For example, if CMS issues a Rebate Report through the method and process described in proposed § 428.404 on June 30, 2026, then July 1, 2026, will be the date of receipt and day one of the 30-calendar-day payment period.

ii. Reports of Rebate Amounts and Suggestion of Error

Consistent with the process specified in section 50 of the revised Medicare Part D Drug Inflation Rebate Guidance involving preliminary and final reports, CMS proposes to codify a multi-step process to provide a manufacturer as defined in proposed § 428.20 with the rebate information specified under section 1860D–14B(a) of the Act. CMS considered the following factors in determining a method and process for providing the rebate information: meeting statutorily provided deadlines in section 1860D–14B(a) of the Act (for example, dates by which to provide the rebate amount owed to the manufacturer); the operational time to acquire the relevant information specified in proposed part 428; the operational time to calculate the rebate amount specified in subparts B and C of proposed part 428; clarity of the information provided as well as potential burden on manufacturers; and how to ensure the accuracy of the rebate amount.

CMS proposes at proposed § 428.401 the use of an initial Preliminary Rebate Report and a subsequent Rebate Report, with an opportunity for manufacturers to identify certain mathematical errors (see proposed § 428.403 and discussed in further detail later in this section) and two regular reconciliations of the rebate amount to account for updates to claims and payment data at 12 months and 36 months after the Rebate Report is issued as described in proposed § 428.401(d).

CMS proposes in proposed § 428.401 that the multi-step reporting process for providing rebate information to a manufacturer would include: (1) an initial report, which CMS proposes to entitle the ''Preliminary Rebate Report'' in proposed § 428.401(b) and (2) a second report, which CMS proposes to entitle the ''Rebate Report'' in proposed § 428.401(c). The Rebate Report would serve as the invoice for the rebate amount due, if any, for each product determined to be a Part D rebatable drug for the applicable period, as specified in proposed § 428.101. Manufacturers of Part D rebatable drugs would receive a Rebate Report for their rebatable drugs even if the amount due is $0. CMS proposes at proposed § 428.401(d)(1) two regular reconciliations of the rebate amount to occur 12 months and 36 months after issuance of the subsequent Rebate Report specified in proposed § 428.401(c), which would include any restatements that have occurred in the drug pricing data and claims billing data reported to CMS and used in the rebate calculation specified in subpart C of this part.

As the first step in the reporting process, as proposed in proposed § 428.401(b) and consistent with section 50 of the revised Medicare Part D Drug Inflation Rebate Guidance, CMS would provide each manufacturer of a Part D rebatable drug with the preliminary rebate amount through a Preliminary Rebate Report at least 1 month prior to the issuance of the Rebate Report specified in proposed § 428.401(c) for an applicable period (that is, approximately 8 months after the end of the applicable period unless otherwise specified). To facilitate manufacturer understanding of the Preliminary Rebate Report, CMS is proposing in proposed § 428.401(b)(1) that the Preliminary Rebate Report would include the following information: the NDC(s) for the Part D rebatable drug as defined under proposed § 428.20; the total

number of units for the Part D rebatable drug for the applicable period as determined under proposed § 428.203 (which would remove units when a generic drug is no longer a Part D rebatable drug in proposed § 428.203(b)(1) and would exclude units acquired through the 340B Program in proposed § 428.203(b)(2)); the benchmark period manufacturer price as described in proposed § 428.202(d); the AnMP for the Part D rebatable drug for the applicable period as determined in proposed § 428.202(b); the applicable benchmark period and applicable period CPI-Us as identified in proposed §§ 428.202(e) and 428.20; the inflation-adjusted payment amount as specified in proposed § 428.202(f); the amount, if any, of the excess AnMP for the Part D rebatable drug for the applicable period as determined under proposed § 428.202(a); any applied reductions as described in proposed §§ 428.301, 428.302, and 428.303; and the rebate amount due as specified in proposed § 428.201(a). As proposed under proposed § 428.204, in cases where a Part D rebatable drug is a line extension, CMS proposes to include the same elements described above in the Preliminary Rebate Report as well as: the NDC for the initial drug; the inflation rebate amount ratio for the initial drug; and the alternative rebate amount (see proposed § 428.401(b)(2)).

When determining what information should be included on rebate reports, CMS considered the statutory requirements outlined in section 1860D–14B(a)(1) of the Act to determine which data elements are necessary to review the Preliminary Rebate Report for error (described later in this section) and to protect proprietary information. In response to comments on the initial Medicare Part D Drug Inflation Rebate Guidance, CMS has proposed to disclose data elements as suggested by interested parties that are not enumerated in the statute, such as NDCs for Part D rebatable drugs and the applicable period CPI–U. CMS acknowledges requests from interested parties to provide additional data elements including claims-level data such as days' supply, fill number, and prescription ID number on rebate reports that are not included in this proposal. CMS considered these requests in development of this proposed rule but does not believe it necessary to provide this further information to fulfill its statutory obligation and believes that the potential benefit to manufacturers of additional data are outweighed by the administrative burdens additional reporting would impose to the agency. The elements listed above provide sufficient information for a manufacturer to review the Preliminary Rebate Report for mathematical error, while protecting proprietary information, and these elements are operationally feasible for CMS to provide. In proposed § 428.203(b)(2)(i)(A) and (B), CMS would exclude 340B units beginning with January 1, 2026, which is the second calendar quarter in the applicable period starting October 1, 2025, and beyond (as discussed in further detail in section III.I.3.f of this proposed rule). This exclusion applies to all Preliminary Rebate Reports, Rebate Reports, and reconciliations of a rebate amount that include the applicable period starting with October 1, 2025, and beyond with claims for service dates on or after January 1, 2026. As such, 340B units would not be excluded from the Rebate Reports for the applicable periods beginning October 1, 2022, October 1, 2023, and October 1, 2024, as discussed in proposed § 428.402.

By structuring the Rebate Report process to include a Preliminary Rebate Report before the Rebate Report, CMS is able to provide manufacturers with an opportunity to review the Preliminary Rebate Report before the rebate amount is invoiced via the Rebate Report. While CMS is not required to provide a preliminary report, CMS seeks to facilitate manufacturer understanding of the Rebate Report and believes it would be beneficial for manufacturers to review the report for mathematical errors that could be corrected before invoicing via the Rebate Report. Further, a Preliminary Rebate Report would provide additional notice to manufacturers regarding whether they may owe a rebate amount.

In proposed § 428.403, CMS proposes a process in which a manufacturer may suggest to CMS that the manufacturer believes the Preliminary Rebate Report includes a mathematical error within 10 calendar days after the date of receipt of the Preliminary Rebate Report. For example, if the Preliminary Rebate Report is provided on May 31, 2026, then June 1, 2026, would be the date of receipt and, therefore, day one of the 10-calendar-day period to submit a Suggestion of Error; the Suggestion of Error would be due at 11:59 p.m. PT on June 10, 2026, in this example. CMS reviewed comments on the 10-day Suggestion of Error period submitted in response to the initial Medicare Part D Drug Inflation Rebate Guidance, many of which suggested that manufacturers receive at least 30 days to review the Preliminary Rebate Report. CMS considered a 10-day, 15-day, and 30-day Suggestion of Error period and believes a 10-calendar-day period as (see proposed § 428.403(c)) is sufficient after considering the volume of the data to be provided to manufacturers, the narrow scope of items that may be identified as a Suggestion of Error, and the operational time necessary for CMS to provide a Rebate Report within 9 months of the end of the applicable period as required under section 1860D–14B(a)(1) of the Act. However, CMS proposes in § 428.402(c)(1)(i) to expand the Suggestion of Error period to 30 calendar days for the Preliminary Rebate Reports for the first two applicable periods (beginning October 1, 2022, and October 1, 2023). This extended Suggestion of Error period will provide additional time and flexibility during the first invoicing cycle of the Medicare Part D Drug Inflation Rebate Program.

Section 1860D–14B(f) of the Act precludes administrative or judicial review on the determination of units, whether a drug is a Part D rebatable drug, and the calculation of the rebate amount (see proposed § 428.403(a)(1)). Therefore, the Suggestion of Error process will be limited to mathematical steps involved in determining the rebate amount and the elements precluded from administrative or judicial review will not be considered in-scope for the Suggestion of Error process. Additionally, CMS is not providing an administrative dispute resolution process. CMS intends to consider all in-scope submissions under the Suggestion of Error process (for example, suggestions regarding a mathematical error) as described in proposed § 428.403(a). CMS does not intend to review suggestions of error that are out-of-scope or submissions for a rebatable drug with an amount due of $0.

As the second step in the reporting process, CMS proposes in proposed § 428.401(c) to provide the rebate amount to the manufacturer through the Rebate Report no later than 9 months after the end of the applicable period. As proposed in proposed§ 428.401(c)(1), the Rebate Report would include the same data elements as the Preliminary Rebate Report (specified in proposed § 428.401(b)(1)) and include any recalculations based on CMS acceptance of a manufacturer's Suggestion of Error from proposed § 428.403, or any CMS-determined recalculations from proposed § 428.401(d)(2), if applicable. Manufacturers must pay the rebate amount within 30 calendar days from the date of receipt of the Rebate Report (see proposed § 428.405(a)). For

example, if the Rebate Report is provided on June 30, 2026, then July 1, 2026, would be the date of receipt and therefore day one of the 30-calendar-day payment period; payment would be due no later than 11:59 p.m. PT on July 30, 2026.

In proposed §§ 428.404 and 428.405, CMS proposes that it will establish a standard method and process to issue Rebate Reports and accept manufacturer rebate payments. This method and process may include an online portal administered by a CMS contractor which would provide manufacturers with access to their Rebate Report, the ability to submit a Suggestions of Error, and pay a rebate amount due. CMS intends to provide technical instructions separate from this rulemaking to manufacturers of Part D rebatable drugs regarding how to access Rebate Reports and how to receive notifications alerting the manufacturer when information is available. CMS also intends to issue reminder notices to manufacturers regarding the due date of rebate payments. In proposed § 428.404(a), CMS notes that the manufacturer that may access Rebate Reports and make applicable rebate amount payments is the manufacturer responsible for paying a rebate, and as stated above, CMS proposes to identify the manufacturer that is responsible for paying a rebate using the same approach used for reporting AMP data.

iii. Reconciliation of a Rebate Amount

As discussed in section 50 of the revised Medicare Part D Drug Inflation Rebate Guidance, CMS considered options consistent with section 1860D–14B(b)(6) of the Act to establish a method and process to determine adjustment to the rebate amount in the case of a Part D plan sponsor submitting revisions to the number of units of a part D rebatable drug. As is also discussed in section 50, CMS considered options for establishing a standardized method and process at regular intervals to determinate any appropriate adjustments to the rebate amount for a Part D rebatable drug for an applicable period to account for additional revised information as well as options for recalculation based on CMS identifying an agency error or determining manufacturer data was misreported. CMS is proposing policies for reconciliation, including with respect to enforcement of payment of any reconciled rebate amount, consistent with both the statutory framework for the Part D Drug Inflation Rebate Program and the express authority in sections 1102 and 1871 of the Act to adopt regulations for the proper administration of the Medicare Prescription Drug Inflation Rebate Program.

As proposed at § 428.401(d), CMS believes that it is necessary and appropriate for CMS to recalculate the rebate amount for an applicable period at regular intervals to include updated information about key data elements included in the calculation of the rebate amount, not limited to those data described in section 1860D–14B(b)(6) of the Act. These data elements as set forth in proposed § 428.401(d)(1)(i) include: total units; the benchmark period manufacturer price; the payment amount in the payment amount benchmark period; the AnMP; and updated data on line extension calculations. Updating these calculation inputs at regular reconciliation intervals will result in a rebate amount that more fully reflects the majority of shifts in the underlying data following additional time for claims run-out, which refers to the maturation of PDE records in CMS' internal PDE database. Because the information extracted represents the PDE records' status in CMS' internal PDE database at that moment in time, additional run-out may yield different information, either because more PDE records with dispensing dates during the applicable period were finalized and added to the database or because the status of the existing PDE records changed. CMS refers to ''X months of run-out'' as the period between the end of the applicable period and the date when CMS accesses information about the PDE records; for example, ''3 months of run-out'' means that PDE records are accessed for PDE records with dispensing dates during an applicable period 3 months after the end of such applicable period. Conducting a reconciliation of the rebate amount with additional claims run-out will improve the accuracy of the rebate amount. Additionally, reconciliation of payment amounts is consistent with the approach to the calculation of the payment amounts in other CMS programs (such as the Coverage Gap Discount Program) that provide for a reconciliation period.

CMS notes that the reconciliation of a rebate amount, whether during a reconciliation proposed at § 428.401(d)(1) or a discretionary reconciliation proposed at § 428.401(d)(2) discussed further below, will not create a separately payable and distinct rebate amount. Rather, reconciliation updates the prior rebate amount owed to CMS, if any, by a manufacturer of a Part D rebatable drug so that the rebate amount ultimately reflects a more precise calculation of the rebate amount, as required by section 1860D–14B(a)(1) of the Act, to account for shifts in the underlying data following additional time for claims run-out after the Rebate Report is issued as well as subsequently identified data integrity issues. Moreover, because the reconciled rebate amount is an adjustment of the prior rebate amount, CMS proposes at § 428.405(a)(1) for a report of a reconciled rebate amount to also identify the difference between the rebate amount due as specified on the Rebate Report set forth in proposed § 428.401(c) and the reconciled rebate amount. CMS would only collect the net rebate amount due, if any, upon reconciliation, so as to prevent any duplicate payments. CMS also proposes to refund any overpayment made by a manufacturer, as determined during reconciliation, as discussed in proposed § 428.405(b).

Additionally, as CMS suggested in section 50 of the revised Medicare Part D Drug Inflation Rebate Guidance, CMS considered multiple options for establishing a standardized method and process to occur at regular intervals to determine an appropriate adjustment to the rebate amount for a Part D rebatable drug for an applicable period to account for revised information prior to adopting the proposal described here with two proposed regular reconciliations of the Part D inflation rebate amount. CMS considerations included the length of time needed to capture relevant changes to data inputs for recalculation, whether the timing should align with the reconciliation of Part B rebate amounts, and manufacturer burden. Specifically, CMS considered the average time span needed to ensure submission of the majority of Part D plan unit revisions specified in section 1860D–14B(b)(6) of the Act, and the average time span needed for the submission of the majority of manufacturer restatements of AMP data. CMS also considered the 36-month period provided by MDRP for AMP restatements as described in § 447.510(d)(3) of this title and whether consistency among program reconciliation timelines is beneficial. CMS believes a longer period of claims run-out (at least 12 and 36 months of run-out time in the proposed approach) would ensure that CMS more fully accounts for capturing of revised units. Further, the first reconciliation would be performed to include at least 13 months of claims run-out for the applicable period and would be issued 12 months after the Rebate Report for the same applicable period. The second reconciliation would include 37 months of claims run-out for the applicable period and would be issued 36 months

after the Rebate Report for the same applicable period. The first reconciliation, issued 12 months after the Rebate Report, would provide sufficient time to capture the majority of updates to the data specified in proposed § 428.401(b)(1). The second reconciliation, to be issued 36 months after the Rebate Report, is sufficient to capture the remainder of the run-out for MDRP AMP restatements (that do not require CMS review in § 447.510) while also closing out the calculation of the rebate amount for a Part D rebatable drug for an applicable period within a reasonable time period after the Rebate Report is issued (except for the circumstances in proposed § 428.401(d)(2) regarding CMS' identification of mathematical errors or manufacturer misreporting).

Further, in considering whether consistency across CMS programs is critical, CMS believes that consideration for the completeness of data, as discussed above, should be prioritized over consistency across program timelines. That is, when examining timelines from other CMS programs that collect data contributing to calculation of the rebate amount, CMS prioritized that, to the extent feasible, completeness and accuracy of the data elements contributing to the calculation of the rebate amount rather than prioritizing consistency among the data collection and reconciliation timelines themselves. Finally, CMS believes that solely updating total units without updating other elements of the rebate calculation would lead to an inaccurate rebate amount, and therefore proposes to update additional calculation inputs as described in proposed § 428.401(d)(1)(i)(A) through (F). CMS believes that a restatement of each data element included in proposed § 428.401(d)(1) to reconcile the rebate amount provided in the Rebate Report in proposed § 428.401(c) is appropriate to capture an updated rebate amount and is in line with other CMS programs that provide for a reconciliation period. While some data points may not change, CMS would review the data to determine if there are any updates in the data and use the updated data in the reconciliation to provide a reconciled rebate amount to the manufacturer.

Based on these considerations, similar to the multi-step process for the Rebate Report proposed in § 428.401(b) and (c), CMS proposes a multi-step process to provide each manufacturer of a Part D rebatable drug with a reconciled rebate amount on a regular basis. At both the 12 month reconciliation point and the 36 month reconciliation point, CMS proposes a reconciliation process that will include: (1) a preliminary reconciliation of the rebate amount, which CMS would provide to manufacturers of Part D rebatable drugs as proposed in § 428.401(d)(1)(i) and (d)(2) a reconciled rebate amount, which CMS would provide to manufacturers of a Part D rebatable drug as proposed in § 428.401(d)(1)(ii). CMS also proposes to apply the Suggestion of Error process specified in proposed § 428.403 to each preliminary reconciliation.

In detail, first, as specified in proposed § 428.401(d) and similar to the Preliminary Rebate Report process proposed in § 428.401(b), for each reconciliation CMS proposes to provide the manufacturer with information about the preliminary reconciliation of the rebate amount at least 1 month prior to the issuance of the reconciled rebate amount (see proposed § 428.401(d)) to each manufacturer of a Part D rebatable drug for an applicable period. CMS proposes in § 428.401(d)(1) that the preliminary reconciliation would include, at a minimum, the same information outlined for the Rebate Report and the following updated information, if applicable: updated total number of rebatable units, including updates submitted by a PDP or MA–PD plan sponsor and updates to 340B units (as applicable to the dates of service and applicable periods specified in proposed § 428.203(b)(2)(i)(A) and (B)), or units otherwise excluded as specified in proposed § 428.203(b); the benchmark period manufacturer price if any inputs are restated within the reconciliation run-out period as specified in proposed § 428.202(d); the AnMP if any inputs are restated within the reconciliation run-out period as specified in proposed § 428.202(b); the excess amount by which the AnMP exceeds the inflation-adjusted payment amount for the applicable period as specified in proposed § 428.202(a), using the most recent AMP (if any inputs are restated within the reconciliation run-out period); updated data on line extension calculations, including the initial drug identified in accordance with § 447.509(a)(4)(iii)(B), the inflation rebate amount ratio, and the alternative total rebate amount as set forth in proposed § 428.204 if any inputs are restated within the reconciliation run-out period; the reconciled rebate amount as set forth in proposed § 428.201(a); and the difference between the total rebate amount due as specified on the Rebate Report set forth in proposed § 428.201(a) and the reconciled rebate amount as set forth in proposed § 428.201(a). CMS also notes that changes to status of 5i drugs (defined at § 447.507) are captured through AMP restatements.

In proposed § 428.403(a), similar to the Suggestion of Error process proposed for the Preliminary Rebate Report in proposed § 428.401(b), within 10 calendar days after date of receipt of the information about the preliminary reconciliation of the rebate amount, CMS proposes that a manufacturer may suggest to CMS that the manufacturer believes the preliminary reconciliation of the rebate amount contains a mathematical error. CMS believes a 10-calendar-day period is sufficient due to the same considerations of data volume, the narrow set of in-scope items for review, and the operational time necessary for CMS to publish the reconciled rebate amount. The preclusions in section 1860D–14B(f) of the Act on administrative and judicial review apply to the reconciliation process.

Second, in detail, CMS proposes in § 428.401(d)(1)(ii) to provide a reconciled rebate amount to the manufacturer within 12 months and 36 months after the Rebate Report was issued for each applicable period. As proposed in § 428.401(d)(1)(ii), the information in the report for a reconciled rebate amount would include the same data elements as provided in the information provided to the manufacturer of a Part D rebatable drug regarding the preliminary reconciliation of a rebate amount (specified in proposed § 428.401(d)(1)(i)) and would include any recalculations based on CMS acceptance of a manufacturer's Suggestion of Error from proposed § 428.403. A reconciliation of the rebate amount may result in an increase, decrease, or no change to the rebate amount, compared to the Rebate Report for an applicable period or a previous reconciliation in the case of reconciliation conducted 36 months after issuance of the Rebate Report (see proposed § 428.401(d)(3)).

Additionally, as suggested in section 50 the revised Medicare Part D Drug Inflation Rebate Guidance, CMS considered options for establishing circumstances where a recalculation of the rebate amount may be appropriate for an applicable period after issuing the Rebate Report and/or a reconciled rebate amount based on CMS identifying an error or CMS determining that the information used by CMS to calculate a rebate amount was inaccurate due to false reporting or similar fault by the manufacturer. CMS also considered potential time limits for revisions and whether certain circumstances, such as instances of false reporting, should be exempt from such time limits.

Based on these considerations, CMS believes that, to capture an accurate rebate amount and consistent with reconciliations of pricing data submitted to CMS that provide for revisions when necessary due to errors, including mathematical errors, and manufacturer misreporting, certain circumstances merit reconciliation of the rebate amount separate from the 12-month and 36-month reconciliations proposed at § 428.401(d)(1). Specifically, CMS proposes in § 428.401(d)(2) that CMS may reconcile a rebate amount of an issued Rebate Report when CMS identifies either: (1) an agency error such as a mathematical error or an error in the information specified in a Rebate Report as described in proposed § 428.401(c) or report of a reconciled rebate amount as described in proposed § 428.401(d), including reporting system or coding errors; or (2) CMS determines that information used to calculate the rebate amount was inaccurate due to manufacturer misreporting. Examples of agency errors could include CMS incorrectly calculating the billing units per Part D rebatable drug or the mechanism that provides a Rebate Report to the manufacturer or the Rebate Report incorrectly displays a rebate amount. Examples of manufacturer misreporting could include instances in which the manufacturer has made a correction to previously submitted data as well as instances in which the reporting individual or entity reporting data or information to CMS on behalf of the manufacturer knows or should know is inaccurate or misleading (for example, inaccurate manufacturer pricing or product data under section 1927(b)(3) of the Act). This does not include standard restatements to AMP or other data outside of the standard process of issuing the reconciled rebate amount. In addition to manufacturer-initiated corrections, CMS may become aware of manufacturer misreporting based on fact finding and conclusions of enforcement authorities, for example, the HHS Office of Inspector General, the CMS Center for Program Integrity, or the Department of Justice. In a situation where an error or manufacturer misreporting is identified prior to the 12- or 36-month reconciliation of the rebate amount proposed in § 428.401(d)(1), CMS may choose to include a correction based on the circumstances proposed in § 428.401(d)(2) concurrently with the 12- or 36-month reconciliation. When CMS reconciles data due to an instance of agency error or manufacturer misreporting, CMS proposes that the agency would limit the scope of the reconciliation to the specific information that is the basis for the reconciliation and not update or otherwise revise any other data elements in the Rebate Report (specified in proposed § 428.401(c)) or the report of the reconciled rebate amount (specified in proposed § 428.401(d)) unless the correction directly impacts additional data fields. For example, corrections to an AMP file may not change the AnMP for the applicable period.

In addition, because reconciling a rebate amount imposes substantial administrative burden on CMS to reprocess the rebate amount, retest the reporting system, and reissue a Rebate Report, CMS proposes in § 428.401(d)(2) that it may exercise discretion not to initiate recalculation of the rebate amount in these situations which are outside of the regular reconciliation process proposed in § 428.401(d)(1).

CMS proposes that for a recalculation due to an agency error, the error must be identified within 5 years of the date of receipt of the Rebate Report for the applicable period (see proposed § 428.401(d)(2)(i)). Identification means that CMS has knowledge of the error; CMS does not need to have completed its revision of the impacted data or determined if the revision impacts the rebate amount within the 5-year period. CMS would timely complete these steps and determine, when reconciliation does impact the rebate amount, whether the reconciliation must be included in a discretionary revision or within an upcoming reconciled rebate amount for the applicable period. CMS proposes 5 years for Part D (as opposed to the 3-year limit proposed for Part B) to account for the additional time of the second reconciliation for Part D rebatable drugs to be conducted at 36-months proposed in § 428.401(d)(1). CMS believes that a 5-year period dating from the issuance of the Rebate Report allows for sufficient time to include AMP restatements in the MDRP while also placing a reasonable time limit on potential discretionary reconciliations, after which a manufacturer of a Part D rebatable drug would not receive additional Rebate Reports for the applicable period.

CMS proposes in § 428.401(d)(2)(ii) that for a circumstance in which a manufacturer misreports data, CMS is not bound by the 5-year time limit for revision of the rebate amount. For example, if a determination is made that a manufacturer misreported AMP data, which affected the calculation of the AnMP, then CMS may recalculate the rebate amount owed for a Part D rebatable drug. CMS requests comments on the proposals related to manufacturer misreporting.

CMS proposes in § 428.405(a)(1) that upon receipt of a reconciled rebate amount, manufacturers must pay that reconciled rebate amount within 30 calendar days from the date of receipt of the reconciled rebate amount. A 30-day payment deadline aligns with the payment period set forth in statute at section 1860D–14B(b)(6) of the Act. As specified in proposed § 428.404, CMS would use the same method and process for issuing Rebate Reports and submission of payments for reports with a reconciled rebate amount. CMS would provide notice to manufacturers for reports with a reconciled rebate amount. CMS proposes in § 428.405(b) that if a refund is owed to a manufacturer based on a reconciled rebate amount, CMS would initiate the process to issue such refund within 60 days from the date of receipt of the reconciled rebate amount (proposed in § 428.401(d)). CMS will issue additional information on this method and process through additional program communications.

iv. Rebate Reports for the Applicable Periods Beginning October 1, 2022, and October 1, 2023

Section 1860D–14B(a)(3) of the Act provides the CMS with the option to delay sending the information required by section 1860D–14B(a)(1) for the applicable periods beginning October 1, 2022, and October 1, 2023, until not later than December 31, 2025. In § 428.402, consistent with section 50.2 of the revised Medicare Part D Drug Inflation Rebate Guidance, CMS proposes to issue a Preliminary Rebate Report for each applicable period followed by issuance of the Rebate Report for each applicable period no later than December 31, 2025. For these reports, CMS proposes in § 428.402 to provide an extended 30 calendar day Suggestion of Error period for these Preliminary Rebate Reports.

Because this approach provides for 13 months of claims run-out for the Rebate Report for the applicable period beginning October 1, 2022, CMS intends to conduct a single reconciliation 21 months after issuance of the Rebate Report for this applicable period (see proposed § 428.402(c)(1)(ii)). As specified in § 428.402(c)(2)(ii), for the applicable period beginning October 1, 2023, the rebate amount would be reconciled twice, in alignment with the reconciliation process discussed previously. The first reconciliation would occur 9 months after issuance of the Rebate Report to include 13 months of claims run-out and payment data; the second reconciliation would occur 24

months after the first reconciliation and would include 37 months of claims run-out and payment data. This approach aligns claims and payment data run-out with the run-out used during a regular invoicing cycle. The Suggestion of Error period would be 10 calendar days for the reconciliations of the rebate amount for the applicable periods beginning October 1, 2022, and the applicable period beginning October 1, 2023.

This approach also minimizes the number of reports issued to manufacturers as a result of the delay in reporting and simplifies payment procedures, thereby minimizing manufacturer burden. Starting with the applicable period beginning October 1, 2024, reporting would begin a standard cadence and follow the procedures otherwise proposed in subpart E of this part 428.

CMS proposes that manufacturers that do not pay the Medicare Part D drug inflation rebate amount owed for a Part D rebatable drug within 30 calendar days of receiving a Rebate Report, including reports containing a reconciled rebate amount, may be subject to a civil money penalty of 125 percent of the rebate amount, as applicable, for such drug for the applicable periods. The civil money penalty is in addition to the rebate amount.

f. Enforcement of Manufacturer Payment of Rebate Amounts (§ 428.500)

Section 1860D–14B(e) of the Act gives CMS the authority to impose a civil money penalty equal to 125 percent of the rebate amount for each drug for each applicable period on a manufacturer that fails to pay the rebate amount, for each dosage form and strength for each rebatable drug. Subpart F would implement this section of the Act and establish the procedures for determining and collecting a civil money penalty.

In accordance with sections 1860D–14B(a)(2) and 1860D–14B(b) of the Act and proposed § 428.405(a), manufacturers must provide to CMS a rebate amount owed within 30 calendar days of receipt of the rebate amount due. As described in proposed § 428.500(a), CMS is proposing it may impose a civil money penalty when a manufacturer fails to pay the rebate amount in full by the payment deadlines in proposed § 428.405(a). This means a manufacturer may be subject to a civil money penalty if the manufacturer fails to pay the full rebate amount as invoiced in the Rebate Report or any reconciled rebate amount that is greater than the amount invoiced in the Rebate Report. More specifically, a manufacturer could be subject to a civil money penalty when a manufacturer fails to pay a rebate amount due by any payment deadline proposed in § 428.405(a)(1), for: (1) a Rebate Report specified in proposed § 428.401(c); (2) a reconciled rebate amount greater than the amount reflected in the Rebate Report specified in proposed § 428.401(d); or (3) a Rebate Report and a reconciled rebate amount greater than the amount reflected in the Rebate Report, if applicable, for the applicable periods beginning October 1, 2022, and October 1, 2023 specified in proposed § 428.402. As discussed earlier in section III.I.3.e, CMS notes that the reconciled or corrected rebate amount is not a separately payable and distinct rebate amount. Rather, the reconciled rebate amount is an update to the rebate amount owed to CMS by a manufacturer of a Part D rebatable drug.

Civil money penalties are a point-in-time penalty tied to the rebate amount due at the applicable payment deadline, which occurs 30 days after the date of receipt of a Rebate Report. In proposed § 428.500(b), CMS proposes to establish the methodology for determining the amount of the civil money penalty as equal to 125 percent of the rebate amount for such drug for such applicable period, and that this penalty would be due in addition to the rebate amount due. That is, a manufacturer would be responsible for paying the full rebate amount due in addition to any civil money penalty imposed because of late payment. CMS is proposing this approach to civil money penalties based on section 1860D–14B(a)(2) of the Act, which establishes a requirement by the manufacturer to provide CMS with a rebate not later than 30 days after receipt from CMS of the report on the amount of the excess annual manufacturer price increase. CMS believes that the ability to assess civil money penalties is necessary in all circumstances where a payment is due for a rebate amount to CMS to ensure compliance with the rebate program's requirements. The civil money penalty would be calculated based on the outstanding rebate amount due at the payment deadline, which is defined in proposed § 428.405(a)(1) as 30 calendar days after the date of receipt of a Rebate Report containing any rebate amount due; once a civil money penalty is assessed due to a late payment, the penalty would remain in effect even if the manufacturer pays the outstanding rebate amount as the penalty is initiated due to a missed payment deadline. Because the payment deadline is clearly defined in section 1860D–14B(a)(2) of the Act, any late payments of a rebate amount due, including late payment of any reconciled rebate amounts greater than the amount reflected in the Rebate Report, would be considered a violation potentially subject to a civil money penalty. Any civil money penalty would be assessed before the next 12- or 36-month reconciliation.

CMS is proposing in § 428.500(b) that civil money penalties may be calculated at several points in time associated with missing a payment deadline for the rebate amount due reflected in the Rebate Report or missing a payment deadline associated with any rebate amount determined after a reconciliation to be greater than the amount invoiced in the Rebate Report. As these separate events can result in distinct assessments of civil money penalties, this means that CMS would not modify a civil money penalty from a prior missed payment deadline based on changes to the rebate amount due following reconciliation, including scenarios where the rebate amount is reduced following reconciliation. However, in the event that the rebate amount due on a Rebate Report was not paid and a civil money penalty was issued for violation of the payment deadline, CMS would not issue a second civil money penalty on a reconciled rebate amount if reconciliation decreased the rebate amount stated on the Rebate Report. CMS believes that enforcing this requirement after each payment deadline, regardless of what rebate amount a manufacturer may or may not owe at a future payment deadline, is necessary to maintain the integrity of the program and consistency of the implementation of the program. Further, CMS is proposing this approach to ensure an enforcement approach that is operationally feasible and applied consistently in all cases.

For examples of how this approach to civil money penalties will work in practice, see section III.I.2.g of this preamble. CMS is proposing that civil money penalties will function in the same way for both the Part B and Part D rebate programs. Given that the Part D rebate program has two proposed regular reconciliations, payment would be due no later than 30 days after issuance of a report of a reconciled rebate amount for each reconciliation under Part D.

Further, note that payment of any civil money penalty does not obviate the requirement for the manufacturer to pay any outstanding rebate amount due, including any rebate amount due following a reconciliation. Therefore, paying a civil money penalty does not satisfy the obligation to pay the underlying rebate amount on which the

civil money penalty is calculated. In addition, CMS is evaluating all available options to ensure manufacturers' timely compliance with their rebate payment obligations, including, without limitation, potential recovery approaches and enforcement actions. For example, CMS may refer manufacturers to the Department of Justice, Department of the Treasury, and/or the Department of Health and Human Services Office of Inspector General for further review and investigation.

In proposed § 428.500(c), CMS proposes that if CMS makes a determination to impose a civil money penalty on a manufacturer for violation of a payment deadline, CMS would send a written notice of the decision to impose a civil money penalty that includes a description of the basis for the determination, the basis for the penalty, the amount of the penalty, the date the penalty is due, the manufacturer's right to a hearing, and information about where to file the request for a hearing. To ensure a consistent approach to civil money penalties, CMS proposes applying existing appeal procedures for civil money penalties in 42 CFR 423, subpart T of this title to manufacturers appealing a civil money penalty imposed under the Medicare Part D Drug Inflation Rebate Program. CMS has utilized this appeals process for many years for civil money penalty determinations affecting MA organizations and Part D sponsors. CMS therefore proposes to use this well-established process for civil money penalty appeals from manufacturers that do not make inflation rebate payments by the payment deadline. CMS also proposes in § 428.500(e)(1) that the scope of appeals is limited to: (1) CMS determinations relating to whether the rebate payment was made by the payment deadline; and (2) the calculation of the penalty amount. Section 1860D–14B(f) of the Act precludes judicial review of specific data inputs or calculations related to the underlying Rebate Report and reconciliation; therefore, such data and calculations are not appealable through this process.

Section 1860D–14B(e) of the Act states that the provisions of section 1128A of the Act (except subsections (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a civil money penalty or procedure under section 1128A(a) of the Act. CMS proposes to codify this requirement in proposed § 428.500(f). In alignment with the procedure outlined in section 1128A of the Act, CMS proposes in § 428.500(d) that collection of the civil money penalty would follow expiration of the timeframe for requesting an appeal, which is 60 calendar days from the civil money penalty determination in cases where the manufacturer did not request an appeal. In cases where a manufacturer requests a hearing and the decision to impose the civil money penalty is upheld, CMS would initiate collection of the civil money penalty once the administrative decision is final. CMS is seeking comment on proposals related to the violations of payment deadlines and issuance of a civil money penalty.

CMS proposes in § 428.500(g) that in the event that a manufacturer declares bankruptcy, as described in title 11 of the United States Code, and as a result of the bankruptcy, fails to pay either the full rebate amount owed or the total sum of civil monetary penalties imposed, the government reserves the right to file a proof of claim with the bankruptcy court to recover the unpaid rebate amount and/or civil monetary penalties owed by the manufacturer.

g. Severability (§ 428.10)

Proposed § 428.10 provides that, were any provision of part 428 to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, such provisions would be severable from this part and the invalidity or unenforceability would not affect the remainder thereof or any other part of this subchapter or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances. While the provisions in part 428 are intended to present a comprehensive approach to implementing the Medicare Part D Drug Inflation Rebate Program, we intend that each of them is a distinct, severable provision, as proposed, and would not affect similar provisions in the Medicare Part B Drug Inflation Rebate Program. Through this rulemaking, the Part D drug inflation rebate proposals are intended to operate independently of each other, even if each serves the same general purpose or policy goal. For example, CMS intends that the policies CMS is proposing related to exclusion of units acquired through the 340B Program (proposed § 428.203(b)(2)) are distinct and severable from the proposals related to Determination of Part D Rebatable Drugs (proposed §§ 428.100 and 428.101). Even where one provision makes reference to a second provision, the preamble and the regulatory text clarify the intent of the agency that the two provisions would be severable if one provision were to be invalidated in whole or in part. For example, CMS would still be able to calculate a Part D drug inflation rebate even if the provision to identify the payment amount benchmark period for a Part D rebatable drug as the first calendar year in which such drug has at least 1 quarter of AMP in certain instances of missing AMP is deemed invalid (proposed § 428.202(c)(3) and (4)). CMS welcomes comments on this severability policy.

J. Request for Information: Building Upon the MIPS Value Pathways (MVPs) Framework To Improve Ambulatory Specialty Care

This request for information seeks input from the public regarding the design of a future ambulatory specialty model. Responses to this request for information may be used to inform potential future rulemaking and other policy development.

1. Background

Medicare beneficiaries' care is becoming more fragmented as they are increasingly seeing (1) more specialists and (2) specialists more often, while the number of visits with their primary care clinician remains relatively constant.[598] [599] A primary care team must now coordinate with more specialists than ever before [600] to achieve continuity in beneficiary care. Medicare beneficiaries with chronic conditions, in particular, are at high risk of excess emergency department visits due to fragmented care.[601]

In 2021, the Innovation Center announced a strategic refresh with a vision for a health care system that achieves equitable outcomes through high-quality, affordable, person centered-care. This includes a bold goal of having 100 percent of Medicare fee-for-service (FFS) beneficiaries and the vast majority of Medicaid beneficiaries in an accountable care relationship by

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[600] Center for Medicare and Medicaid Services. The CMS Innovation Center's Strategy to Support Person-centered, Value-based Specialty Care. November 7, 2022. *https://www.cms.gov/blog/cms-innovation-centers-strategy-support-person-centered-value-based-specialty-care.*

[601] Kern, LM, Seirup, JK. Fragmented Ambulatory Care and Subsequent Healthcare Utilization Among Medicare Beneficiaries. *The American Journal of Managed Care.* 2018;24(9):e278–e284.

2030.[602] To expand accountable care among specialists and to drive more person-centered care thereby improving the quality, clinical outcomes, and affordability of healthcare for beneficiaries, the Innovation Center has created a comprehensive specialty strategy to test models and innovations. This strategy includes: (1) enhancing transparency of specialist data and performance measures; (2) maintaining momentum established by episode payment models by extending the Bundled Payments for Care Improvement Advanced (BPCI Advanced) Model, launching a new model focusing on beneficiaries with cancer, and testing a new mandatory acute episode payment model; (3) creating financial incentives to improve coordination and collaboration between primary care and specialty care in both advanced primary care models and in condition-based models; and (4) creating additional financial incentives for specialists to affiliate with population-based models and move to value-based care.[603] [604]

As part of this strategy, we are considering a model design that would increase the engagement of specialists in value-based payment and encourage specialty care provider engagement with primary care providers and beneficiaries. Specifically, we are currently exploring developing a model for specialists in ambulatory settings that would leverage the Merit-based Incentive Payment System (MIPS) Value Pathways, or MVP, framework. As currently envisioned, participants under this model would not receive a MIPS payment adjustment. Instead, a model participant would receive a payment adjustment based on (1) a set of clinically relevant MVP measures that they are required to report and (2) comparing the participant's final score against a limited pool of clinicians (other model participants of their same specialty type and clinical profile, who are also required to report on those same clinically relevant MVP measures). Currently, under MIPS, performance and the subsequent payment adjustment are based on a range of measures voluntarily reported by clinicians, who receive a final score based on the submitted measures. A clinician's performance is assessed against a pool of all clinicians, regardless of specialty type or the services they provide. We expect that a more targeted approach where clinicians are evaluated (1) on a set of relevant performance measures they are required to report, and (2) among clinicians furnishing similar sets of services, would produce scores and subsequent payment adjustments that are more reflective of clinician performance. A more targeted approach to measurement would also offer more insight into how clinical decisions and processes, such as care coordination, affect patient outcomes. We believe this insight is necessary to support and incentivize accountable care, increasing beneficiary access to coordinated specialty care. Furthermore, equipped with more specialty-relevant performance information, we expect clinicians would be more likely to invest resources in pursuit of better outcomes, reducing the incidence of poor outcomes arising from care fragmentation, ultimately resulting in better care for patients.

MVPs are a reporting option under MIPS, which is one of the two primary ways a clinician may participate in the CMS Quality Payment Program. The Quality Payment Program, which commenced on January 1, 2017, was established pursuant to the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10, April 16, 2015). The Quality Payment Program rewards the delivery of high-quality patient care through two avenues: Advanced Alternative Payment Models (Advanced APMs) and MIPS for eligible clinicians or groups under the Physician Fee Schedule (81 FR 77008). CMS assesses performance on measures and activities in four performance categories to determine each MIPS eligible clinician's performance under MIPS: quality; cost; clinical practice improvement activities; and Promoting Interoperability (42 CFR 414.1330, 414.1350, 414.1355, and 414.1375).

In response to concerns made by interested parties that MIPS requirements are confusing, burdensome, and that it is difficult to choose measures from the several hundred MIPS and QCDR quality measures that are meaningful to their practices and have a direct benefit to patients, CMS developed the MVP reporting option to create a simplified MIPS clinician experience, improve value, reduce burden, and better inform patient choice in selecting clinicians (86 FR 65376). MVPs provide MIPS eligible clinicians with a more cohesive subset of measures and activities related to a specific specialty or condition (86 FR 65420 through 65427). MVPs are developed in coordination with interested parties through an established process in which clinician and patient perspectives are incorporated (85 FR 84850). The use of MVPs can create more meaningful performance data, reduce complexity of the MIPS program for clinicians, and lower the burden on participating clinicians. MIPS eligible clinicians have been able to report on MVPs beginning with the CY 2023 MIPS performance period.

Like MIPS eligible clinicians participating in traditional MIPS, those who report MVPs receive an adjustment to their Medicare Part B fee-for-service payments 2 years after the corresponding MIPS performance period based on a total score calculated from reported measures and activities across the 4 MIPS performance categories (see §§ 414.1365, 414.1405(e), and 414.1305). MVPs are designed to cover a range of medical conditions, care settings, and clinician types, including primary care providers and specialists. For the 2024 performance year, 16 MVPs are reportable, allowing for a range of specialties to report a streamlined set of measures most applicable to services they provide (88 FR 79978 through 80047). For information on the MVPs reportable for the 2024 performance period we refer readers to sections IV.A.4 and Appendix 3 of this proposed rule.

Currently, 5 MVPs have quality measures including patient-reported outcome measures and chronic condition episode-based cost measures, which could be the foundation for assessing the value of care provided to chronic care patients. We believe coordination between primary and specialty care is particularly critical to the ongoing management of chronic conditions with beneficiaries not only for reasons of quality and cost, but also in understanding beneficiary goals, expectations, and experiences with care.

CMS conducts ongoing MVP development through engagement with interested parties with the long-term goal of sunsetting traditional MIPS reporting and making MVP reporting mandatory for MIPS eligible clinicians in the future (86 FR 65395 and 87 FR 70040). For more information on the long-term goal of sunsetting traditional MIPS reporting, see section IV.A.3.b. of this proposed rule. For more information on CY 2025 MVP reporting option proposals under the MIPS

[602] Centers for Medicare and Medicaid Services. Driving Health System Transformation—A Strategy for the CMS Innovation Center's Second Decade. October 2021. *https://www.cms.gov/priorities/innovation/strategic-direction-whitepaper.*

[603] Center for Medicare and Medicaid Services. The CMS Innovation Center's Strategy to Support Person-centered, Value-based Specialty Care. November 7, 2022. *https://www.cms.gov/blog/cms-innovation-centers-strategy-support-person-centered-value-based-specialty-care.*

[604] ''The CMS Innovation Center's Strategy to Support Person-Centered, Value-Based Specialty Care: 2024 Update.'' Health Affairs Forefront, April 2, 2024. *DOI: 10.1377/forefront.20240328.868596.*

program, see section IV.A.4 of this proposed rule.

Using the MVP framework as the foundation for a model has many benefits. First, the MVP framework advances value-based care by narrowing the available measure set based upon clinician specialty, medical condition, or patient population, which allows for meaningful comparisons to be made across providers and relevant feedback to be available to participants on their performance, strengthening the foundation for accountability in specialty care. The MVPs provide a framework for reporting a cohesive set of measures and activities focused on the clinician's performance in rendering care for their specialty or clinical condition.

Second, the payment methodology for the model built on MVPs could address concerns interested parties have raised about the MIPS program. For instance, CMS has heard from interested parties that the current range of Medicare Part B payment adjustments resulting from MIPS participation may be insufficient to encourage meaningful specialty care transformation that results in increased integration between primary and specialty care. The model could test ways to enhance existing incentives, allowing for more specific comparisons to be made between clinicians of the same type who are providing similar services to patients.

Third, such a model could reach a broad range of clinicians of various specialty types that have limited opportunity to participate in Advanced APMs. There are 16 MVPs for the 2024 performance year spanning numerous specialties, and CMS is proposing additional MVPs for the 2025 performance year with the goal of creating MVPs that would be relevant to the practices of 80 percent of MIPS eligible clinicians. Using an existing framework that is agnostic to specialty type, as opposed to creating multiple unique models that are each narrowly defined by a condition or specialty, would allow the Innovation Center to take a more inclusive and unified approach to increasing specialist engagement in value-based payment.

While CMS continues to develop more MVPs for additional health conditions and specialties, an ambulatory specialty model leveraging the MVP framework could focus on a subset of published MVPs in the initial years of implementation, with the goal of increasing the number of MVPs, and thus the range of health conditions or specialty areas, included in the model over time. Using specific MVPs as the basis for a model would, in part, require that selected MVPs cover a sufficient volume of clinicians, address chronic conditions with high Medicare expenditures, align with existing Innovation Center models (for example, the Making Care Primary model), and present an opportunity to strengthen the integration between specialty care and primary care.

We are soliciting comments on several parameters of a potential model, including considering mandatory participation of relevant specialty care providers to overcome challenges such as selection bias and participant attrition, and to ensure the model is reaching a representative group of providers and beneficiaries to facilitate scaling of the model test. If CMS were to propose a mandatory specialty model, it would be done via notice and comment rulemaking. We expect this ambulatory specialty model would be implemented no earlier than 2026, ensuring participants have sufficient time to prepare for the model.

2. Solicitation of Public Comments

The Innovation Center is releasing this request for information (RFI) to gather feedback on testing a new model design to improve clinical outcomes and reduce or maintain Medicare spending. We request feedback on the design of a future ambulatory specialty model, specifically on the following—

- Participant definition;
- MVP performance assessment;
- Payment methodology;
- Care delivery and incentives for partnerships with accountable care entities and integration with primary care;
- Health information technology and data sharing;
- Health equity; and
- Multi-payer alignment.

Whenever possible, respondents are requested to draw their responses from objective, empirical, and actionable evidence and to cite this evidence within their responses.

a. Participant Definition

A key component of this potential model is to define the Medicare Part B clinicians that could participate in the model. Participants in an ambulatory specialty model using the MVP framework could be limited to MIPS eligible clinicians (see § 414.1305) with specific ambulatory-based specialties for a specific clinical focus area(s). The model design must also consider whether and how clinicians participating in other APMs and Advanced APMs (see §§ 414.1305 and 414.1415) would participate in the model.

To select participants, an ambulatory specialty model would need to determine which clinicians are specialists and sub-specialists practicing in the specified clinical areas prioritized in the model. This process may be complex as a single specialty often comprises several sub-specialties, all of which have specific clinical areas of expertise and practice. For example, the specialty of cardiology has subspecialties, including general cardiology, interventional cardiology, electrophysiology, among others; and interventional cardiologists treat a wide range of acute and chronic cardiovascular conditions and may receive advanced training in the endovascular treatment of specific conditions, including coronary artery disease and peripheral artery disease. The MVP framework could provide a natural starting point to identifying participants within a given specialty or sub-specialty. Each MVP provides measures and activities for a range of specialties and sub-specialties in a clinical area or health topic, allowing for specialties and sub-specialists to select an applicable MVP and report the measures and activities most relevant to them.

MVP currently policies do not require specialists to report specific MVPs but encourage individuals or groups that are MIPS eligible clinicians to elect to be an MVP Participant and report an MVP that is clinically relevant to them. Beginning with the CY 2026 performance period, an MVP Participant is assessed on an MVP in accordance with § 414.1365 as an individual MIPS eligible clinician,[605] a single specialty group,[606] subgroup,[607] or APM entity [608] (see § 414.1305, ''MVP

[605] A MIPS eligible clinician who is an individual and elects to report 1 MVP relevant to the clinician's clinical practice area(s).

[606] A single specialty group that is a MIPS eligible clinician and reports 1 MVP. Single specialty group means a group that consists of one specialty type as determined by CMS using Medicare Part B claims (see § 414.1305). A groups means a single TIN with two or more clinicians (including at least one MIPS eligible clinician), as identified by their individual NPI, who have reassigned their billing rights to the TIN (*Id.*).

[607] Subgroups means a subset of a group which contains at least one MIPS eligible clinicians and is identified by a combination of the group TIN, subgroup identifier, and each eligible clinician's NPIs (see § 414.1305). Each subgroup consists of 2 or more clinicians from a group that is a MIPS eligible clinician. Multiple subgroups can form from a single group, which may be either a single specialty group or a multispecialty group. Each subgroup reports 1 MVP. An individual eligible clinician (as represented by a TIN–NPI combination) may register for no more than one subgroup within a group's TIN. (see § 414.1318(a)(3)).

[608] An APM entity is a participant in an APM or other payer arrangement through a direct agreement with CMS, other payer, or through Federal or State

participant''). CMS has encouraged MIPS eligible clinicians that are multispecialty groups to participate in subgroup reporting to allow the group to report measures more relevant to each of the group's constituent specialties. Multispecialty groups that choose to report an MVP will be required to form subgroups for that purpose beginning in the CY 2026 performance period (§ 414.1305, ''MVP participant'').

Within an ambulatory specialty model, identification of a given specialty or sub-specialty—including whether an individual would be selected to participate in the model at an individual, group, or subgroup level based on TIN and NPI combinations—would need to rely on data sources to which CMS already has access. Further, approaches to participant identification would need to appropriately identify non-physician clinician types (for example, physician assistants or nurse practitioners) that may practice within a specific specialty or sub-specialty or both but may not be categorized as practicing within a specific specialty within existing data systems.

As multispecialty groups reporting MVPs in the 2026 MIPS performance period must divide into subgroups, CMS finalized a process by which it will determine whether a MIPS eligible clinician that is a group practice is a single specialty group or multispecialty group. CMS finalized that it will use Medicare Part B claims data to determine a group's specialty type based on the strong alignment between the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) and Medicare Part B claims data sources, and historical use of claims data to identify a clinician or practice's specialty (87 FR 70038 through 70040).

Given the different circumstances and challenges faced by clinicians working in specific contexts, an ambulatory specialty model could consider additional characteristics of clinicians or practices in addition to the identification of participants based on specialty or sub-specialty.[609] Additional characteristics that could be considered in participant selection in a model could be related to factors documented to be associated with disparities in access to specialty care and disparities in specialty-sensitive outcomes. Such factors could include being a solo clinician, practicing within a rural area, serving a higher proportion of Medicare and Medicaid dually eligible beneficiaries and patients receiving Medicare Part D low-income subsidies, operating within a designated Health Provider Shortage Area, among others. For further discussion on additional health equity considerations for the model, see section III.J.2.f. of this proposed rule, Health Equity.

Participant identification approaches would also need to consider the heterogeneity of existing specialty group practices as the variation in clinical practice across different specialties has historically presented challenges for specialists to engage more deeply in value-based care.

Assuming an ambulatory specialty model would initially focus on a subset of specialists and eventually incorporate additional specialties over time, CMS would need to identify specialists for the prioritized clinical areas before the model begins. CMS seeks feedback on the following questions:

(1) How should CMS identify single specialty and multispecialty groups while accounting for regular clinician turnover? Which data sources and methodology should CMS use to consider identifying specialists and sub-specialties that could potentially participate in an ambulatory specialty model?

(2) Should CMS consider different identification approaches to identify individual clinician specialist type versus practice- or group-level specialty types? If so, how?

(3) Are there certain characteristics of clinicians or practices or both that may warrant additional policy flexibilities or exemption from participation in a mandatory ambulatory specialty model? What flexibilities should CMS consider for these participants?

(4) How should CMS collect unbiased comparison group data on quality and costs for evaluation purposes? Would mandating a control group to report MVPs be appropriate for model evaluation?

(5) How can CMS support a multispecialty group's ability to successfully participate in MIPS and the model if a portion of its clinicians are reporting separate measures pursuant to the model? What steps could CMS take to reduce any added administrative burden that might arise from such separate reporting?

b. MVP Performance Assessment

CMS adjusts future Medicare Part B payments to MIPS eligible clinicians based on the assessment of measures and activities[610] reported across the 4 MIPS *performance categories:* Quality (including Population Health), Cost, Improvement Activities, and Promoting Interoperability (see §§ 414.1380 and 414.1405). MVP Participants are assessed in the same manner (see § 414.1365(d)). Scoring policies and procedures are standardized across MVPs (see § 414.1365(d)(3)). Resulting performance category scores are weighted as defined in regulations (see §§ 414.1365(e)(1) and 414.1380(c)) and are aggregated to compute an overall final MVP score, which ranges from 0 to 100 points.

Quality—Each MVP defines a set of reportable quality measures relevant to the specialty or medical condition that provide meaningful and actionable results. Quality measure sets are designed to cover a range of process and outcomes measures that are applicable to a range of clinicians working within a given specialty or medical condition. As of the CY 2024 performance period, MVP Participants must report at least 4 quality measures, including at least 1 outcome measure or 1 measure designated ''high priority'' if an outcome measure is not available within an MVP (see §§ 414.1365(c)(1) and 414.1305). Individual quality measures must also meet case minimums to be scored (see § 414.1380(b)(1)). Please refer to section IV.A.4.c.(1). of this proposed rule for proposed quality measure reporting and scoring policies for the CY 2025 performance period. MVP participants are also scored on population health administrative claims-based measures, which are factored into the MVP participant's overall quality performance category score (see § 414.1365(c)(4)(ii)) (please refer to sections IV.A.4.c.(1).(a). and IV.A.4.c.(1).(b). of this proposed rule for proposed population health measure reporting and scoring policies for the CY

law or regulation. An APM Entity can report and be scored on multiple MVPs that are of clinical interest or relevance (see § 414.1305).

[609] For example, special status designations for MIPS eligible clinicians confer additional flexibilities in performance category reporting requirements and category reweighting within final score calculations. For the 2024 performance period, several provider designations can receive additional flexibilities in MVP reporting. Ambulatory Surgical Center (ASC)-based, hospital-based, non-patient facing, and small practice-based (15 or fewer clinicians) providers are eligible for automatic reweighting of the Promoting Interoperability performance category to 0 percent, with the category weight redistributed to other performance categories. Small practice-based participants are also eligible for additional scoring flexibilities in the quality performance category (see § 414.1380). MVP policies for the CY 2024 performance period state that special status determination is determined at the group level for subgroup participants (see § 414.1365).

[610] Pursuant to section 1848(q)(2)(D) of the Act, CMS selects measures for inclusion in the MIPS program through notice and comment rulemaking. To date, CMS has also elected to subject each MIPS measure to the pre-rulemaking process pursuant to section 1848(q)(2)(D)(ix) of the Act.

2025 performance period).[611] The population health measures help indicate the quality of a population or cohort's overall health and well-being, such as, access to care, clinical outcomes, coordination of care and community services, health behaviors, preventive care and screening, health equity, or utilization of health services (see § 414.1305).

Cost—Each MVP identifies cost measures that are relevant and applicable to the MVP topic or medical condition. Given the availability of applicable cost measures, the number of reportable cost measures varies across MVPs. An MVP may include the episode-based cost measures (EBCM) that are relevant to MVP topic, total per capita cost (TPCC) measure, and Medicare Spending Per Beneficiary Clinician (MSPB Clinician) measure. Cost measures are calculated by CMS using administrative claims data, and CMS scores MVP participants on all cost measures included in the MVP that they select and report (see § 414.1365(d)(3)(ii)). Please refer to section IV.A.4.c.(2). of this proposed rule for proposed cost measure reporting and scoring policies for the CY 2025 performance period/2027 MIPS payment year.

Improvement Activities—Improvement activities (IAs) are activities that relevant MIPS eligible clinician, organizations and other relevant interested parties identify as improving clinical practice or care delivery and that are likely to result in improved outcomes. (see § 414.1305). Improvement activities may cover multiple improvement domains, including expanded patient access, population management, care coordination, beneficiary engagement, patient safety and practice assessment, health equity, emergency response and preparedness, and behavioral and mental health (see § 414.1355(c)). MVP participants must report IAs included in a given MVP while meeting overall IA reporting requirements for the performance period. Please refer to section IV.A.4.c.(3). of this proposed rule for proposed IA reporting and scoring policies for the CY 2025 performance period.

Promoting Interoperability—The Promoting Interoperability requirements of MVPs are intended to emphasize the electronic exchange of information using certified electronic health record technology (CEHRT), patient access to health information, exchange of information among clinicians, and the systematic collection, analysis, and interpretation of health care data. As of the CY 2024 performance period/2026 MIPS payment year, MVP participants are required to report the entire MIPS Promoting Interoperability measure set, which includes measures related to use of CEHRT for e-prescribing, health information exchange, public health and clinical data exchange, and clinician-to-patient exchange, as well as required attestations, as specified by CMS (see §§ 414.1365(c)(4)(i) and 414.1375(b)). Please also refer to section IV.A.4.c.(4). and Table 62 for required objectives and measures for the MIPS Promoting Interoperability performance category for the CY 2025 performance period/2027 MIPS payment year.

Operating within the MVP measures framework, an ambulatory specialty model would collect data on measures across quality, cost, and improvement activities performance categories that would be clinically relevant to specialties or sub-specialties or both within an MVP topic specified by the model. As discussed in III.J.1. of this proposed rule, the model could use a subset of measures and activities included in an MVP that are most clinically relevant to the model's clinical topics and specialties. A clinically focused measure and activity set could allow CMS to set performance standards that are most clinically relevant to sub-specialties within an MVP topic under the model.

CMS requests the following feedback related to incorporating measures and activities from MVP performance categories in a possible ambulatory specialty model:

(6) If CMS were to reduce the number of measures and activities in an MVP for clinicians participating in the model to those measures and activities most relevant to a specified specialty or subspecialty, how should CMS select the measures and activities? Consider the following prioritization approaches: (a) measures with a performance gap; (b) measures with meaningful benchmarks that can be applied; (c) measures that are reliable in the model context given the expected sample size; (d) measures that are evidence-based and either strongly linked to outcomes or an outcome measure; (e) measures that capture an adequate number and representativeness of the clinicians intended by a possible ambulatory specialty model; (f) measures that drive specialty integration with primary care and meaningful involvement with accountable entities. Are there other measure selection principles that should be prioritized when narrowing measuring in an MVP?

(7) Are there specific measure focus areas or objectives that should be prioritized across MVPs (such as equity, population health measures, or patient-reported outcome-based performance measures (PRO–PMs) and patient-reported experience measures)?

(8) To support improvements in primary and specialty care integration, an ambulatory specialty model could initially focus on specialty types eligible to become rostered specialty care partner clinicians in the MCP model, which include general cardiologists and physical medicine and rehabilitation clinicians. Accordingly, which measures within the Advancing Care for Heart Disease MVP and the Rehabilitative Support for Musculoskeletal Care MVP might be subset to apply to general cardiology and physical medicine and rehabilitation, respectively?

(9) Similar to how other Innovation Center models may test new measures during their implementation (for example, the Comprehensive Joint Replacement model (80 FR 73358 through 73382 and 86 FR 23543 through 23549) and the Guiding an Improved Dementia Experience (GUIDE) Model[612]), what role could an ambulatory specialty model have in testing potential new measures, such as relevant PRO–PMs, by gathering data for consideration in future MVP measure sets?

(10) What kinds of strategies could be tested to obtain patient and family feedback on how they experience care coordination between primary care and specialty care for the clinical focus areas of the model?

(11) What types of peer engagement would specialists consider valuable to enhance their performance within a given sub-specialty or clinical topic?

c. Payment Methodology

MIPS final scores are used to determine payment adjustments for future Medicare Part B payments during the payment year that occurs 2 calendar years following the MIPS performance period (for example, scores from the CY 2021 MIPS performance period resulted in Part B Medicare payment adjustments for the 2023 calendar year) (see

[611] For the CY 2024 performance period, the two population health measures from which participants could select to be scored are: Hospital-Wide, 30-day, All-Cause Unplanned Readmission Rate for the MIPS Groups and Clinician, or Clinician Group Risk-standardized Hospital Admission Rate for Patients with Multiple Chronic Conditions. If the participant does not meet the case minimum for either measure, then the population health measure is excluded from scoring within the quality performance category.

[612] *https://www.cms.gov/files/document/guide-rfa.pdf.*

§ 414.1305). CMS scores a MIPS eligible clinician's performance on measures and activities in accordance with section 1848(q)(5) of the Act and regulations at §§ 414.1317, 414.1365, 414.1367, and 414.1380, as applicable to determine a final score for each MIPS eligible clinician.

In accordance with section 1848(q)(6) of the Act and § 414.1405(b), CMS compares each MIPS eligible clinician's final score against the performance threshold established for that MIPS payment year and against one another in a single comparison pool to determine whether each MIPS eligible clinician will receive a positive, negative, or neutral payment adjustment. CMS calculates MIPS payment adjustment factors in accordance with regulations at § 414.1405. Scores equal to the defined performance threshold receive a neutral (0 percent) payment adjustment. Scores falling below one-quarter of the performance threshold receive a negative adjustment of minus 9 percent, while scores between one-quarter of the performance threshold and the performance threshold receive a negative payment adjustment less than 0 percent and up to minus 9 percent based on a linear sliding scale. Scores above the performance threshold can receive positive payment adjustments greater than 0 percent and up to positive 9 percent based on a linear sliding scale. Depending on the range of scores within a given performance period, a scaling factor (ranging from 0 to 3) is applied to positive adjustments to retain budget neutrality.

For the CY 2022 performance period/2024 MIPS payment year, over 624,000 clinicians received MIPS payment adjustments to their Medicare Part B payments based on participation in traditional MIPS: 14 percent of MIPS eligible clinicians received negative MIPS payment adjustments, 7 percent received neutral MIPS payment adjustments, and 79 percent received positive MIPS payment adjustments with a maximum positive payment adjustment of 8.26 percent.[613] MVPs were not a reporting option for the CY 2022 performance period/2024 MIPS payment year.

As discussed in III.J.1. of this proposed rule, an ambulatory specialty model allow for more specific comparisons between clinicians of the same type who are providing similar services to patients. Comparing clinicians that provide a similar type of specialty care to determine future Medicare Part B payment adjustments could lead to payment adjustments that are more reflective of the range of performance of similar clinicians caring for beneficiaries within a given clinical topic area. Such comparisons could create financial incentives that drive quality improvement and care transformation within a given clinical topic and specialty. Further, a more targeted approach to performance measurement and assessment, including enhanced data on clinical and financial performance relative to similar clinicians, could incentivize shared accountability for care and lead to increased beneficiary access to coordinated specialty care.

In considering an ambulatory specialty model that leverages the MVP framework to increase specialist engagement in value-based care and transform specialist care delivery, CMS is requesting feedback on the following questions:

(12) How could a model for applicable specialists improve the comparison of similar specialists to determine future Medicare Part B payment adjustments?

(13) What range of upside and downside risk (as measured by the range of possible payment adjustments to future Medicare Part B claims) could incentivize increased and meaningful participation of specialists in APMs, care transformation, and strengthened integration between primary and specialty care?

(14) What model design features should CMS consider in designing an ambulatory specialty care model that increases risk over time to potentially qualify the model for Advanced APM (AAPM) status under the Quality Payment Program (see § 414.1415)?

d. Care Delivery and Incentives for Partnerships With Accountable Care Entities and Integration With Primary Care

CMS is exploring how an ambulatory specialty model could encourage model participants to better engage with primary care providers engaged in care coordination activities in the MCP model, Shared Savings Program, and other current and future accountable care models. By promoting coordination and partnership between specialists and these accountable entities, CMS seeks to extend opportunities for specialists to deliver comprehensive longitudinal care and improve the quality of care provided by both parties. For example, CMS could test the inclusion of new improvement activities in model MVPs that are fulfilled through care coordination activities with an accountable care entity or its participant clinicians. As CMS considers opportunities to encourage specialist delivery of comprehensive longitudinal care, an underlying priority is care delivery from the beneficiary's perspective. To address the issue of highly fragmented care delivery to the beneficiary, CMS recognizes the need for meaningful engagement among those who deliver care and seeks to create incentives for partnerships between specialist clinicians, accountable care entities, and primary care clinicians. To help us ensure these accountable entities reduce fragmentation and provide patients with the highest value care, we seek input on the following questions:

(15) Are there model design features not discussed here that would incentivize primary care and specialty care providers to improve how beneficiaries experience care coordination?

(16) How can CMS best encourage specialist clinicians and accountable care entities collaborate to establish clear care pathways and protocols that optimize patient outcomes while ensuring efficient resource utilization?

(17) How may CMS identify specialists who are most engaged in care management, care coordination, and care improvement activities with an accountable care entity?

(18) In what ways can the model define clear expectations and performance metrics for specialists, beyond what exists in the current MVP measure sets, to foster a collaborative environment with ACOs and primary care clinicians to enhance healthcare outcomes and reduce costs? What levers, such as the MIPS's Improvement Activities, could be used to support participants to close the care loop back to accountable care entities or primary care or both?

(19) What characteristics should CMS consider in the design of this model to account for variations between ACOs, such as whether the ACO is physician-owned versus hospital-owned (or a low revenue ACO versus a high revenue ACO), whether or not an ACO identifies as an integrated delivery system (IDS), and differences in regional healthcare landscapes and local dynamics? What other characteristics should we consider?

(20) How can the model proactively address concerns related to increased consolidation, ensuring that integration efforts do not lead to reduced

[613] QPP 2022 Participation Results At-a-Glance *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2816/QPP-2022-Participation-and-Performance-Results-At-A-Glance.pdf*. Note that for the CY 2022 performance period, MIPS participants were eligible for an additional MIPS payment adjustment factor for exceptional performance (see § 414.1405).

competition and potential negative impacts on healthcare quality and costs?

(21) How might risk categorization of ACOs influence the design of incentive structures of model participants engaging with ACOs, and what adjustments might be necessary to accommodate different risk levels?

e. Health Information Technology and Data Sharing

The Quality Payment Program releases publicly the QPP Experience Report Public Use Files (with companion methodology and data dictionary documentation), which allow users to review details concerning participation and performance information in the MIPS program during each performance period. These files cover eligibility and participation, performance categories, and final score and payment adjustments, with details at the TIN/NPI level on each of the performance categories for the previous performance period. Data can be sorted by variables like clinician type, practice size, scores, and payment adjustments. Clinicians and authorized representatives of practices, virtual groups, and APM Entities (including Shared Savings Program ACOs) also have access to summaries of data that they have submitted and that CMS has collected on their behalf. This includes performance category-level scores and weights, bonus points, measure-level performance data and scores, activity-level scores, payment adjustment information, and patient-level reports. Clinicians frequently request more timely and expansive data feedback through MIPS to help guide continuous improvement efforts. CMS requests the following feedback on health information technology and data sharing:

(22) What specific issues should CMS consider when determining whether additional requirements and objectives may be necessary beyond those currently specified in the MVP framework around the use of health IT by specialists participating in a potential model?

(23) What investments in health IT or information exchange would be most beneficial to helping specialists succeed in such a model?

(24) What is your experience with the integration of health IT systems? Please highlight any interoperability issues or opportunities for seamless data exchange between different systems, such as electronic health records (EHRs) and telehealth platforms.

(25) How should CMS structure the model and any health IT and data sharing requirements to align with, build upon, and otherwise leverage advances in Federal interoperability policy (for example, USCDI and USCDI+ or FHIR; TEFCA)?

(26) What data or metrics or both are important to clinicians in terms of monitoring performance and improving patient outcomes? What data or metrics or both should CMS share publicly to help inform beneficiaries of clinician performance?

(27) What additional resources or support mechanisms could CMS provide to help clinicians make sense of the data, enhancing the data's usability, effectiveness, and frequency of updates, so that clinicians acquire actionable insights for improving patient care and experience? And to enable data-driven referrals?

(28) What supports can this new model provide for decreasing burden of data collection and measure reporting?

f. Health Equity

Disparities in access to ambulatory specialty care and chronic condition outcomes are well documented, such as racial/ethnic and geographic disparities in rates of ischemic heart disease (IHD) among Medicare fee-for-service beneficiaries.[614] For example, Medicare fee-for-service beneficiaries identifying as American Indian/Alaska Native (28 percent) had the highest age-standardized prevalence of IHD and Asian/Pacific Islander (22 percent) beneficiaries had the lowest prevalence, compared to the IHD prevalence among White (27 percent), Black/African American (26 percent), and Hispanic (25 percent) beneficiaries in 2021.[615] Medicare fee-for-service beneficiaries with complex chronic conditions in rural areas have also been shown to have comparable access to primary care physicians but significantly lower access to ambulatory specialists and higher rates of avoidable hospitalizations for chronic conditions compared to similar beneficiaries in urban areas.[616] Engaging specialists in value-based care to create more integrated and efficient care provides an opportunity to expand access to specialty care for historically underserved beneficiaries and advance health equity.

Consistent with President Biden's Executive Order 13985 on ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government'' (86 FR 7009) and Executive Order 14091 on ''Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government'' (88 FR 10825), CMS has made advancing health equity[617] the first pillar in its Strategic Plan. Health equity is also one of the five objectives in the Innovation Center's 2021 Strategy Refresh. Improving access to high-quality, patient-centered care is a goal for the Innovation Center, and ensuring historically underserved beneficiaries are adequately represented in value-based care models may help reduce inequities when designed with the proper incentives.

The Innovation Center is also committed to prioritizing the unique needs of clinicians that care for a large proportion of underserved populations, such as creating flexibilities clinicians may need to be successful in models. To advance health equity goals within payment models, the Innovation Center has implemented multiple equity-focused strategies within existing models, including, but not limited to development of participant health equity plans, reporting of aggregated health-related social need (HRSN) screening,[618] reporting and analysis of attributed beneficiary sociodemographic data to support identification and monitoring of health disparities, and payment adjustments.

Within the MVP framework, several MVPs include equity-focused measures within the quality and improvement activities performance categories, such as screening for HRSNs or engaging community resources to address HRSNs. MVPs also provide additional reporting

[614] Centers for Medicare & Medicaid Services. Ischemic Heart Disease Disparities in Medicare Fee-for-Service Beneficiaries Data Snapshot. April 2021. *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Dwnld-DataSnashot-Ischemic-Heart-Disease.pdf.*

[615] Centers for Medicare & Medicaid Services. Ischemic Heart Disease Disparities in Medicare Fee-for-Service Beneficiaries Data Snapshot. April 2021. *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Dwnld-DataSnashot-Ischemic-Heart-Disease.pdf.*

[616] Johnston KJ, Wen H, Joynt Maddox KE. Lack Of Access to Specialists Associated with Mortality and Preventable Hospitalizations of Rural Medicare Beneficiaries. *Health Aff (Millwood).* 2019;38(12): 1993–2002. *doi: 10.1377/hlthaff.2019.00838.*

[617] We define health equity as the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, and other factors that affect access to care and health outcomes.

[618] Health-related social needs are adverse social conditions that negatively impact a person's health or healthcare such as lack of access to transportation for appointments. See A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tools: Promising Practices and Key Insights. CMS. (Updated Aug. 2022). *https://www.cms.gov/priorities/innovation/media/document/ahcm-screeningtool-companion;* Accountable Health Communities Health-Related Social Needs Screening Tool.

and scoring flexibilities for certain special status designations, many of which may include clinicians caring for historically underserved beneficiaries. There may be additional clinician- and practice-level characteristics, including the characteristics of beneficiaries served, that would be important to account for within an ambulatory specialty model to support clinicians in identifying and working to improve disparities related to access to specialty care and associated outcomes.

To understand the potential health equity impacts of a new ambulatory specialty model and to help ensure the goals laid out in the CMS Strategic Plan and the Innovation Center Strategy Refresh are met, we request feedback on the following questions:

(29) Similar to how other Innovation Center models may offer financial and technical supports to certain qualifying clinicians (for example, safety net clinicians) as part of a model's health equity strategy (for example, the GUIDE model [619]), how might CMS support the participation of clinicians in an ambulatory specialty model that may serve a higher proportion of underserved patients (for example, small practices or clinicians in rural areas)?

(30) How could an ambulatory specialty model support participant efforts to identify health disparities within their practices, identify actionable equity goals, and design and implement strategies to improve identified disparities?

(31) How could an ambulatory specialty focused model work synergistically with other primary care focused models to improve health disparities?

(32) How could an ambulatory specialty model encourage clinicians to collect and use HRSN screening and follow-up data collected on patients attributed to the model?

(33) How can measure stratification among patient subgroups or use of composite health equity measures improve how participants identifies and quantifies potential disparities in care and outcomes related to ambulatory specialty care?

g. Multi-Payer Alignment

Given the Innovation Center's strategic goal to make multi-payer alignment available in all new models by 2030,[620] we are seeking feedback on how to best promote multi-payer alignment between a potential ambulatory model, established models and programs, and payers to achieve sustainable system-wide transformation. The increased engagement in value-based care proposed in the model could support other payers like Medicare Advantage, Medicaid, and commercial plans in achieving their goals around value-based care activities by providing an onramp for specialists inexperienced with this form of payment. Also, leveraging existing design principles from MIPS promotes directional alignment as they adhere to the broader CMS National Quality Strategy, including an effort to move toward digital quality measurement,[621] and plans to employ a ''Universal Foundation'' of quality measures to create greater consistency in quality reporting across payers.[622]

We request feedback on the following questions:

(34) Are there opportunities to reduce clinician burden between this model, other CMMI models, and beyond through multi-payer alignment, in areas such as performance measurement, quality measurement, and data/reporting requirements?

(35) How could this model align with value-based care approaches in the Medicare Advantage, Medicaid, and commercial payer space that focus on specialty integration? What model components and payment incentives can be aligned with other payers to support improvement goals?

(36) How can CMS align with other payer approaches to equity and disparity reduction? This could include alignment on definitions, methods, and requirements for equity-related data collection, etc.

(37) What technical assistance can CMS provide to support alignment and reduce burden?

K. Expand Colorectal Cancer Screening

Medicare coverage for colorectal cancer (CRC) screening tests under Part B are described in statutes (sections 1861(s)(2)(R), 1861(pp), 1862(a)(1)(H) and 1834(d) of the Social Security Act (the Act)), regulation (42 CFR 410.37), and National Coverage Determination (NCD) (Section 210.3 of the Medicare National Coverage Determinations Manual). The statute and regulations expressly authorize the Secretary to add other tests and procedures (and modifications to tests and procedures) for colorectal cancer screening with such frequency and payment limits as the Secretary finds appropriate based on consultation with appropriate organizations. (Section 1861(pp)(1)(D) of the Act; § 410.37(a)(1)(v)) We are proposing to exercise our authority at section 1861(pp)(1)(D) of the Act to update and expand coverage for CRC screening by:

- Removing coverage for the barium enema procedure in regulations at § 410.37,
- Adding coverage for the computed tomography colonography (CTC) procedure in regulations at § 410.37, and
- Expanding a ''complete colorectal cancer screening'' in § 410.37(k) to include a follow-on screening colonoscopy after a Medicare covered blood-based biomarker CRC screening test (described and authorized in NCD 210.3).

1. Background

The Center for Disease Control and Prevention (CDC) describes CRC as ''a disease in which cells in the colon or rectum grow out of control . . . Sometimes abnormal growths, called polyps, form in the colon or rectum. Over time, some polyps may turn into cancer. Screening tests can find polyps so they can be removed before turning into cancer. Screening also helps find colorectal cancer at an early stage, when treatment works best.'' [623] The National Cancer Institute reports that CRC is the fourth most common type of cancer and estimates that the United States experienced 153,020 new cases and 52,550 new deaths from CRC in 2023. In addition, the rate of new cases and new deaths from CRC is more common in men than women and significantly greater for those of African American and Non-Hispanic American Indian/Alaska Native descent compared to all races.[624]

At § 410.37(a)(4), we define the barium enema procedure as a screening double contrast barium enema of the entire colorectum (including a physician's interpretation of the results of the procedure); or in the case of an individual whose attending physician decides that he or she cannot tolerate a screening double contrast barium

[619] Center for Medicare and Medicaid Services. Guiding an Improved Dementia Experience (GUIDE) Model. *https://www.cms.gov/priorities/innovation/innovation-models/guide.*

[620] Centers for Medicare and Medicaid Services. Driving Health System Transformation—A Strategy for the CMS Innovation Center's Second Decade. October 2021. *https://www.cms.gov/priorities/innovation/strategic-direction-whitepaper.*

[621] Centers for Medicare and Medicaid Services. dQMs—Digital Quality Measures. dQM Strategic Roadmap.

[622] Jacobs DB, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher LA. Aligning Quality Measures across CMS—The Universal Foundation. 2023. *New England Journal of Medicine,* 388 (9), 776–779. *DOI: 10.1056/NEJMp2215539.*

[623] CDC website: *https://www.cdc.gov/cancer/colorectal/basic_info/what-is-colorectal-cancer.htm.*

[624] NCI website: *https://seer.cancer.gov/statfacts/html/colorect.html.*

enema, a screening single contrast barium enema of the entire colorectum (including a physician's interpretation of the results of the procedure). The CDC describes CTC, (also called a virtual colonoscopy), as ''a screening test that uses X-rays and computers to produce images of the entire colon, which are displayed on a computer screen for the doctor to analyze.'' [625]

The U.S. Preventative Services Task Force (USPSTF) included CTC as a CRC screening method in their June 2016 revised Final Recommendation Statement which included the topline recommendations ''[t]he USPSTF recommends the (CRC screening) service. There is high certainty that the net benefit is substantial (Grade A)'' and ''[t]he USPSTF recommends the (CRC screening) service. There is high certainty that the net benefit is moderate, or there is moderate certainty that the net benefit is moderate to substantial) (Grade B)''.[626] The USPSTF cautioned, ''[t]here is insufficient evidence about the potential harms of associated extracolonic findings, which are common.'' The USPSTF further wrote, ''[t]here are numerous screening tests to detect early-stage colorectal cancer, including stool-based tests (gFOBT, FIT, and FIT–DNA), direct visualization tests (flexible sigmoidoscopy, alone or combined with FIT; colonoscopy; and CT colonography), and serology tests (SEPT9 DNA test). The USPSTF found no head-to-head studies demonstrating that any of these screening strategies are more effective than others, although they have varying levels of evidence supporting their effectiveness, as well as different strengths and limitations.'' [627] The USPSTF again included CTC as a CRC screening method in the most recent May 2021 revised Final Recommendation Statement, which included the topline recommendations ''[t]he USPSTF recommends screening for colorectal cancer in all adults aged 50 to 75 years (Grade A)'' and ''[t]he USPSTF recommends screening for colorectal cancer in adults aged 45 to 49 years (Grade B)''.[628] CMS describes our consultations with additional organizations and our review of clinical guidelines later in our proposal.

2. Statutory Authority

Section 4104 of the Balanced Budget Act of 1997 (Pub. L. 105–33) authorized the benefit colorectal cancer screening tests under Medicare Part B. Section 1861(s)(2)(R) of the Act includes CRC screening tests in the definition of medical and other health services that fall within the scope of Medicare Part B benefits described in section 1832(a)(1) of the Act. Section 1861(pp) of the Act defines colorectal cancer screening tests and specifically names the following tests:

- Screening fecal-occult blood test;
- Screening flexible sigmoidoscopy; and
- Screening colonoscopy.

Section 1861(pp)(1)(D) of the Act also authorizes the Secretary to include in the definition of CRC screening tests other tests or procedures and modifications to the tests and procedures described under this subsection, with such frequency and payment limits as the Secretary determines appropriate, in consultation with appropriate organizations.

3. Regulatory and NCD Authority

In the CY 1998 PFS final rule (62 FR 59048), after consulting with appropriate organizations, we finalized regulations to cover barium enema procedures for CRC screening in § 410.37. Barium enema screening examinations have to be ordered by the beneficiary's attending physician (§ 410.37(h)). Currently, the regulations cover barium enemas as a CRC screening tests subject to frequency limitations and whether or not the individual was at high risk for colorectal cancer. As described in the CY 1998 PFS final rule (62 FR 59048), CMS consulted with a number of appropriate organizations such as the American Cancer Society, American College of Physicians, American Gastroenterological Association and U.S. Preventive Services Task Force (USPSTF) and the decision to cover the barium enema procedure was based on the prevailing clinical guidelines and recommendations at the time. In the CY 2023 PFS final rule (87 FR 69404), we lowered the age limit for barium enema procedures for CRC screening to age 45 at § 410.37(i)(1).

In May 2009, we established a non-coverage policy for CTC in NCD 210.3 CTC Screening Tests. We noted in the Final Decision Memorandum, ''there is insufficient evidence on the test characteristics and performance of screening CT colonography in Medicare aged individuals and that the evidence is not sufficient to conclude that screening CT colonography improves health benefits for asymptomatic, average risk Medicare beneficiaries.'' [629] At that time, the October 2008 USPSTF revised Final Recommendation Statement read, ''[t]he USPSTF concludes that the evidence is insufficient to assess the benefits and harms of computed tomographic colonography and fecal DNA testing as screening modalities for colorectal cancer. (Grade I)'' [630] As described in the Final Decision Memo, guidelines from Professional Societies were mixed. A joint guideline from the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology concluded ''[i]n terms of detection of colon cancer and advanced neoplasia, which is the primary goal of screening for CRC and adenomatous polyps, recent data suggest CTC is comparable to Optical Colonoscopy for the detection of cancer and polyps of significant size when state-of-the-art techniques are applied.'' [631] The American Gastroenterological Association issued the following recommendation statement in 2008, ''[t]he AGA does not endorse CT colonography as a first-line colon cancer screening test. While AGA supports CT colonography as a screening option, colonoscopy is the definitive test for colorectal cancer screening and prevention. Colonoscopy is the only test that can both detect cancer at an early curable stage and prevent cancer by removing pre-cancerous polyps. At this time, while CT colonography may be another technology for colorectal cancer screening, many questions about CT colonography remain to be

[625] CDC website: *https://www.cdc.gov/cancer/colorectal/basic_info/screening/tests.htm.*

[626] USPSTF June 2016 Revised Final Recommendation Statement *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening-june-2016.*

[627] USPSTF June 2016 Revised Final Recommendation Statement *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening-june-2016.*

[628] USPSTF January 2021 Revised Final Recommendation Statement *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening.*

[629] National Coverage Analysis CAG–00396N Screening Computed Tomography Colonography (CTC) for Colorectal Cancer on Medicare Coverage Database (*https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=220&NcaName=Screening+Computed+Tomography+Colonography+(CTC)+for+Colorectal+Cancer*),).

[630] USPSTF October 2008 Final Recommendation Statement: *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening-2008.*

[631] National Coverage Analysis CAG–00396N Screening Computed Tomography Colonography (CTC) for Colorectal Cancer on Medicare Coverage Database: *https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=220&NcaName=Screening+Computed+Tomography+Colonography+(CTC)+for+Colorectal+Cancer*).

answered.'' [632] The American Society for Gastrointestinal Endoscopy published guidelines in 2006 that concluded ''virtual colonoscopy is an evolving technique and is not currently recommended as the primary method of screening for CRC.'' [633]

In the 2023 PFS final rule (87 FR 69404) we expanded the regulatory definition of CRC Screening to include a complete colorectal cancer screening, which includes a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based colorectal cancer screening test returns a positive result. (§ 410.37(k)) Although CMS had previously viewed a colonoscopy after a positive non-invasive stool-based CRC screening test to be a diagnostic colonoscopy, the clinical recommendations and guidance of medical professional societies and screening experts have since evolved for stool-based colorectal cancer screening due to the relative number of false positive results, low follow-up colonoscopy rates and patient access barriers. Published evidence highlighted that individuals who did not get a follow-up colonoscopy were about twice as likely to die of colorectal cancer compared to individuals who had one. Since the overall goal of programmatic cancer screening using any CRC screening test is to prevent cancer, allowing for early detection and treatment and reducing cancer mortality, the follow-up colonoscopy was found to be integral with non-invasive stool-based CRC screening, since improvements in health outcomes would not be possible without the follow-up colonoscopy. Our goal was that the patient and their healthcare professional make the most appropriate choice in CRC screening, which included considerations of the risks, burdens and barriers presented with an invasive screening colonoscopy in a clinical setting as their first step. We went on to describe that CRC screening presents a unique scenario where there are significant differences between screening stool-based tests and screening colonoscopy tests in terms of invasiveness and burdens to the patient and healthcare system. We recognized there are several advantages to choosing a non-invasive stool-based CRC screening test as a first step compared to a screening colonoscopy, including relative ease of administering the test and potentially reducing the experience of unnecessary burdensome preparation and invasive procedures.

We noted in preamble of the CY 2023 PFS final rule (87 FR 69404) that many commenters asked that CMS further expand our approach of a complete colorectal cancer screening. Many requested that we remove the text ''stool-based'' from our proposed regulatory text at § 410.37(k), resulting in a complete CRC screening including a follow-on screening colonoscopy after a Medicare covered non-invasive screening test. Many commenters requested that a complete CRC screening include a screening colonoscopy after a positive result from a blood-based biomarker test, as well as a stool-based test. We responded to these public comments by writing that ''we disagree with the commenters that requested a further expansion of a complete colorectal cancer screening that would include additional first step tests beyond a non-invasive stool-based test. We believe the stool-based tests are unique to other CRC screening tests in terms of their non-invasiveness, the fact that stool-based tests can be implemented by the patient at home and mailed into the lab, the absence of bowel preparation and anesthesia and the comparatively lighter burden and mitigated potential for over servicing of the patient and the healthcare system.'' We further wrote, ''[w]e agree that blood-based biomarker CRC screening tests have significant potential and we expanded coverage to include them in the reconsidered NCD 210.3, effective January 2021.'' We also recognized that blood-based biomarker CRC screening tests continue to be an emerging and quickly evolving technology. However, we also noted that, as of September 2022, no blood-based Biomarker tests for CRC screening had achieved the coverage requirements of NCD 210.3 and that the May 2021 USPSTF revised Final Recommendation Statement did not include serum tests.

In the CY 2023 PFS final rule (87 FR 69404) we also established regulatory text at § 410.37(k) that the frequency limitations described for screening colonoscopy shall not apply in the instance of a follow-on screening colonoscopy test. We wrote that we aimed to avoid disruption to the existing conditions of coverage and payment for CRC screening for this unique scenario and continuum of screening.

4. Proposed Revisions

We propose to exercise our authority in section 1861(pp)(1)(D) of the Act to remove coverage for the barium enema procedure from CRC screening in regulations at § 410.37. CMS has consulted with appropriate organizations and has heard that, while the barium enema procedure was reasonable and necessary for CRC screening when it was initially covered in the CY 1998 PFS final rule (62 FR 59048), circumstances have changed. The organizations have expressed that barium enema procedures no longer meet modern clinical standards, are no longer recommended in clinical guidelines, and would not be an appropriate CRC screening test given the advancement of alternatives such as Stool-based tests, Colonoscopies, and CT Colonography. In developing our proposal, we also considered that June 2016 and the May 2021 USPSTF revised Final Recommendation Statements did not include the barium enema procedure as a CRC screening method in their revised Final Recommendation Statements.[634] [635] We also considered the 2017 U.S. Multi-Society Task Force of Colorectal Cancer (MSTF) recommendation statement, which reads, ''CT colonography has replaced double-contrast barium enema as the test of choice for colorectal imaging for nearly all indications. CT colonography is more effective than barium enema and better tolerated.'' [636] The 2018 American Cancer Society (ACS) Colorectal Cancer Screening for Average-Risk Adults Guideline Update also reads, ''double-contrast barium enema is no longer included as an acceptable screening option.'' [637]

During the CY 2023 PFS, CMS received a joint public comment from the American College of Gastroenterology (ACG), American Gastroenterological Association (AGA) and the American Society for

[632] National Coverage Analysis CAG–00396N Screening Computed Tomography Colonography (CTC) for Colorectal Cancer on Medicare Coverage Database: *https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=220&NcaName=Screening+Computed+Tomography+Colonography+(CTC)+for+Colorectal+Cancer*).

[633] National Coverage Analysis CAG–00396N Screening Computed Tomography Colonography (CTC) for Colorectal Cancer on Medicare Coverage Database: *https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=220&NcaName=Screening+Computed+Tomography+Colonography+(CTC)+for+Colorectal+Cancer*).

[634] USPSTF June 2016 Revised Final Recommendation Statement, *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening-june-2016.*

[635] USPSTF January 2021 Revised Final Recommendation Statement, *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening.*

[636] Am J Gastroenterol 2017; 112:1016–1030; doi: 10.1038/ajg.2017.174; published online 6 June 2017.

[637] doi: 10.3322/caac.21457. Available online at *cacancerjournal.com.*

Gastrointestinal Endoscopy (ASGE) [638] that brought to our attention that barium enema is not a recommended CRC screening modality in guidance from the USPSTF or the U.S. Multi-Society Task Force on Colorectal Cancer. The public comment went on to note that while the Barium Enema procedure once was considered a CRC screening modality and has been included in guidelines in the past, barium enema is no longer included in any recent CRC guidelines and is rarely performed today as it is considered inadequate for the exclusion of CRC. They urged CMS to remove Barium Enema as a covered CRC screening test for all individuals. An internal claims analysis indicates that Medicare only paid claims for barium enema for CRC screening for 72 beneficiaries in CY 2022.

A 2016 study titled ''[n]ew era of colorectal cancer screening,'' states, ''double-contrast barium enema (DCBE) is a non-invasive radiological test, which provides a complete evaluation of the large intestine. The sensitivity and specificity of barium enema for polyps of any size is 38 percent and 86 percent, respectively. One study comparing barium enema to CTC and colonoscopy showed that DCBE has the lowest sensitivity and specificity with sensitivity of 41 percent for lesions ≥6 mm and sensitivity and specificity of 48 and 90 percent respectively for lesions ≥10 mm. These results are consistent with a meta-analysis comparing the performance of barium enema to that of CTC showing CTC is more sensitive and more specific than barium enema for large polyps (≥10 mm) and small polyps (6–9 mm) in average-risk and high-risk populations. In the United States, CTC has largely replaced DCBE as a radiographic option for CRC screening.'' [639]

In light of the new evidence and our consultations with appropriate organizations, we are proposing to remove barium enema as a colorectal screening test under 42 CFR 410.37(a)(1)(iv). We look forward to further consultation with the public and appropriate organizations through the public comment period of this proposed rule. We invite public comment on this proposal to remove all references to barium enemas in § 410.37.

We also propose to exercise our authority in section 1861(pp)(1)(D) of the Act to add coverage for the CTC procedure for CRC screening in regulations at § 410.37. If finalized, we will also address and revise the current non-coverage policy for CTC in NCD 210.3. In developing our proposal to expand coverage for the CTC procedure, we consulted with appropriate organizations and considered a number of potential benefits, risks and tradeoffs described in guidelines and recommendations by professional societies and government bodies.

In developing the proposed rule, we considered that the USPSTF included the CTC procedure as a CRC screening method in their June 2016 and May 2021 revised Final Recommendation Statements.[640] [641] In terms of benefits, the USPSTF wrote in their May 2021 revised Final Recommendation Statement, that CTC usually allows for greater colon visualization compared to Flexible Sigmoidoscopy. In terms of risks and tradeoffs, USPSTF noted that CTC, like Colonoscopy and flexible sigmoidoscopy, requires the burden of bowel preparation. The USPSTF wrote ''[u]nlike Colonoscopy and Flexible Sigmoidoscopy, CTC may reveal extracolonic findings that require additional workup, which could lead to other potential benefits or harms.'' The USPSTF went on to state, ''[h]arms from CT colonography are uncommon (19 studies; n = 90,133), and the reported radiation dose for CT colonography ranges from 0.8 to 5.3 mSv (compared with an average annual background radiation dose of 3.0 mSv per person in the U.S.). Accurate estimates of rates of serious harms from colonoscopy following abnormal CTC results are not available.'' Regarding extracolonic findings, the USPSTF wrote, ''[e]xtracolonic findings on CTC are common. Based on 27 studies that included 48,235 participants, 1.3 percent to 11.4 percent of examinations identified extracolonic findings that required workup. Three percent or less of individuals with extracolonic findings required definitive medical or surgical treatment for an incidental finding. A few studies suggest that extracolonic findings may be more common in older age groups. Long-term clinical follow-up of extracolonic findings was reported in few studies, making it difficult to know whether it represents a benefit or harm of CT colonography.'' The USPSTF recommends screening CTC frequency of every 5 years.[642]

In a study titled ''Incidental Extracolonic Findings on CT Colonography: The Impending Deluge and Its Implications,'' Lincoln L. Berland, MD, describes extracolonic findings as findings on CTC that have potential deleterious health effects and are asymptomatic, unsuspected, and unrelated to the colon. The study goes on to state, ''as CT image quality has improved, there has been an increase in the frequency of detecting 'incidental findings,' defined as findings that are unrelated to the clinical indication for the imaging examination performed. These 'incidentalomas,' as they are also called, often confound physicians and patients with how to manage them. Although it is known that most incidental findings are likely benign and often have little or no clinical significance, the inclination to evaluate them is often driven by physician and patient unwillingness to accept uncertainty, even given the rare possibility of an important diagnosis.'' [643] The potential for extracolonic findings, both clinically significant and insignificant, is an important tradeoff to be considered by the patient and clinician when considering CTC as a CRC Screening option.

We also consider the 2018 ACS Colorectal Cancer Screening for Average-Risk Adults Guideline Update, which includes the CTC procedure with their recommended tests and procedures for CRC Screening.[644] In terms of benefits, the ACS guideline describes CTC Sensitivity and specificity for cancer and advanced adenomas comparable to colonoscopy, longer recommended screening intervals compared to stool-based tests, and no need for sedation (compared to colonoscopy). In terms of risks and tradeoffs, the ACS guideline notes incidental extracolonic findings may require workup (with unclear benefit-burden balance), exposure to low-dose radiation and requires full bowel cleansing. The ACS guidelines

[638] CY 2023 PFS Public Comment CMS–2022–0113–21851_attachment_1.

[639] El Zoghbi M, Cummings LC. *New era of colorectal cancer screening. World J Gastrointest Endosc. 2016 Mar 10;8(5):252–8. doi: 10.4253/wjge.v8.i5.252. PMID: 26981176; PMCID: PMC4781905.*

[640] USPSTF June 2016 Revised Final Recommendation Statement, *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening-june-2016.*

[641] USPSTF January 2021 Revised Final Recommendation Statement, *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening.*

[642] USPSTF January 2021 Revised Final Recommendation Statement, *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening.*

[643] Lincoln L. Berland, Incidental Extracolonic Findings on CT Colonography: The Impending Deluge and Its Implications, Journal of the American College of Radiology, Volume 6, Issue 1, 2009, Pages 14–20, ISSN 1546–1440, *https://doi.org/10.1016/j.jacr.2008.06.018.*

[644] doi: 10.3322/caac.21457. Available online at *cacancerjournal.com.*

recommended screening CTC frequency of every 5 years.

We also consider the United States Multi-Society Task Force (MSTF) of Colorectal Cancer, which represents the American College of Gastroenterology, the American Gastroenterological Association, and The American Society for Gastrointestinal Endoscopy, 2017 Colorectal Cancer Screening recommendations,[645] which include CTC as a ''Tier 2'' procedure alongside FIT-fecal DNA and Flexible Sigmoidoscopy. The recommendation states that ''CRC screening tests are ranked in 3 tiers based on performance features, costs, and practical considerations. The first-tier tests are colonoscopy every 10 years and annual fecal immunochemical test (FIT). Colonoscopy and FIT are recommended as the cornerstones of screening regardless of how screening is offered. Thus, in a sequential approach based on colonoscopy offered first, FIT should be offered to patients who decline colonoscopy. Colonoscopy and FIT are recommended as tests of choice when multiple options are presented as alternatives. A risk-stratified approach is also appropriate, with FIT screening in populations with an estimated low prevalence of advanced neoplasia and colonoscopy screening in high prevalence populations. The second-tier tests include CT colonography every 5 years, the FIT-fecal DNA test every 3 years, and flexible sigmoidoscopy every 5 to 10 years. These tests are appropriate screening tests, but each has disadvantages relative to the tier 1 tests.'' In terms of benefits of CTC, the MSTF describes lower risk of perforation compared with colonoscopy and write, ''CT colonography appeals to a niche of patients who are willing to undergo bowel preparation and are concerned about the risks of colonoscopy.'' In terms of risks and tradeoffs, the MSTF describe the requirement for bowel preparation, extracolonic findings, inferior sensitivity compared to other screening tests and radiation exposure. The MSTF writes, ''[e]vidence that CT colonography reduces CRC incidence or mortality is lacking.''

We also consider the online resource RadiologyInfo,[646] which is an online public information resource developed by health care professionals in collaboration with patients. RadiologyInfo is sponsored by the Radiological Society of North America (RSNA) and the American College of Radiology (ACR). In terms of benefits of CTC, RadiologyInfo described CTC as less invasive than a Colonoscopy, though for CTC a small tube is inserted into the rectum to allow for inflation with carbon dioxide or air. In addition, CTC does not require sedation (and transportation accommodations) and carries less risk of bowel perforation compared to Colonoscopy. In addition, CTC can identify precancerous polyps that may not be detected by stool-based and blood-based tests. CTC may be a less burdensome first option for patients who are medically fragile or have complex or unusual anatomy. In terms of risks and tradeoffs, RadiologyInfo describes a very small risk of perforated bowel (during inflation), a small risk of secondary cancer due to radiation exposure and it being not recommended for individuals who are pregnant. RadiologyInfo reports that CTC applies a patient radiation exposure similar to Barium Enema at 6 millisieverts (mSv), which is greater than other preventive screenings, such as CT Lung Cancer Screening at 1.5mSv and screening digital mammography at 0.21 mSv.[647]

After considering the above recommendations and guidelines from appropriate organizations, we believe CTC to be reasonable and necessary as CRC screening test, especially for patients and clinicians who seek a direct visualization procedure as a first step in CRC screening that is less invasive and less burdensome on the patient and healthcare system compared to Screening Colonoscopy. Our goal is that the patient and their clinician make the most appropriate choice in CRC screening, which includes considerations of the risks, burdens and tradeoffs for each covered test or procedure. We expect that clinicians who order CTC for CRC Screening will educate their patients on risks and context of radiation exposure and potential extracolonic findings. A shared decision-making tool is not mandated but may be helpful for clinicians and patients to weigh their options for CRC screening.

We propose to add CTC as a covered CRC screening test at § 410.37. We propose to describe in regulatory text that CTC means a test that uses X-rays and computers to produce images of the entire colon (including image processing and a physician's interpretation of the results of the procedure). We also propose to codify in regulatory text that Medicare Part B pays for a screening computed tomography colonography if it is ordered in writing by the beneficiary's attending physician, physician assistant, nurse practitioner, or clinical nurse specialist. We also propose the following limitations of coverage for CTC:

- In the case of an individual age 45 or over who is not at high risk of colorectal cancer, payment may be made for a screening computed tomography colonography performed after at least 59 months have passed following the month in which the last screening computed tomography colonography or 47 months have passed following the month in which the last screening flexible sigmoidoscopy or screening colonoscopy was performed.
- In the case of an individual who is at high risk for colorectal cancer, payment may be made for a screening computed tomography colonography performed after at least 23 months have passed following the month in which the last screening computed tomography colonography or the last screening colonoscopy was performed.

Congress has eliminated Part B coinsurance (section 1833(a)(1)(Y) of the Act, § 410.152(l)(5)) and deductibles (section 1833(b)(1) of the Act) for covered prevention services recommended with a grade of A or B by the USPSTF. As described earlier in our proposal, the USPSTF included CTC as a screening method in their May 2021 revised Final Recommendation Statement on CRC screening (Grade A). Thus, if our proposal is finalized, CTC will require no Part B coinsurance nor deductible when furnished as a CRC screening procedure. We clarify that CTC will continue to require Part B coinsurance and deductible when furnished as a diagnostic or other non-preventive/screening procedure.

We look forward to further consultation with the public and appropriate organizations through the public comment period of this proposed rule. We invite public comment on this proposal.

We also propose to exercise our authority in section 1861(pp)(1)(D) of the Act to expand our approach to a ''complete CRC screening'' finalized in § 410.37(k). We propose to add a Medicare covered Blood-based Biomarker CRC screening test (described and authorized in NCD 210.3) alongside the Medicare covered non-invasive stool-based CRC screening test within our approach of a ''complete CRC screening.''

Our goal is for the patient and their healthcare professional to make the most appropriate choice in CRC

[645] Am J Gastroenterol 2017; 112:1016–1030; doi: 10.1038/ajg.2017.174; published online 6 June 2017.

[646] RadiologyInfo website: *https://www.radiologyinfo.org/.*

[647] *https://www.radiologyinfo.org/en/info/safety-xray.*

screening, which include considerations of the risks, burdens and barriers presented with an invasive screening colonoscopy in a clinical setting as their first step. CRC screening presents a unique scenario where there are significant differences between screening stool-based tests and direct visualization procedures such as colonoscopy, flexible sigmoidoscopy and CTC tests in terms of invasiveness and burdens to the patient and healthcare system. We recognize there are several advantages to choosing a non-invasive CRC screening test as a first step compared to a screening colonoscopy, including relative ease of administering the test and potentially reducing the experience of burdensome preparation and invasive procedures. Since the CY 2023 PFS final rule we have heard from many interested parties, including a number of professional societies, that Medicare covered blood-based biomarker tests would be appropriately placed alongside covered non-invasive stool-based tests within a complete colorectal cancer screening context. We have reconsidered our position that Medicare covered blood-based biomarker tests would not belong alongside covered non-invasive stool-based tests within our approach to a complete CRC screening. We consider that some patients may consider a blood test less uncomfortable than administering a stool-based test, especially if the blood draw is concurrent to a routine blood draw for other covered routine bloodwork. We have also heard that some patients may prefer a non-invasive test as their first step but view the stool sample collection process for stool-based tests as a meaningful barrier.[648] We also consider that a blood test may be more accessible to many patients in rural and underserved communities than facilities that furnish screening colonoscopies, flexible sigmoidoscopies and CTC.

NCD 210.3 requires that Blood-based Biomarker Tests for CRC screening must have Food and Drug Administration (FDA) market authorization with an indication for colorectal cancer screening; and proven test performance characteristics for a blood-based screening test with both sensitivity greater than or equal to 74 percent and specificity greater than or equal to 90 percent in the detection of colorectal cancer compared to the recognized standard (accepted as colonoscopy at this time), as minimal threshold levels, based on the pivotal studies included in the FDA labeling. We have heard from interested parties that Blood-based Biomarker tests for CRC screening may achieve the coverage requirements described in NCD 210.3 within the near term and thereafter quickly become adopted as a non-invasive option within the healthcare system and patient community. Given our existing coverage policy for Blood-based Biomarker Tests for CRC Screening (NCD 210.3), we believe our proposal is appropriately proactive, provides for consistent regulatory treatment between blood and stool-based tests, and will ready our regulatory policies for the quickly evolving state of medical technology in methods for CRC screening. We note that while blood-based biomarker tests were not included as a screening method within the May 2021 USPSTF revised Final Recommendation Statement on CRC Screening, they do not require beneficiary cost sharing (coinsurance and deductible) because blood-based biomarker tests will be paid under the Clinical Laboratory Fee Schedule (CLFS). For additional information, see the CMS website at *https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs.*

We propose to revise the regulatory text describing a complete CRC screening at § 410.37(k) to state that colorectal cancer screening tests include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based colorectal cancer screening test or a Medicare covered blood-based biomarker CRC screening test returns a positive result. We also propose to revise the regulatory text at § 410.37(k) to state the instance of the follow-on colonoscopy in the context of a complete colorectal cancer screening shall not apply to the frequency limitations for colorectal cancer screenings. We believe this statement in regulatory text is clearer and recognizes, outside the context of a complete colorectal cancer screening, the instance of a screening colonoscopy is factored into the calculation of frequency limitations of other covered CRC screening tests and procedures in addition to a subsequent screening colonoscopy.

We look forward to further consultation with the public and appropriate organizations through the public comment period of this proposed rule. We invite public comment on this proposal.

6. Summary

In summary, we are proposing to exercise our authority at section 1861(pp)(1)(D) of the Act update and expand coverage for CRC screening by (1) removing coverage for the barium enema procedure for CRC screening; (2) adding coverage of the CTC procedure for CRC screening; and (3) expanding our approach to a ''Complete CRC Screening'' to include a covered blood-based biomarker test alongside a covered non-invasive stool-based test.

Our proposal to update and expand CRC screening aligns with the administration's strategic pillar to advance health equity by addressing the health disparities that underlie our health system. In addition, our proposal supports Executive Order 13985 by advancing racial equity and support for underserved communities in the Medicare program. We believe our proposal will directly advance health equity by promoting access and removing barriers for much needed cancer prevention and early detection within rural communities and communities of color that are especially impacted by the incidence of CRC. Our proposal to expand colorectal cancer screening directly supports the Administration's Cancer Moonshot Goal of reducing the deadly impact of cancer and improving patient experiences in the diagnosis, treatment, and survival of cancer.[649]

Our proposal is also supportive of the Administration's Proclamation of March as National Colorectal Cancer Awareness Month in 2024, which includes the statement, ''As a country, we have made impressive progress in the struggle to end cancer over the past several decades due to advancements in prevention, early-detection measures, and new medicines and therapies. Despite remarkable breakthroughs, every year, more Americans are diagnosed with cancer under the age of 50. Earlier detection and improved treatment of colorectal cancer continue to be critical goals of medical research. Further progress is also needed to improve outcomes for those who are disproportionately impacted by this disease—including Americans over the age of 45, Native Americans, Black Americans, and people with a family history of colorectal cancer. There is still more work to be done to ensure more Americans can prevent, detect, treat, and survive colorectal cancer.'' [650]

[648] Kolata, Gina. ''A Blood Test Shows Promise for Early Colan Cancer Detection'' The New York Times, March 13, 2024.

[649] *https://www.whitehouse.gov/cancer-moonshot/.*

[650] *https://www.whitehouse.gov/briefing-room/presidential-actions/2024/02/29/proclamation-on-national-colorectal-cancer-awareness-month-2024/.*

L. Requirements for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan

1. Previous Regulatory Action

Section 2003 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act (Pub. L. 115–271, October 24, 2018) generally mandates that the prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D be done electronically in accordance with an electronic prescription drug program beginning January 1, 2021, subject to any exceptions, which HHS may specify. In the CY 2021, CY 2022, CY 2023, and CY 2024 PFS final rules, we finalized policies for the CMS Electronic Prescribing for Controlled Substances (EPCS) Program requirements specified in section 2003 of the SUPPORT Act. We refer readers to 85 FR 84802 through 84807, 86 FR 65361 through 65370, 87 FR 70008 through 70014, and 88 FR 79285 through 79292 for the details of those finalized policies. Specifically, in the CY 2021 PFS final rule, we established a requirement that all prescribers conduct electronic prescribing of Schedule II, III, IV, and V controlled substances covered under the Medicare prescription drug program, subject to any exceptions, which HHS may specify, using the NCPDP SCRIPT standard version 2017071 with an effective date of January 1, 2021, and a compliance date of January 1, 2022 (85 FR 84807). In the CY 2022 PFS final rule, we finalized a policy to require prescribers to electronically prescribe at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs, except in cases where an exception or waiver applies (86 FR 65366); and finalized multiple proposals related to the classes of exceptions specified by section 2003 of the SUPPORT Act (86 FR 65366 through 65369). We also extended the earliest date of compliance actions to no earlier than January 1, 2023 (86 FR 65364). For prescribers who do not meet the compliance threshold based on prescriptions written for a beneficiary in a long-term care (LTC) facility, we extended the earliest date of compliance actions to no earlier than January 1, 2025 (86 FR 65364 and 65365). We also finalized our proposal to limit compliance actions with respect to compliance through December 31, 2023, to a non-compliance notice (86 FR 65370).

In the CY 2023 PFS final rule (87 FR 70012 through 70013), we extended the non-compliance action of sending notices to non-compliant prescribers, which we had finalized for the CY 2023 CMS EPCS Program implementation year (January 1, 2023, through December 31, 2023), to the CY 2024 Program implementation year (January 1, 2024, through December 31, 2024). We also finalized a change to the data sources used to identify the geographic location of prescribers for purposes of the recognized emergency exception at § 423.160(a)(5)(iii) (87 FR 70011 through 70012) and finalized our proposal to use the Prescription Drug Event (PDE) data from the current evaluated year instead of the preceding year when CMS determines whether a prescriber qualifies for an exception based on issuing 100 or fewer Part D controlled substance prescriptions per calendar year (87 FR 70009 through 70011).

In the CY 2024 PFS final rule (88 FR 79285 through 79287), we identified certain terms that we will use in the CMS EPCS Program and clarified that, by virtue of the cross reference in § 423.160(a)(5) to ''the applicable standards in paragraph (b) of this section,'' which refers to the standards in § 423.160(b), the CMS EPCS Program will automatically adopt the electronic prescribing standards at § 423.160(b) as they are updated. Additionally, we finalized our proposals to remove the same entity exception from the CMS EPCS Program and to add ''subject to the exemption in paragraph (a)(3)(iii) of this section'' to § 423.160(a)(5) (88 FR 79287 through 79288). As a result, prescriptions that are prescribed and dispensed within the same legal entity are included in CMS EPCS Program compliance calculations as part of the 70 percent compliance threshold at § 423.160(a)(5), and prescribers are not exempt from the requirement to prescribe electronically at least 70 percent of their Schedule II through V controlled substances that are Part D drugs—but such prescriptions have to meet the applicable standards in § 423.160(b) subject to the exemption in § 423.160(a)(3)(iii). We also finalized a policy to count only the unique prescriptions in the measurement year for the purposes of CMS EPCS Program compliance threshold calculations (88 FR 79288). Furthermore, for the exceptions that we moved to § 423.160(a)(5)(ii) and (iii), we modified the exceptions to permit prescribers to apply for waivers in times of an emergency and disaster and to limit the emergencies or disasters that will trigger the recognized emergency exception. We also modified the duration of both exceptions and established timing requirements for submitting a waiver application (88 FR 79288 through 79291). Lastly, we stated that we will send notices of non-compliance for each measurement year a prescriber is non-compliant and will provide educational opportunities to support prescribers in becoming compliant (88 FR 79291 through 79292).

2. Timeline for Including Prescriptions Written for Beneficiaries in Long-Term Care (LTC) Facilities in CMS EPCS Program Compliance Calculation

a. Background

In the CY 2021 PFS final rule (85 FR 84807), we adopted the requirement for all Schedule II, III, IV, and V controlled substances for covered Part D drugs prescribed electronically to be prescribed using the applicable standards in § 423.160(b), including the NCPDP SCRIPT standard version 2017071. In the CY 2022 PFS final rule (86 FR 65364), we finalized a policy to extend the date on or after which we will pursue compliance actions against prescribers based on Part D controlled substance prescriptions those prescribers write for beneficiaries in long-term care (LTC) facilities to January 1, 2025. We acknowledged that prescribers who work in LTC facilities or who provide care to residents in LTC facilities faced technological barriers that other prescribers did not face. One such barrier was that the NCPDP SCRIPT standard version 2017071 lacked appropriate guidance for EPCS in LTC facilities. We also noted that NCPDP was in the process of creating a new version of the SCRIPT standard that would be better suited for use by prescribers serving LTC facilities, which would allow willing partners to enable three-way communication between the prescriber, LTC facility, and pharmacy to bridge any outstanding gaps that impede use of the NCPDP SCRIPT standard version 2017071 for EPCS in the LTC setting (86 FR 65364).

We received public comments on the CY 2022 PFS proposed rule requesting that we exempt prescribers writing Part D controlled substance prescriptions for beneficiaries in LTC facilities from having to conduct EPCS until after NCPDP SCRIPT standard version 2022011 was adopted. In response to those comments, in the CY 2022 PFS final rule, we noted that our intent when extending the date on or after which we will pursue compliance actions against prescribers based on Part D controlled substance prescriptions those prescribers write for beneficiaries in LTC facilities was to strike a balance between being responsive to stakeholder

concerns surrounding the increased implementation barriers faced by LTC facilities, while at the same time helping to ensure that these facilities eventually implement, and receive the benefits of EPCS (86 FR 65364). Furthermore, we noted that we were not persuaded to further delay commencing compliance actions to await publication of the NCPDP SCRIPT standard version 2022011. We acknowledged that three-way communication is not as seamless in the NCPDP SCRIPT standard version 2017071 as it may be in upcoming versions. We also stated that three-way communication is still possible with some modifications to EPCS, and therefore, we did not believe it would be appropriate to adopt a further delay on this basis alone (86 FR 65364).

In the 2024 PFS final rule (88 FR 79286 through 79287), we clarified that based on the existing regulatory text at § 423.160(a)(5), the CMS EPCS Program will automatically adopt the electronic prescribing standards at § 423.160(b) as they are updated. We noted that in the ''Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications'' proposed rule (CY 2024 Medicare Advantage and Part D Policy and Technical Changes proposed rule) (87 FR 79550), we proposed to update provisions related to e-prescribing standards at § 423.160(b), including, after a transition period, requiring the NCPDP SCRIPT standard version 2022011 proposed for adoption at 45 CFR 170.205(b) and retiring NCPDP SCRIPT standard version 2017071 by January 1, 2025.

Although we did not propose any policy changes regarding the NCPDP SCRIPT standard version in the CY 2024 PFS proposed rule (88 FR 52532), we received public comments requesting clarification on when the new NCPDP SCRIPT standard version would be adopted and the implications for measuring EPCS compliance in LTC. In response to those comments, in the CY 2024 PFS final rule (88 FR 79286), we acknowledged that we had not finalized our proposal regarding the NCPDP SCRIPT standard version 2022011 that was proposed in the CY 2024 Medicare Advantage and Part D Policy and Technical Changes proposed rule. We also acknowledged that some prescribers prescribing for beneficiaries in LTC facilities have adopted EPCS, but that others have waited for the standard to be updated (88 FR 79286 through 79287). We noted that if the requirement to use an updated version of the NCPDP SCRIPT standard is finalized for a date after January 1, 2025, we may explore whether a waiver is appropriate for prescribers who are not compliant solely as a result of prescriptions they have written for beneficiaries in LTC facilities or we may revisit the compliance start date, if needed, through future rulemaking (88 FR 79287).

In the ''Medicare Program; Medicare Prescription Drug Benefit Program; Health Information Technology Standards and Implementation Specifications'' final rule (89 FR 51242 through 51247), which appeared in the June 17, 2024 **Federal Register** (hereinafter referred to as the June 2024 Part D and Health IT Standards final rule), we finalized at § 423.160(b)(1) the requirement that Part D sponsors, prescribers and dispensers, when electronically transmitting prescriptions and prescription-related information for covered Part D drugs for Part D eligible individuals, must comply with a standard in 45 CFR 170.205(b). Taken in conjunction with the standards and expiration date adopted by the Office of the National Coordinator for Health Information Technology (ONC), as described in the June 2024 Part D and Health IT Standards final rule (89 FR 51258 through 51259), § 423.160(b)(1) will require use of NCPDP SCRIPT standard version 2023011, which ONC is adopting at 45 CFR 170.205(b)(2), beginning January 1, 2028, and retire use of NCPDP SCRIPT standard version 2017071, which ONC previously adopted at 45 CFR 170.205(b)(1) and to which it is applying an expiration date of January 1, 2028. ONC finalized January 1, 2028, as the expiration date for NCPDP SCRIPT standard version 2017071 instead of January 1, 2027, in consideration of public comments requesting that the date be delayed. As a result of these policies being finalized, the NCPDP SCRIPT standard version 2023011 will be required for the CMS EPCS Program by January 1, 2028. As both NCPDP SCRIPT standard version 2017071 and NCPDP SCRIPT standard version 2023011 will be adopted at 45 CFR 170.205(b) and unexpired as of the effective date of the June 2024 Part D and Health IT Standards final rule, entities subject to the requirement at § 423.160(b)(1) may use either version of the NCPDP SCRIPT standard during the transition period beginning July 17, 2024, the effective date of the June 2024 Part D and Health IT Standards final rule, and ending December 31, 2027, which is the last day before NCPDP SCRIPT standard version 2017071 will expire for the purposes of HHS use.

b. Barriers to Electronic Prescribing of Controlled Substances for Beneficiaries in LTC and the Role of Three-Way Communication in the NCPDP SCRIPT Standard

We understand the challenges of conducting EPCS in the LTC setting to be multifactorial. The specific challenges include prescribers being responsible for covering multiple LTC facilities, each with different electronic health record (EHR) systems; reliance on LTC nursing staff to communicate prescriptions to the pharmacy on behalf of the prescriber; and with respect to NCPDP SCRIPT standard version 2017071, lack of three-way (or multi-party) communication between the prescriber, the LTC facility, and the pharmacy.

When conducting EPCS using the NCPDP SCRIPT standard version 2017071, prescribers can submit prescriptions electronically to the pharmacy, but the prescriber must subsequently contact the LTC facility separately to give an order for the medication so the LTC facility can administer the medication to the patient as prescribed. In cases where EPCS is being conducted and the prescriber has not communicated a separate order to the LTC facility, the pharmacy may deliver a prescription to the LTC facility and the facility staff has no record of the order. Then the LTC facility staff must contact the prescriber for an order to be able to administer the drug to the patient.

To conduct EPCS without having to separately communicate an order to the LTC facility, prescribers can use a web portal to enter an order in the LTC facility's EHR and then, if the EHR supports the necessary EPCS capability,[651] the prescription can be transferred to the pharmacy. However, not all LTC facilities have EHRs with this functionality. Additionally, each LTC facility may have its own web portal, making the number of portals and credentials overly burdensome for prescribers who treat patients who

[651] According to the Drug Enforcement Administration (DEA), for an electronic prescribing system to be used to transmit controlled substance prescriptions, a third party must audit the electronic prescribing application for compliance with the requirements of 21 CFR part 1311, or a certifying organization whose certification process has been approved by DEA must verify and certify that the application meets the requirements of 21 CFR part 1311. See *https://www.deadiversion.usdoj.gov/ecomm/thirdparty.html.*

reside in multiple different LTC facilities. After providing an order to the LTC facility, prescribers often rely on LTC facility nursing staff to relay verbal prescription orders to pharmacies as permitted under 21 CFR 1306.03(b) and 1306.21(a).

NCPDP SCRIPT standard version 2023011 permits three-way communication that would better facilitate LTC workflows in a way that NCPDP SCRIPT standard version 2017071 does not. In comments NCPDP submitted in response to the CY 2025 Medicare Advantage and Part D Policy and Technical Changes proposed rule, NCPDP confirmed that it attempted to create guidance on three-way communication using the NCPDP SCRIPT standard version 2017071, but it was not realistic in that version of the standard.[652] In NCPDP SCRIPT standard version 2023011, through use of a MessageIndicatorFlag, an RxFill transaction may be sent as a copy to inform or synchronize systems.[653] Through use of this functionality, a prescriber can electronically send a controlled substance prescription (including for a covered Part D drug) to a pharmacy, and the pharmacy can use the MessageIndicatorFlag in an RxFill transaction when dispensing the prescription to inform the LTC facility of the medication order. This functionality streamlines prescribers' workflows and ensures that the LTC facility responsible for providing the controlled substance to the patient is aware of the order.

c. Timeframe for Including Prescriptions Written for Beneficiaries in LTC in the CMS EPCS Program Compliance Calculation

We received multiple public comments in response to the proposal in section III.B.4. of the CY 2025 Medicare Advantage and Part D Policy and Technical Changes proposed rule (88 FR 78489) to require NCPDP SCRIPT standard version 2023011 and retire NCPDP SCRIPT standard version 2017071, requesting that we reconsider the current January 1, 2025, compliance date for when we will include prescriptions written for covered Part D drugs for Part D eligible individuals in a LTC facility in the CMS EPCS Program compliance calculation. Commenters requested that we align the CMS EPCS Program compliance date for prescriptions written for beneficiaries in LTC with the date that NCPDP SCRIPT standard 2023011 will be required. In the June 2024 Part D and Health IT Standards final rule, we indicated that we would consider a change to the CMS EPCS Program compliance date for LTC through the annual Medicare Physician Fee Schedule rulemaking process (89 FR 51247).

In this proposed rule, we are proposing to revise § 423.160(a)(5) to state that prescriptions written for a beneficiary in a LTC facility would not be included in determining compliance until January 1, 2028, and that compliance actions against prescribers who do not meet the compliance threshold based on prescriptions written for a beneficiary in a LTC facility would commence on or after January 1, 2028. We do not otherwise propose to revise the text of § 423.160(a)(5).

As of the effective date of the June 2024 Part D and Health IT Standards final rule, July 17, 2024, Part D sponsors, prescribers and dispensers, when electronically transmitting prescriptions and prescription-related information for covered Part D drugs for Part D eligible individuals, may use NCPDP SCRIPT standard version 2023011. However, as discussed, there will be a transition period where both NCPDP SCRIPT standard version 2023011 and NCPDP SCRIPT standard version 2017071 can be used. ONC finalized an expiration date for NCPDP SCRIPT standard version 2017071 of January 1, 2028 (rather than January 1, 2027, as proposed), in part due to commenters' concern about implementing the new standard in LTC facilities (89 FR 51247).

We recognize the administrative burden prescribers could potentially face when implementing EPCS for prescriptions written for covered Part D drugs for Part D eligible individuals in LTC facilities using NCPDP SCRIPT standard version 2017071, particularly with the lack of guidance. We also believe that even though prescribers can use NCPDP SCRIPT standard version 2023011 as of July 17, 2024, it may not be feasible to have electronic prescribing systems configured to NCPDP SCRIPT standard version 2023011 by January 1, 2025, the current date by which prescriptions written for covered Part D drugs for Part D eligible individuals in LTC facilities would be included in the CMS EPCS Program compliance threshold calculation. By delaying the inclusion of prescriptions written for covered Part D drugs for Part D eligible individuals in LTC facilities in the CMS EPCS Program compliance threshold calculation to January 1, 2028, we would be aligning CMS EPCS Program compliance calculations to the date by which the NCPDP SCRIPT standard version 2017071 is retired and the new NCPDP SCRIPT standard version 2023011 is required for prescribers when electronically transmitting prescriptions and prescription-related information for covered Part D drugs for Part D eligible individuals. We believe doing so would provide sufficient time for prescribers and pharmacies to adopt the new standard. Moreover, LTC facilities will need to configure their EHR systems to be able to receive the MessageIndicatorFlag from the pharmacy, indicating that the prescription has been filled, and establish the necessary policies or operations to convert such a message into an order for the patient in the LTC facility.

We considered an alternative where we would permit prescribers to apply for a waiver for circumstances beyond their control rather than modify the date to include prescriptions for beneficiaries in LTC in the compliance threshold calculation. In 2022, approximately 4.7 percent (4.5 million) of Part D Schedule II, III, IV, and V controlled substance prescriptions were written for beneficiaries in LTC facilities, with roughly 52 percent (2.4 million) of them not meeting the CMS EPCS Program standards for e-prescribing. If we kept the existing start date of January 1, 2025, as in the current regulatory text at § 423.160(a)(5) for the CMS EPCS Program, we estimate at least 6,800 additional prescribers would become non-compliant. These estimates are prior to considering emergency and disaster exceptions and waivers, which could reduce these numbers. If we do not extend the current date by which prescriptions written for covered Part D drugs for Part D eligible individuals in LTC facilities would be included in the CMS EPCS Program compliance threshold calculation, then starting with the CY 2025 measurement year, thousands of prescribers may become non-compliant, and those prescribers would potentially apply for a waiver. We would expect that by the CY 2028 measurement year, many of these prescribers would be compliant and would not need to apply for a waiver because beginning January 1, 2028, NCPDP SCRIPT standard version 2023011 will be the required standard for prescribing and dispensing Part D

[652] *https://standards.ncpdp.org/Standards/media/pdf/Correspondence/2024/NCPDP-Letter-to-CMS-regarding-CMS-4205-P.pdf.*

[653] National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard, Implementation Guide, Version 2023011. Approval Date for American National Standards Institute (ANSI): January 17, 2023, April 2023. NCPDP SCRIPT standard implementation guides are available to NCPDP members for free and to non-members for a fee at *https://standards.ncpdp.org/Access-to-Standards.aspx.*

drugs to Part D eligible individuals and commenters have indicated that this version of the standard will facilitate EPCS in LTC. We remind prescribers that the CMS EPCS Program compliance rate is calculated using the Prescription Origin Code data element in the PDE record (88 FR 79287), and the PDE is a record of the prescription dispensing event.[654] We believe that the three-way communication in the NCPDP SCRIPT standard version 2023011 improves communication of the controlled substance prescription as a medication order to the LTC facility's EHR when the pharmacy fills the prescription, but we seek comment on how the NCPDP SCRIPT standard version 2023011 will improve prescribers' ability to conduct EPCS to the pharmacy dispensing the prescription for individuals in LTC facilities.

Should we finalize our proposal, we encourage prescribers who write Schedule II, III, IV, or V controlled substance prescriptions for covered Part D drugs for Part D eligible individuals in LTC facilities to use the additional time to prepare for when such prescriptions for beneficiaries in LTC facilities would be included in the CMS EPCS Program compliance threshold calculation by working to adopt the new standard or investing in technology necessary to conduct EPCS.

We seek comment on our proposals to extend the date after which prescriptions for covered Part D drugs for Part D eligible individuals in LTC facilities would be included in our CMS EPCS Program compliance threshold calculation from January 1, 2025, to January 1, 2028, and that related non-compliance actions would commence on or after January 1, 2028. We additionally seek comment on how NCPDP SCRIPT standard version 2023011 is expected to improve prescribers' ability to conduct EPCS to pharmacies dispensing covered Part D drugs to Part D eligible individuals in LTC facilities.

[654] CMS Memorandum. ''Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE).'' April 27, 2006. Available from: *https://www.csscoperations.com/internet/csscw3_files.nsf/F/CSSCPDEGuidance.pdf/$FILE/PDEGuidance.pdf.*

M. Expand Hepatitis B Vaccine Coverage

Hepatitis B vaccines are currently covered as a Medicare Part B benefit under section 1861(s)(10)(B) of the Act. Medicare beneficiaries who are at high or intermediate risk of contracting hepatitis B can receive hepatitis B vaccines, with no cost to the beneficiary. The statute expressly authorizes the Secretary to determine who is at high or intermediate risk of contracting hepatitis B by issuing regulations. The Secretary, through past rulemaking, defined high and intermediate risk groups for hepatitis B vaccine at 42 CFR 410.63. This definition was last updated in the CY 2013 PFS final rule (77 FR 69363). Beneficiaries with coverage under Medicare Part D whose level of risk falls outside high or intermediate may have their vaccine covered under the Part D benefit.[655]

Medicare coverage of hepatitis B vaccination is outdated in light of more recent information about the risks of contracting hepatitis B. As explained in more detail in this section, we are proposing to improve access and utilization of hepatitis B vaccines by expanding the list of individuals who are at high or intermediate risk of contracting hepatitis B in § 410.63(a).

1. Background

Hepatitis B is a vaccine-preventable liver disease caused by the hepatitis B virus.[656] The vaccine consists of a series of typically 2–3 doses depending on the formulation delivered at various intervals.[657] Hepatitis B virus is transmitted when body fluid (blood, semen, or other) from a person infected with the virus enters the body of someone who is uninfected.[658] This can happen through sexual contact; sharing needles, syringes, or other drug-injection equipment; transmission from the gestational parent to baby during pregnancy or at birth; direct contact with blood or open sores; or sharing contaminated items such as toothbrushes, razors or medical equipment (such as a glucose monitor) of a person who has hepatitis B.[659] Hepatitis B can be an acute, short-term illness and it can develop into a long-term, chronic infection. Chronic hepatitis B can lead to serious health problems, including cirrhosis, liver cancer, and death. Treatments for hepatitis B are available but no cure exists. There are currently an estimated 2.4 million individuals in the U.S. living with hepatitis B virus and an estimated 20,000 new infections every year.[660] Acute hepatitis B infections among adults leads to chronic hepatitis B disease in an estimated 2–6 percent of cases.[661] Rates of reported cases of acute hepatitis B have steadily increased among persons aged 40–49, 50–59 years, and 60 years and older from 2015–2019.[662] In 2020, rates declined in all adult age groups. In 2021, rates among all age groups remain stable or declined compared to 2020. The highest rates were among persons 40–49 years (1.6 cases per 100,000 population) and 50–59 years (1.0 case per 100,000 population). The rates for people aged 60 years and older were 0.5 cases per 100,000 population.

[655] Sayed, BA, Finegold, K, Ashok, K, Schutz, S, De Lew, N, Sheingold, S, Sommers, BD. Inflation Reduction Act Research Series: Medicare Part D Enrollee Savings from Elimination of Vaccine Cost-Sharing. (Issue Brief No. HP–2023–05). Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. September 2023. Retrieved from *https://aspe.hhs.gov/sites/default/files/documents/407d41b6534e7af6702eb280b3945d00/aspe-ira-vaccine-part-d.pdf.*

[656] CDC, 2023. Hepatitis B surveillance 2021. Retrieved from *https://www.cdc.gov/hepatitis/statistics/2021surveillance/hepatitis-b.htm.*

[657] CDC. Viral hepatitis. FAQ for health professionals. Atlanta, GA: U.S. HHS, CDC; 2022. Retrieved from *https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm.*

[658] CDC, 2023. Hepatitis B surveillance 2021. Retrieved from *https://www.cdc.gov/hepatitis/statistics/2021surveillance/hepatitis-b.htm.*

[659] CDC. 2024. Viral Hepatitis FAQs for the public. Retrieved from *https://www.cdc.gov/hepatitis/hbv/bfaq.htm.*

[660] Conners EE, Panagiotakopoulos L, Hofmeister MG, et al. Screening and testing for hepatitis B virus infection: CDC recommendations—United States, 2023. *MMWR Recomm Rep.* 2023;72(1):1–25. Retrieved from *https://www.cdc.gov/mmwr/volumes/72/rr/rr7201a1.htm.*

[661] Weng, M., Doshani, M., Khan, M., Frey, S., et al. Universal hepatitis B vaccination in adults aged 19–59 years: Updated recommendations of the Advisory Committee on Immunization Practices—United States, 2022. *MMWR,* April 1, 2022, Vol 71(13);477–483.

[662] CDC. Viral hepatitis. 2021 viral hepatitis surveillance report. Atlanta, GA: U.S. HHS, CDC; 2023. Retrieved from *https://www.cdc.gov/hepatitis/statistics/2021surveillance/hepatitis-b/figure-2.4.htm.*

Hepatitis B vaccines are safe and effective in preventing hepatitis B virus.[663] The number of reported hepatitis B cases has declined substantially since the vaccine was introduced in 1982, which was achieved through incremental expansion of groups for whom the vaccine was recommended. However, vaccination coverage among adults has been deficient and further reduction in hepatitis B infections in the U.S. has stalled. Approximately 34 percent of adults aged ≥19 years have been vaccinated against hepatitis B.[664] Furthermore, an estimated 20 percent of adults aged ≥60 years have been vaccinated against hepatitis B.

Since 2011, rates of reported cases of acute hepatitis B decreased among children and adolescents aged 0–19 years and persons aged 20–29 years.[665] The Centers for Disease Control and Prevention (CDC) states that this is due, in part, because of the childhood hepatitis B vaccine recommendations that were first implemented in 1991. The Advisory Group for Immunization Practices (ACIP) is a group of medical and public health experts that develops recommendations on how to use vaccines to control diseases in the U.S. and the CDC updates the U.S. adult and childhood immunization schedules consistent with ACIP recommendations.[666] As the cohort of persons vaccinated as children have grown older, rates of acute hepatitis B among persons aged 30–39 years began to consistently decrease beginning in 2015.[667] Conversely, rates of reported cases of acute hepatitis B have steadily increased among persons aged 40–49, 50–59 years, and 60 years and older from 2015–2019 (see Table 52). Overall, the rate of acute hepatitis B cases increased 11 percent from 2014 (0.9 per 100,000) to 2018 (1.0 per 100,000).[668] Injection drug use and sexual transmission are known risk factors associated with rising acute hepatitis B cases. For example, acute hepatitis B infections increased 114 percent from 2006 to 2013 in three states affected by the opioid epidemic (Kentucky, Tennessee, and West Virginia).[669]

TABLE 52: Rates of Reported Acute Hepatitis B Virus Infection, by Age Group – United States

Age (years)	2015	2016	2017	2018	2019
0–19	0.0	0.0	0.0	0.0	0.0
20–29	0.8	0.6	0.6	0.6	0.5
30–39	2.6	2.4	2.3	2.0	1.8
40–49	2.4	2.2	2.5	2.6	2.7
50–59	1.4	1.5	1.6	1.6	1.6
≥60	0.5	0.5	0.6	0.6	0.6
Source: CDC, National Notifiable Diseases Surveillance System.					
* Rates per 100,000 population. Beginning in 2021, single-race population estimates are used for rate calculations. For prior years, bridged-race population estimates are used.					
† Reported confirmed cases. For the case definition, see https://ndc.services.cdc.gov/conditions/hepatitis-b-acute/.					

2. Statutory Authority

Section 1861(s)(10)(B) of the Act provides a benefit category under Part B for hepatitis B vaccine and its administration, furnished to an individual who is at high or intermediate risk of contracting hepatitis. The statute expressly authorizes the Secretary to determine who is at high or intermediate risk of contracting hepatitis B for coverage of the hepatitis B vaccine.

3. Regulation

Medicare Part B pays for the hepatitis B vaccine as defined in § 410.63(a), which describes individuals who are at high or intermediate risk of contracting hepatitis and covered for hepatitis B vaccinations. In the CY 2013 PFS final rule (77 FR 69363), CMS expanded the definition of individuals at risk of contracting hepatitis B, citing updated ACIP recommendations about increased risk for diabetes patients to support the change. The ACIP stated that the hepatitis B outbreaks were associated with adults with diabetes receiving assisted blood glucose monitoring.[670] Today, the regulations are outdated as these risk categories have been shown ineffective and are no longer the focus of how the medical community discusses hepatitis B infection and

[663] Weng, M., et al. 2022. Universal hepatitis B vaccination.

[664] CDC. 2023. Vaccination Coverage among Adults in the United States, National Health Interview Survey, 2021. Retrieved from *https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/vaccination-coverage-adults-2021.html#:~:text=Hepatitis%20B%20vaccination%20coverage%20in,and%20Other%20(40.2%25)%20adults.*

[665] CDC. Viral hepatitis. 2021 viral hepatitis surveillance report. Atlanta, GA: U.S. HHS, CDC; 2023. Retrieved from *https://www.cdc.gov/hepatitis/statistics/2021surveillance/hepatitis-b/figure-2.4.htm.*

[666] CDC. ACIP. Retrieved from *https://www.cdc.gov/vaccines/acip/index.html.*

[667] CDC. Viral hepatitis. 2021 viral hepatitis surveillance report. Atlanta, GA: U.S. HHS, CDC; 2023. Retrieved from *https://www.cdc.gov/hepatitis/statistics/2021surveillance/hepatitis-b/figure-2.4.htm.*

[668] CDC 2020. Viral hepatitis surveillance report 2018—Hepatitis B. Retrieved from *https://www.cdc.gov/hepatitis/statistics/2018surveillance/HepB.htm.*

[669] HHS. 2016. Viral Hepatitis in the United States: Data and Trends. Retrieved from *https://www.hhs.gov/hepatitis/learn-about-viral-hepatitis/data-and-trends/index.html.*

[670] CDC. 2011. Use of Hepatitis B Vaccination for Adults with Diabetes Mellitus: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR. 60(50);1709–1711. Retrieved from *https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6050a4.htm#:~:text=Based%20on%20the%20Work%20Group,made%20(recommendation%20category%20A).*

prevention. In 2019, risk behavior and exposure data were missing for 37 percent of case reports (1,183 of 3,192) of acute hepatitis B infections received by CDC.[671] ACIP also cited a large national survey of family medicine and internal medicine physicians assessing barriers to adult hepatitis B vaccination and found that 68% cited patients' non-disclosure of risk factors.[672]

4. Proposed Regulatory Revisions

Since 1991, hepatitis B vaccination has been recommended by ACIP and the CDC for infants at birth, completing the vaccination series by 16 months of age.[673] This is important because in the U.S., the age cohorts who have received the completed series have low to no risk of contracting the hepatitis B virus, as evidenced by the rate of zero acute hepatitis B virus infections for the 0–19 age group.[674] The infant and childhood recommendations were not in place for most of today's adults which is evidenced by no other age group reaching a rate of zero acute hepatitis B virus infections. Given this information, we consider the population of people who have completed the vaccination series to be at low risk of contracting the hepatitis B virus. Individuals who remain unvaccinated against hepatitis B are at intermediate risk, at minimum, of contracting hepatitis B virus.

We conclude that anyone who is not fully vaccinated to be at intermediate risk of contracting the hepatitis B virus as their risk would be above zero. Additionally, rates of reported cases of acute hepatitis B steadily increased among age groups 40 and over between 2015 and 2019, with stabilizing or declining rates between 2020 and 2021, which may be due to the COVID–19 pandemic.[675] While it is encouraging to see declining rates, these populations remain at intermediate risk given their reported cases remained above zero. Therefore, we propose to revise § 410.63(a)(2), Intermediate Risk Groups, by adding a new paragraph (a)(iv) to include individuals who have not previously received a completed hepatitis B vaccination series or whose vaccination history is unknown. We include the latter group in this proposal because the CDC has stated that it is not harmful to receive either extra doses or a repeat vaccination series.[676] This will allow these individuals to receive a covered vaccination series when medical history may not be available. Also, the CDC states that screening for hepatitis B virus is not a requirement for vaccination, and in settings where screening is not feasible, vaccination of persons recommended to receive the vaccine should continue.

We note that § 410.63(a)(3) provides an exception to individuals considered intermediate or high risk of contracting hepatitis B. This includes individuals who have undergone a prevaccination screening and have been found to be currently positive for antibodies to hepatitis B. We propose that this exception apply to the proposed § 410.63(a)(2)(iv) because individuals with previous infection would not benefit from the vaccine. However, it should be noted that the CDC states that it is not harmful to vaccinate people who are immune to hepatitis B virus because of current or previous infection or vaccination, nor does it increase the risk for adverse events.[677]

5. Summary

This proposal will help protect Medicare beneficiaries from acquiring hepatitis B infection, contribute to eliminating viral hepatitis as a public health threat in the United States and is in the best interest of the Medicare program and its beneficiaries. We look forward to receiving public comment on these proposals.

N. Low Titer O+ Whole Blood Transfusion Therapy During Ground Ambulance Transport

1. Ambulance Fee Schedule Background

Section 1861(s)(7) of the Act establishes an ambulance service as a Medicare Part B service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. Our regulations relating to coverage for ambulance services are set forth at 42 CFR part 410, subpart B. Since April 1, 2002, payment for ambulance services has been made under the ambulance fee schedule (AFS), which the Secretary established, as required by section 1834(l) of the Act, in 42 CFR part 414, subpart H. Payment for an ambulance service is made at the lesser of the actual billed amount or the AFS amount, which consists of a base rate for the level of service, a separate payment for mileage to the nearest appropriate facility, a geographic adjustment factor (GAF), and other applicable adjustment factors as set forth at section 1834(l) of the Act and § 414.610 of the regulations. In accordance with section 1834(l)(3) of the Act and § 414.610(f), the AFS rates are adjusted annually based on an inflation factor. The AFS also incorporates two permanent add-on payments in § 414.610(c)(5)(i) and three temporary add-on payments in § 414.610(c)(1)(ii) and (c)(5)(ii) to the base rate and/or mileage rate.

2. Low Titer O+ Whole Blood Transfusion Therapy During Ground Ambulance Transport

Under the AFS, Medicare Part B covers seven levels of service for ground (including water) ambulance transports and two levels of service for air ambulance transports. The levels of service for ground ambulance transports include basic life support (emergency); basic life support (non-emergency); advanced life support, level 1 (ALS1) (emergency); ALS1 (non-emergency); advanced life support, level 2 (ALS2); paramedic intercept; and specialty care transport (§ 410.40(c)). Definitions for the levels of service can be found at § 414.605 and in the Medicare Benefit Policy Manual, Chapter 10, Ambulance Services, section 30.1.1, Definition of Ground Ambulance Services.

At § 414.605, ALS2 is defined as either transportation by ground ambulance vehicle, medically necessary supplies and services, and the administration of at least three medications by intravenous push/bolus or by continuous infusion, excluding crystalloid, hypotonic, isotonic, and hypertonic solutions (Dextrose, Normal Saline, Ringer's Lactate); or transportation, medically necessary supplies and services, and the provision of at least one of the following ALS procedures: (1) Manual defibrillation/cardioversion; (2) Endotracheal intubation; (3) Central venous line; (4) Cardiac pacing; (5) Chest decompression; (6) Surgical airway; (7) Intraosseous line. These procedures must be performed by ALS personnel trained to the level of the emergency

[671] Weng, M., et al. 2022. Universal hepatitis B vaccination.

[672] Daley MF, Hennessey KA, Weinbaum CM, et al. Physician practices regarding adult hepatitis B vaccination: a national survey. Am J Prev Med 2009;36:491–6. PMID:19362798 *https://doi.org/10.1016/j. amepre.2009.01.037.*

[673] CDC, 2024. Vaccine safety: Hepatitis B vaccines. Retrieved from *https://www.cdc.gov/vaccinesafety/vaccines/hepatitis-b-vaccine.html#:~:text=CDC%20recommends%20hepatitis%20B%20vaccine,not%20yet%20gotten%20the%20vaccine.*

[674] CDC. Viral hepatitis. 2021 viral hepatitis surveillance report. Atlanta, GA: U.S. HHS, CDC; 2023. Retrieved from *https://www.cdc.gov/hepatitis/statistics/2021surveillance/hepatitis-b/figure-2.4.htm.*

[675] CDC, 2023. Hepatitis B surveillance 2021. Retrieved from *https://www.cdc.gov/hepatitis/statistics/2021surveillance/hepatitis-b.htm.*

[676] CDC. Viral hepatitis. FAQ for health professionals. Atlanta, GA: U.S. HHS, CDC; 2022. Retrieved from *https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm.*

[677] CDC. Viral hepatitis. FAQ for health professionals. Atlanta, GA: U.S. HHS, CDC; 2022. Retrieved from *https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm.*

medical technician-intermediate (EMT-Intermediate) or paramedic (§ 414.605).

According to the 2020 National Association of State Emergency Medical Services Organizations Assessment (NASEMSO), there are approximately 11,450 ground EMS agencies that provide 9–1–1 response with transport to an acute care hospital.[678] The administration of low titer O+ whole blood transfusions, otherwise referred to as whole blood transfusion therapy (WBT), began in 2017 when two Emergency Medical Services (EMS) systems in Texas began providing WBT to patients in hemorrhagic shock during ambulance transports. Prior to this, use of blood products in the treatment of hemorrhagic shock in the form of blood component therapy was available only in the hospital setting and by one EMS system. Low titer O+ whole blood contains low levels of antibodies that patients of any blood type can receive and is provided in EMS settings to significantly increase these patients' chances of survival.

By September 2023, over 121 EMS systems in the United States were using blood products in the form of either WBT, packed red blood cells (PRBCs), plasma, or a combination of PRBCs and plasma.[679] Seventy percent of these systems were using WBT.[680] As of March 2024, 147 (1.2 percent of the EMS systems in the United States) now carry whole blood products, with 200 or more systems anticipated to provide some form of blood product transfusion by the end of 2024.[681] Today, nearly 60 percent of those 147 EMS systems carry low titer O+ whole blood, with the remainder utilizing other blood products.[682]

EMS systems that administer WBT and other blood products (PRBCs and plasma) generally utilize it for patients suffering hemorrhagic shock stemming from traumatic injury, though it may also be indicated in certain non-traumatic medical conditions such as hemorrhagic shock from a gastrointestinal bleed.[683] Traditional resuscitation protocol for massive hemorrhage from trauma and other medical conditions such as gastrointestinal bleeding consists of crystalloid fluids and blood component transfusions, which consist of a balanced portion of PBRCs, platelets, and fresh frozen plasma.[684]

During the conflicts in Iraq and Afghanistan, use of this traditional protocol was difficult due to the austere combat environment and limited availability of blood components, which often necessitated the use of fresh whole blood (FWB) in traumatic resuscitation.[685] Data collected related to these conflicts demonstrated improvements in survival rate and reductions in transfusion requirements for military casualties in hemorrhagic shock who received FWB versus those receiving traditional blood component transfusion and spurred research and interest in the use of WBT in civilian trauma.[686] Additional data demonstrating an improvement in 24-hour and 30-day survival rate among medically evacuated combat casualties in Afghanistan who received prehospital transfusion encouraged research and interest in these techniques for possible deployment by EMS services.[687]

In the treatment of civilian patients with hemorrhagic shock from trauma, studies have demonstrated that WBT provides a substantial survival benefit versus traditional component therapy,[688] especially when provided early in the prehospital and hospital settings.[689] One study found WBT increased the survival of such patients by as much 60 percent and reduced the need for additional blood products in the 24-hour period following the initial transfusion by 7 percent.[690] Another study noted that there was a significant increase in the 24-hour and 30-day survival rate in patients suffering from severe hemorrhage requiring a large transfusion volume.[691]

Patients suffering from hemorrhagic shock require stabilization in the field and rapid transport to an acute care hospital to treat the source of hemorrhage.[692] Individuals who are experiencing hemorrhagic shock primarily due to blood loss may require WBT as their only resuscitative treatment. Each unit of whole blood takes 5–8 minutes to transfuse.[693] Depending on the time needed to transport and clinical need, patients generally receive 1–2 units of WBT during ground transport.[694]

While there may be variance between jurisdictions, the protocols for many EMS systems currently providing WBT

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[678] National Association of State EMS Officials. 2020 National Emergency Medical Services Assessment 2020. Table 3, p 27. Available from: *www./https://nasemso.org/.* Accessed May 1, 2024.

[679] Krohmer J. Chairman, steering committee of the Prehospital Blood Transfusion Initiative Coalition. Virtual Meeting April 23, 2024.

[680] Levy MJ, Garfinkel EM, May R, et al. Implementation of a prehospital whole blood program: Lessons. J Am Coll Emerg Physicians Open. 2024;5: e13142. *https://doi.org/10.1002/emp2.13142.*

[681] Levy MJ, Garfinkel EM, May ER, et al. Implementation of a prehospital whole blood program: Lessons. learned. J Am Coll Emerg Physicians Open. 2024;5: Apr; 5(2): e13142. *https://doi.org/10.1002/emp2.13142.* Krohmer J. Chairman, steering committee of the Prehospital Blood Transfusion Initiative Coalition. Virtual Meeting April 23, 2024.

[682] Ibid.

[683] Ibid.

Braverman MA, Smith A, Ciaraglia AV, et al. The regional whole blood program in San Antonio, TX: A 3-year update on prehospital and in-hospital transfusion practices for traumatic and non-traumatic hemorrhage. Transfusion. 2022; 62: S80–S89.

[684] Young PP, Cotton BA, Goodnough LT. Massive Transfusion Protocols for Patients with Substantial Hemorrhage. Transfusion Medicine Reviews. 2011, Vol 25(4). 293–303.

Washington State Department of Health Office of Community Health Systems Emergency Medical Services and Trauma Section. Trauma Clinical Guideline: Massive Transfusion for Trauma.

[685] Nessen SC, Eastridge BJ, Cronk D, et al. Fresh whole blood use by forward surgical teams in Afghanistan is associated with improved survival compared to component therapy without platelets. Transfusion. 2013;53: 107S–13S.

[686] Spinella PC, Perkins GJ, Grathwohl KW, Beekley AC, Holcomb J. Warm Fresh Whole Blood is Independently Associated with Improved Survival for Patients with Combat-Related Traumatic Injuries. J Trauma. 2009 April; 66(4 Suppl): S69–S76. *doi:10.1097/TA.0b013e31819d85fb.* Nessen SC, Eastridge BJ, Cronk D, et al. Fresh whole blood use by forward surgical teams in Afghanistan is associated with improved survival compared to component therapy without platelets. Transfusion. 2013;53: 107S–13S.

Gurney J, Staudt A, Cap A, Shackleford A, et al. Improved Survival in Critically Injured Combat Casualties Treated with Fresh Whole Blood by Forward Surgical Teams in Afghanistan. Transfusion. 2020;60; S180–S188.

[687] Shackelford SA, del Junco DJ, Powell-Dunford N, Mazuchowski EL, et al. Association of Prehospital Blood Product Transfusion During Medical Evacuation of Combat Casualties in Afghanistan with Acute and 30-Day Survival. JAMA. 2017; 318(16):1581–1591.

[688] Hazelton JP, Ssentongo AE, Oh JS, et al. Use of Cold-Stored Whole Blood is Associated with Improved Mortality in Hemostatic Resuscitation of Major Bleeding. A Multicenter Study. 2022. Annals of Surgery. Vol 276(4). 579–88.

[689] b. Torres CM, Kent A, Scantling D, et al. Association of Whole Blood With Survival Among Patients Presenting With Severe Hemorrhage in US and Canadian Adult Civilian Trauma Centers. JAMA Surg. 2023;158(5):532–540. doi: *10.1001/jamasurg.2022.6978.*

Brill JB, Tang B, Hatton G, Mueck KM, et al. Impact of incorporating whole blood into hemorrhagic shock resuscitation: Analysis of 1,377 consecutive trauma patients receiving emergency-release uncrossmatched blood products. J Am Coll Surg. 2022;234(4):408–418.

Guyette FX, Sperry JL, Peitzman AB, et al. Prehospital blood product and crystalloid resuscitation in the severely injured patient: a secondary analysis of the prehospital air medical plasma trial. Ann Surg. 2021;273:358–364.

[690] Ibid.

[691] Ibid.

[692] Centers for Disease Control and Prevention. Guidelines for field triage of injured patients. MMWR. 2009;58 (RR–1):1–34.

[693] Vitberg D. Assistant Medical Director. District of Columbia Fire and EMS Department. Zoom meeting. February 20, 2024. Bank EA. Assistant Chief of EMS. Co-Chair of the South East Regional Advisory Council Trauma Committee. Phone conversation, May 10, 2024.

[694] Krohmer J. Chairman, steering committee of the Prehospital Blood Transfusion Initiative Coalition. Virtual Meeting April 23, 2024.

are designed for patients who require complex management at the advanced life support level, demonstrating suspicion of blood loss along with evidence of physiologic shock as indicated by parameters such as low blood pressure, an elevated pulse rate, or slow capillary refill.[695] Other relevant factors may include an elevated lactate level, an EtCO2 waveform capnography reading <25 as surrogate for elevated lactate, a shock index (heart rate/systolic blood pressure) >1, and, where appropriate and consistent with protocol, authorization by online or other medical authority.[696]

We believe that many ground ambulance transports providing WBT already qualify for ALS2 payment, since patients requiring such transfusions are generally critically injured or ill and often suffering from cardio-respiratory failure and/or shock, and therefore are likely to receive one or more procedures currently listed as ALS procedures in the definition of ALS2, with endotracheal intubation, chest decompression, and/or placement of a central venous line or an intraosseous line the most probable to be seen in these circumstances. Patients requiring WBT are typically suffering from hemorrhagic shock, for which the usual course of treatment includes airway stabilization, control of the hemorrhagic source, and stabilization of blood pressure using crystalloid infusion and the provision of WBT or other blood product treatments when available, but not necessarily the administration of advanced cardiac life support medications.[697] Consequently, we do not believe it is likely that most patients who may require WBT would trigger the other pathway to qualify as ALS2, the administration of at least three medications by intravenous push/bolus or by continuous infusion, excluding crystalloid, hypotonic, isotonic, and hypertonic solutions (Dextrose, Normal Saline, Ringer's Lactate).

However, not all ground ambulance transports providing WBT may already qualify for ALS2 payment. An ambulance transport would not qualify for ALS2 payment where a patient received only WBT during a ground ambulance transport, and not one or more other services that, either by themselves or in combination, presently qualify as ALS2. We believe WBT should independently qualify as an ALS2 procedure because the administration of WBT and handling of low titer O+ whole blood require a complex level of care beyond ALS1 for which EMS providers and suppliers at the EMT-Intermediate or paramedic level require additional training. In addition, WBT requires specialized equipment such as a blood warmer and rapid infuser.[698] While there is no established national training protocol, many systems follow the guidelines of the Association for the Advancement of Blood and Biotherapies (AABB), which requires additional training that is 4 hours in length for paramedics and 6 hours in length for EMS supervisory staff.[699] Medicare's requirements for ambulance staffing at 42 CFR 410.41(b) include compliance with state and local laws, which here would establish appropriate training requirements with respect to WBT administration.

Therefore, we believe it is appropriate to modify the definition of ALS2 to account for the instances where patients are administered WBT but do not otherwise qualify for ALS2 payment. Of note, we do not have the authority to provide an additional payment, such as an add-on payment for the administration of WBT under the AFS.

We propose to modify the definition of ALS2 at § 414.605 by adding the administration of low titer O+ whole blood transfusion to the current list of seven ALS2 procedures as a new number 8. We would also reflect this change in the Medicare Benefit Policy Manual, Chapter 10, Ambulance Services, section 30.1.1, Definition of Ground Ambulance Services. Under this proposal, a ground ambulance transport that provides WBT would itself constitute an ALS2-level transport.

We are aware that some established EMS systems may already provide WBT to treat patients in hemorrhagic shock, while other jurisdictions, including those in rural areas, will not and often will rely on alternative blood product treatments such as PRBCs and plasma. The availability of WBT in rural areas is a complex and multifactorial issue. Fluctuating stock of the ''raw product'' (blood donations) along with local healthcare demands for blood products (PRBCs, platelets, plasma, etc.) affect the availability of WBT. Other issues in rural areas include the logistical challenges and the costs involved in acquiring fresh units of WBT and returning any unused units to a supplier.[700]

The training, administration and monitoring is the same for these alternative blood product treatments as it is for WBT. While we are not including alternative blood product treatments in our proposal, we are seeking comment on whether we should add alternative blood product treatments to the list of ALS2 procedures. We invite comments on this proposal to add the administration of low titer O+ whole blood transfusion as an ALS2 procedure and comments on whether we should add alternative blood product treatments such as the administration of PRBCs or plasma.

O. Medicare Parts A and B Overpayment Provisions of the Affordable Care Act

1. Executive Summary

In the proposed rule titled ''Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications'', which appeared in the December 27, 2022 **Federal Register**, we proposed to amend our regulations regarding the standard for an ''identified overpayment'' under Medicare Parts A, B, C, and D to align the regulations with the statutory language in section 1128J(d)(4)(A) of the Act, which provides that the terms ''knowing'' and ''knowingly'' have the meaning given those terms in the Federal False Claims Act (the False

[695] Mark H. Yazer, Philip C. Spinella, Eric A. Bank, Jeremy W. Cannon, Nancy M. Dunbar, John B. Holcomb, Bryon P. Jackson, Donald Jenkins, Michael Levy, Paul E. Pepe, Jason L. Sperry, James R. Stubbs & Christopher J. Winckler (2022) THOR–AABB Working Party Recommendations for a Prehospital Blood Product Transfusion Program, Prehospital Emergency Care, 26:6, 863–875.

Ibid., *https://miemss.org/home/Clinicians/Whole-Blood.*

[696] Ibid.

[697] Prehospital Hemorrhage Control and Treatment by Clinicians: A Joint Position Statement. Ann Emerg Med. 2023;82:e1–e8.

[698] Pokorny DM, Braverman MA, Edmundson PM, et al. The use of prehospital blood products in the resuscitation of trauma patients; a review of prehospital transfusion practices and a description of our regional whole blood program in San Antionio, TX. ISBT science series, 2018–08, Vol, 14(3), p. 332–42.

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Claims Act) at 31 U.S.C. 3729(b)(1)(A) (87 FR 79452). We refer to that rule as the ''December 2022 Overpayment Proposed Rule.'' In the December 2022 Overpayment Proposed Rule, we proposed to remove the existing ''reasonable diligence'' standard and adopt by reference the False Claims Act definition of ''knowing'' and ''knowingly'' as set forth at 31 U.S.C. 3729(b)(1)(A).

We have not yet finalized our proposals with respect to overpayments under Medicare Parts A and B in the December 2022 Overpayment Proposed Rule. Instead, after considering the public comments we received in connection with the December 2022 Overpayments Proposed Rule, we are retaining the Parts A and B proposals published in the December 2022 Overpayment Proposed Rule and we are now making additional proposals to revise existing regulations at § 401.305(b) regarding the deadline for reporting and returning overpayments.

2. Provisions of the Proposed Regulation (Preamble)

Section 6402(a) of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively known as the Affordable Care Act), established section 1128J(d) of the Act. Section 1128J(d)(1) of the Act requires a person who has received an overpayment to report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, and to notify the Secretary, State, intermediary, carrier or contractor to which the overpayment was returned in writing of the reason for the overpayment. Section 1128J(d)(4)(B) of the Act defines the term ''overpayment'' as any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title. For purposes of Medicare Parts A and B, section 1128J(d)(4)(C) of the Act defines the term ''person'' to include providers and suppliers as those terms are defined in the Act. Section 1128J(d)(4)(C) of the Act also defines the term ''person,'' for purposes of Medicare Parts C and D, to also include a Medicare Advantage organization (MAO) (as defined in section 1859(a)(1) of the Act) and a Part D Plan (PDP) sponsor (as defined in section 1860D–41(a)(13) of the Act).

Section 1128J(d)(2) of the Act requires that an overpayment be reported and returned by the later of: (1) the date which is 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable. Section 1128J(d)(3) of the Act specifies that any overpayment retained by a person after the deadline for reporting and returning an overpayment is an obligation (as defined in 31 U.S.C. 3729(b)(3)) for purposes of the False Claims Act, 31 U.S.C. 3729.

Section 1128J(d)(4)(A) of the Act provides that the terms ''knowing'' and ''knowingly'' have the meaning given those terms in the False Claims Act at 31 U.S.C. 3729(b)(1)(A). The False Claims Act (31 U.S.C. 3729(b)(1)(A)) defines the terms ''knowing'' and ''knowingly'' to include information about which a person ''has actual knowledge,'' ''acts in deliberate ignorance of the truth or falsity of the information,'' or ''acts in reckless disregard of the truth or falsity of the information.''

a. Regulations Promulgated Under Section 1128J(d) of the Act

On May 23, 2014, CMS published a final rule titled ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (79 FR 29844) (hereinafter referred to as the ''Parts C and D Overpayment Final Rule''), which provided, among other things, that an MAO or PDP sponsor has identified an overpayment when the MAO or PDP sponsor has determined, or should have determined through the exercise of reasonable diligence, that the MAO or PDP sponsor has received an overpayment.

On February 12, 2016, we published a final rule titled ''Medicare Program; Reporting and Returning of Overpayments'' (81 FR 7654) (hereinafter referred to as the ''Parts A and B Overpayment Final Rule''), which provided, among other things, that a provider or supplier has identified an overpayment when the provider or supplier has determined, or should have determined through the exercise of reasonable diligence, that the provider or supplier has received an overpayment and quantified the amount of the overpayment.

In the December 2022 Overpayment Proposed Rule, we proposed to amend the existing regulations for Medicare Parts A and B, as well as Parts C and D, regarding the standard for an ''identified overpayment'' to align the regulations with the statutory language in section 1128J(d)(4)(A) of the Act. If finalized, these regulations would assign the meaning of the terms ''knowing'' and ''knowingly'' in the False Claims Act at 31 U.S.C. 3729(b)(1)(A) to our regulations for purposes of Medicare overpayments. Specifically, in the December 2022 Overpayment Proposed Rule, we proposed to remove the existing ''reasonable diligence'' standard and adopt by reference the False Claims Act definition of ''knowing'' and ''knowingly'' as set forth at 31 U.S.C. 3729(b)(1)(A). We continue to review the comments we received on the December 2022 Overpayment Proposed Rule, and we plan to respond both to those comments and the comments we receive on our new proposals when we publish the CY 2025 Physician Fee Schedule final rule.

b. Relevant Litigation

In *UnitedHealthcare Insurance Co.* v. *Azar,* a group of MAOs challenged the Parts C and D Overpayment Final Rule, and the District Court held, in relevant part, that by requiring MAOs to use ''reasonable diligence'' in searching for and identifying overpayments, CMS impermissibly established False Claims Act liability for mere negligence. *UnitedHealthcare Ins. Co.* v. *Azar,* 330 F. Supp. 3d 173, 191 (D.D.C. 2018), rev'd in part on other grounds sub nom. *UnitedHealthcare Ins. Co.* v. *Becerra,* 16 F.4th 867 (D.C. Cir. 2021), cert. denied, 142 S. Ct. 2851 (U.S. June 21, 2022) (No. 21–1140). The District Court noted that ''(t)he False Claims Act—which the ACA refers to for enforcement, *see* 42 U.S.C. 1320a–7k(d)(3)—imposes liability for erroneous ('false') claims for payment submitted to the government that are submitted 'knowingly' . . . a term of art defined in the FCA to include false information about which a person 'has actual knowledge,' 'acts in deliberate ignorance of the truth or falsity of the information,' or 'acts in reckless disregard of the truth or falsity of the information.' '' *Id.* at 190.

Although the court's ruling applied only to Medicare Part C, to provide for consistency in Medicare regulations related to reporting and returning overpayments, in the December 2022 Overpayment Proposed Rule, we proposed to amend the regulations at current § 401.305(a)(2) to remove the reference to ''reasonable diligence'' and replace it with language incorporating the terminology of section 1128J(d)(4)(A) of the Act by ascribing the terms ''knowing'' and ''knowingly'' the same meaning given those terms in the False Claims Act at 31 U.S.C. 3729(b)(1)(A). *See UnitedHealthcare,* 330 F. Supp. 3d at 191 (finding that this language would be consistent with a 2000 agency rule, the False Claims Act,

and the Affordable Care Act's reference to the False Claims Act).

c. Provisions of Proposed Regulations

In addition to our earlier proposals, which remain under consideration, we make the following new proposals.

Existing § 401.305(b)(1) specifies when a person who has received an overpayment must report and return an overpayment. We propose to amend this paragraph to reference revised § 401.305(b)(2), as well as to reference newly-proposed § 401.305(b)(3).

Existing § 401.305(b)(2) specifies the circumstances under which the deadline for returning overpayments will be suspended. Overpayments must be reported no later than the date which is 60 days after the date on which the overpayment was identified or the date any corresponding cost report is due, if applicable. However, the deadline for returning a reported overpayment will be suspended under specified circumstances, including the acknowledgement of receipt of a submission to the OIG Self-Disclosure Protocol or the CMS Voluntary Self-Referral Disclosure Protocol, or under specified conditions if a person requests an extended repayment schedule as defined in § 401.603. We are proposing a technical modification to the introductory language in § 401.305(b)(2) to acknowledge that this section might be applicable after the suspension described in new § 401.305(b)(3) is complete.

New proposed § 401.305(b)(3) would specify the circumstances under which the deadline for reporting and returning overpayments would be suspended to allow time for providers to investigate and calculate overpayments. Proposed § 401.305(b)(3)(i) provides that the deadline to report and return an overpayment would be suspended if: (1) a person has identified an overpayment but has not yet completed a good-faith investigation to determine the existence of related overpayments that may arise from the same or similar cause or reason as the initially identified overpayment; and (2) the person conducts a timely, good-faith investigation to determine whether related overpayments exist. Proposed § 401.305(b)(3)(ii) provides that, if the conditions for proposed § 401.305(b)(3)(i) are met, the deadline for reporting and returning the initially identified overpayment and related overpayments that arise from the same or similar cause or reason as the initially identified overpayment will remain suspended until the earlier of the date that the investigation of related overpayments has concluded and the aggregate amount of the initially identified overpayments and related overpayments is calculated, *or* the date that is 180 days after the date on which the initial identified overpayment was identified.

The following example may elucidate a hypothetical circumstance. Assume that, on day 1, a person identifies an overpayment arising from a physician's failure to properly document the medical record to support the coding of a specific claim, and the person has reason to believe that this may be a common practice of the physician, so there could be more affected claims. At this point, the person has up to 180 days to conduct and conclude a good faith investigation to determine whether related overpayments that arise from the same or similar cause or reason as the initially identified overpayment exist. If the person does NOT conduct an investigation, or the investigation is not timely or not conducted in good faith, the identified overpayment must be reported and returned by day 60. If the person does conduct a timely, good faith investigation, suspension of the report and return obligation under § 401.305(b)(3) begins on day 1. The suspension ends when the investigation is concluded and the initially identified overpayment and related overpayments, if any, are calculated, or by day 180, whichever is earlier. The overpayment must be reported and returned within 60 days after either completion of the investigation or day 180, whichever is earlier. However, the suspensions described in § 401.305(b)(2) may also be applicable. For example, if the person is reporting the overpayment to the OIG Self-Disclosure Protocol, as provided for in § 401.305(b)(2) the overpayment return requirement may be further suspended in accordance with that provision.

We make these proposals because many of the comments that we received on the December 2022 Overpayment Proposed Rule expressed concern that we proposed to remove the term ''quantified'' from the original regulatory text. We believe that our proposals, especially proposed § 401.305(b)(3)(ii)(A), would address this concern. Other commenters expressed concern that the December 2022 Overpayment Proposed Rule proposals removed a perceived 6-month time period to investigate all overpayments that was referenced in an example in the preamble to the original 2016 Parts A and B Overpayment Rule. The December 2022 Overpayment Proposed Rule was silent on this point and did not remove this time period to investigate overpayments. We understand the importance of allowing time to investigate and calculate overpayments. Therefore, we propose to codify this allowance into regulation at proposed § 401.305(b)(3)(ii).

We solicit comment on these proposals.

IV. Updates to the Quality Payment Program

A. CY 2025 Modifications to the Quality Payment Program

1. Executive Summary

a. Overview

This section of this proposed rule sets forth proposed changes to the Quality Payment Program starting January 1, 2025, except as otherwise noted for specific provisions. We continue to move the Quality Payment Program forward, including focusing more on alignment and new options for clinicians to participate in a more meaningful way, to achieve continuous improvement in the quality of health care services provided to Medicare beneficiaries and other patients through the Quality Payment Program's Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs) for the CY 2025 performance period/2027 MIPS payment year.

Authorized by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015), the Quality Payment Program is a value-based payment program, by which the Medicare program rewards clinicians who provide high-value, high-quality care to their patients in a cost-efficient manner. There are two ways for clinicians who provide services under the Medicare program to participate in the Quality Payment Program: MIPS and Advanced APMs. The statutory requirements for the Quality Payment Program are set forth in section 1848(q) and (r) of the Act for MIPS and section 1833(z) of the Act for Advanced APMs.

For the MIPS participation track, MIPS eligible clinicians (defined in § 414.1305) [701] are subject to a MIPS payment adjustment (positive, negative, or neutral) based on their performance in four performance categories: cost, quality, improvement activities, and Promoting Interoperability. We assess each MIPS eligible clinician's total performance according to established performance standards with respect to

[701] We note that the term MIPS eligible clinician is defined in § 414.1305 as including a group of at least one MIPS eligible clinician billing under a single tax identification number. We refer readers to our policies governing group reporting and scoring under MIPS as set forth in § 414.1310(e).

the applicable measures and activities specified in each of these four performance categories during a performance period to compute a final composite performance score (a ''final score'' as defined at § 414.1305). In calculating the final score, we must apply different weights for the four performance categories, subject to certain exceptions, as set forth in section 1848(q)(5) of the Act and at § 414.1380. Unless we assign a different scoring weight pursuant to these exceptions, for CY 2025 performance period/2027 MIPS payment year, the scoring weights are as follows: 30 percent for the quality performance category; 30 percent for the cost performance category; 15 percent for the improvement activities performance category; and 25 percent for the Promoting Interoperability performance category.

Once calculated, each MIPS eligible clinician's final score is compared to the performance threshold established in prior rulemaking for that performance period to calculate the MIPS payment adjustment factor as specified in section 1848(q)(6) of the Act, such that the MIPS eligible clinician will receive in the applicable MIPS payment year: (1) a positive adjustment, if their final score exceeds the performance threshold; (2) a neutral adjustment, if their final score meets the performance threshold; or (3) a negative adjustment, if their final score is below the performance threshold. In calculating the MIPS payment adjustment factor for a MIPS eligible clinician, CMS accounts for scaling factor and budget neutrality requirements, as further specified in section 1848(q)(6) of the Act. CMS then applies the MIPS payment adjustment factor to amounts otherwise paid under Part B with respect to covered professional services for the MIPS eligible clinician for the applicable MIPS payment year such that their payments for such covered professional services are increased, decreased, or not adjusted based on the MIPS eligible clinician's final score relative to the performance threshold.

Section 1848(q) of the Act sets forth other requirements applicable to MIPS, including opportunities for feedback and targeted review and public reporting of MIPS eligible clinicians' performance. Section 1848(r) of the Act sets forth more specific requirements for development of measures for the cost performance category under MIPS.

For the Advanced APM track, if an eligible clinician participates in an Advanced APM and achieves Qualifying APM Participant (QP) or Partial QP status, they are excluded from the MIPS reporting requirements and payment adjustment (though eligible clinicians who are Partial QPs may elect to be subject to the MIPS reporting requirements and payment adjustment). Eligible clinicians who are QPs for the CY 2024 performance year receive a 1.88 percent APM Incentive Payment in the 2026 payment year. Beginning with the CY 2024 performance year (payment year 2026), QPs will also receive a higher PFS payment rate (calculated using the differentially higher ''qualifying APM conversion factor'') than non-QPs. QPs will continue to be excluded from MIPS reporting and payment adjustments for the applicable year.

We plan to continue developing policies for the Quality Payment Program that more effectively reward high-quality of care for patients and increase opportunities for Advanced APM participation. We are continuing to develop new MIPS Value Pathways (MVPs) to allow for a more cohesive participation experience by connecting activities and measures from the four MIPS performance categories that are relevant to a specialty, medical condition, or a particular population.

As we move into the eighth year of the Quality Payment Program, we are proposing the updates set forth in this section of this proposed rule, encouraging continued improvement in clinicians' performance with each performance year and driving improved quality of health care through payment policy.

b. Summary of Major Proposals

(1) Transforming the Quality Payment Program

Our National Quality Strategy (*https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy*) addresses the urgent need to advance towards a more equitable, safe, and outcomes-based health care system for all individuals. We have a corresponding cohesive value-based care strategy for Medicare along three main pillars: Alignment, Growth, and Equity.[702] We continue to focus on transforming health care delivery [703] and our 2030 goal to have all traditional Medicare beneficiaries in an accountable care relationship with their health care provider. In pursuit of this vision, we are driving higher value care, supporting Advanced APM participation, increasing alignment to reduce burden, and promoting health equity. We are exploring new care delivery and payment models; for example, we are considering an ambulatory care model that would connect payment to performance for specialists in the ambulatory setting to increase the number of specialists who deliver longitudinal care in an accountable manner and to support greater integration between specialty and primary care. This potential model would utilize MVPs as a foundation for assessing specialist performance (refer to section III.J of this proposed rule). We are proposing in section II.G.2 of this proposed rule to make payment for advanced primary care management (APCM) services furnished by a physician or other qualified health care professional who is responsible for all primary care (for example, physicians and non-physician practitioners, including nurse practitioners, physician assistants, certified nurse-midwives and clinical nurse specialists), and serve as the continuing focal point for all needed health care services during a calendar month. This proposed payment would incorporate several specific, existing care management and communication technology-based services into a bundle and include a performance measurements requirement that could be met by reporting the Value in Primary Care MVP by clinicians billing for APCM services. We are proposing that billing practitioners who are not MIPS eligible clinicians (as defined at 42 CFR 414.1305) would not have to report the MVP in order to furnish and bill for APCM services.

Separately, we are implementing MVPs and subgroup reporting option to allow clinicians to report on a cohesive set of measures that more directly reflect their clinical practice. MVPs allow for more clinically relevant performance measurement, engage more specialists in performance measurement, and help reduce barriers to APM participation. While traditional MIPS continues to be a submission option, we intend to move to full MVP adoption and to sunset traditional MIPS in the future.

In section IV.A.3.d of this proposed rule, we discuss a Request for Information (RFI) that addresses how we can best achieve full MVP adoption and subgroup participation as we plan to move forward with sunsetting traditional MIPS and advancing the three pillars and the National Quality Strategy. We seek feedback on clinician readiness to report MVPs, how we

[702] Update On The Medicare Value-Based Care Strategy: Alignment, Growth, Equity, Health Affairs Forefront, March 14, 2024. *https://www.healthaffairs.org/content/forefront/update-medicare-value-based-care-strategy-alignment-growth-equity.*

[703] Quality in Motion, Acting on the CMS National Quality Strategy, April 2024. *https://www.cms.gov/files/document/quality-motion-cms-national-quality-strategy.pdf.*

should ensure there are applicable MVPs for all clinicians, and what parameters, including logistical and regulatory policies, are needed for multispecialty groups to place clinicians into subgroups for reporting an MVP relevant to the scope of care provided.

(a) MIPS Value Pathways Development and Maintenance

In an effort to promote high-quality, safe, and equitable care and to implement the vision outlined in the CMS National Quality Strategy, we are proposing six new MVPs around the following topics: Complete Ophthalmologic Care, Dermatological Care, Gastroenterology Care, Optimal Care for Patients with Urologic Conditions, Pulmonology Care and Surgical Care. Complete Ophthalmologic Care, Dermatological Care, Gastroenterology Care, Optimal Care for Patients with Urologic Conditions, Pulmonology Care, and Surgical Care.

We are also proposing to modify the MVP maintenance webinar process to provide more flexibility on how we communicate submitted maintenance recommendations prior to proposing them formally in rulemaking (refer to section IV.A.4.a of this proposed rule).

Lastly, we are proposing MVP maintenance updates to our MVP inventory that are in alignment with the MVP development criteria, and in consideration of the feedback from interested parties we have received through the maintenance process.

(b) MVP Scoring

We are proposing to update the scoring of population health measures in MVPs by using the highest score of all available population health measures, and we are proposing to remove the requirement for MVP Participants to select a population health measure at the time of MVP registration. We are also proposing to modify the MVP scoring policies at § 414.1365(d)(3)(ii) with respect to the cost performance category to refer to, and therefore align with, our methodology for scoring cost measures at § 414.1380(b)(2) under our traditional MIPS policies.. Additionally, we are proposing to align MVP scoring with traditional MIPS policies by removing references to high- and medium-weighted improvement activities in MVPs. We are proposing to update MVP scoring to assign 40 points for each improvement activity to provide full credit for the improvement activities performance category for MVP Participants who report one improvement activity. For the MVP Promoting Interoperability performance category, we are proposing to modify our policy at § 414.1365(c)(4)(i)(A), requiring a subgroup to submit the affiliated group's data for the performance category, by removing references to specific performance periods/MIPS payment years, thereby permitting subgroups to report data for this category in this manner for the CY 2025 performance period/2027 MIPS payment year and beyond.

(c) APM Performance Pathway

We are proposing to create within the APM Performance Pathway (APP) the APP Plus quality measure set beginning with the CY 2025 performance period/2027 MIPS payment year to align with the Universal Foundation measures under the CMS National Quality Strategy. We are not proposing to modify the existing APP quality measure set, which already includes five of the ten Universal Foundation measures. Instead, we are proposing to establish the APP Plus quality measure set as a second, optional measure set that would be comprised of all of the measures in the existing APP quality measure set and would additionally incrementally adopt the remaining five Universal Foundation measures from the CY 2025 performance period/2027 MIPS payment year through the CY 2028 performance period/2030 MIPS payment year. Under this proposal, a MIPS eligible clinician, group, or APM Entity that reports the APP may choose to report either the APP quality measure set or the APP Plus quality measure set.

(d) Data Submission for the Performance Categories

We are proposing to adopt minimum criteria for a qualifying data submission for a MIPS performance period for the quality, improvement activities, and Promoting Interoperability performance categories, which we propose to codify at § 414.1325(a)(1)(i) through (iii). Specifically, we are proposing that a qualifying data submission must include numerator and denominator data for at least one MIPS quality measure from the final list of MIPS quality measures for the quality performance category and include a response of ''yes'' for at least one activity in the MIPS improvement activities Inventory for the improvement activities performance category. For the Promoting Interoperability performance category, we are proposing a qualifying data submission must include: (1) performance data, including any claim of an applicable exclusion, for the measures in each objective, as specified by CMS; (2) required attestation statements, as specified by CMS; (3) CMS EHR Certification ID (CEHRT ID) from the Certified Health IT Product List (CHPL); and (4) the start date and end date for the applicable performance period as set forth in § 414.1320.

We are also proposing to codify our existing policies governing our treatment of multiple data submissions received for the quality and improvement activities performance categories at § 414.1325(f)(1). We are also proposing to modify our policy governing our treatment of multiple data submissions received for the Promoting Interoperability performance category, which we propose to codify at § 414.1325(f)(2). Specifically, for the quality and improvement activities performance categories, we are proposing that for multiple data submissions received from submitters in multiple organizations, CMS will calculate a score for each submission received and assign the highest of the scores. For multiple data submissions received from a submitter in the same organization, CMS will score the most recent submission. For the Promoting Interoperability performance category, we are proposing to modify our policy so that, for multiple data submissions received, CMS would calculate a score for each data submission received and assign the highest of the scores.

(e) MIPS Performance Category Measures and Activities

(i) Quality Performance Category

We are proposing to establish the data submission criteria for the Alternative Payment Model (APM) Performance Pathway (APP) quality measure set; maintain the data completeness criteria threshold to at least 75 percent for the CY 2027 and CY 2028 performance periods/2029 and 2030 MIPS payment years; establish a measure set inventory of 196 MIPS quality measures, of which 193 are available in traditional MIPS and 3 are available only for utilization in MVPs; and codify previously established criteria pertaining to the removal of MIPS quality measures. Additionally, in section IV.A.4.e.(1)(e) of this proposed rule, there are two quality-related RFIs. The first RFI pertains to the potential expansion of the survey modes for the administration of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey, particularly expanding the survey modes from a mail-phone protocol to a web-mail-phone protocol. The second RFI pertains to the potential development of a set of guiding principles that would be utilized for the selection and

implementation of Patient-Reported Outcome Measures (PROMs) and Patient-Reported Outcome Performance Measures (PRO–PMs).

(ii) Cost Performance Category

We are proposing to add six new episode-based measures to the cost performance category beginning with the CY 2025 performance period/2027 MIPS payment year: Chronic Kidney Disease, End-Stage Renal Disease, Kidney Transplant Management, Prostate Cancer, Rheumatoid Arthritis, and Respiratory Infection Hospitalization. We are also proposing modifications to two existing episode-based cost measures so that their specifications reflect re-evaluated versions: Cataract Removal with Intraocular Lens (IOL) Implantation (currently titled Routine Cataract Removal with IOL Implantation) and Inpatient (IP) Percutaneous Coronary Intervention (PCI) (currently titled ST-Elevation Myocardial Infarction (STEMI) PCI). We are proposing to adopt a 20-episode case minimum for the six new episode-based cost measures. We are also proposing to maintain the existing case minimums for the two measures we are proposing to modify in this rulemaking, which are a 20-episode case minimum for the IP PCI measure and a 10-episode case minimum for the Cataract Removal with IOL Implantation measure. Additionally, we are proposing to update the operational list of care episode and patient condition groups and codes to reflect these new and modified measures that we are proposing. Lastly, we are proposing to adopt criteria to specify objective bases for the removal of any cost measures from the MIPS cost performance category, which we are also proposing to codify at § 414.1350(e).

(iii) Improvement Activities Performance Category

As part of our regular maintenance of the improvement activities Inventory, we are proposing to add two new, modify two existing, and remove eight existing improvement activities. The new activities help fill gaps we have identified in the Inventory while the modified and removed activities will ensure that it includes only the most meaningful activities that have a clear path to clinical practice improvement. In addition, we are proposing two changes to the traditional MIPS improvement activities reporting and scoring policies for the CY 2025 performance period/2027 MIPS payment year: to eliminate the weighting of activities and to reduce the number of activities to which clinicians are required to attest to achieve a score in the improvement activities performance category. Lastly, we are proposing to codify seven improvement activity removal factors to establish criteria used to identify activities for potential removal or modification.

(iv) Promoting Interoperability Performance Category

We do not have any proposals for the Promoting Interoperability performance category. We are seeking public comment on a RFI regarding the Public Health Reporting and Data Exchange Objective.

(f) MIPS Final Scoring Methodology

(i) Scoring the Quality Performance Category

We are proposing to implement defined topped out benchmarks for topped out measures in specialty sets affected by limited measure choice. Many specialty sets have not had the measure development that was envisioned early on the program. As a result, we have retained topped out measures to ensure there are applicable measures. To accommodate for this limited measure choice and the rising performance threshold, we are proposing to remove the 7-point topped out measure score cap for clinicians reporting measures included in certain specialty measures and implement a benchmarking strategy for affected measures that would ensure clinicians with limited measure choice are not unfairly penalized. Additionally, we are proposing to apply a Complex Organization Adjustment for virtual groups and APM Entities (including SSP ACOs) reporting eCQMs. We are also proposing to score Medicare CQMs using flat benchmarks for their first 2 years in the program consistent with the Shared Saving Program's policies.

(ii) Scoring the Cost Performance Category

We are proposing to modify our methodology for scoring measures for the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year. Additionally, we are proposing to adopt a new cost measure exclusion policy beginning with the CY 2025 performance period/2027 MIPS payment year.

(g) MIPS Payment Adjustments

We are proposing to establish the mean as the methodology for determining the performance threshold for the CY 2025 performance period/2027 MIPS payment year through the CY 2027 performance period/2029 MIPS payment year. To determine the performance threshold for the CY 2025 performance period/2027 MIPS payment year, we are proposing that we will use the mean of the final scores from the CY 2017 performance period/2019 MIPS payment year. Based on the mean final score from that prior period, we are proposing to establish a performance threshold of 75 points for the CY 2025 performance period/2027 MIPS payment year.

(h) Calculating the Final Score

We are proposing to adopt a new reweighting policy at § 414.1380(c)(2)(i)(A)(*10*) and (c)(2)(i)(C)(*12*). Specifically, we are proposing that, beginning with the CY 2024 performance period/2026 MIPS payment year, we may reweight one or more of the performance categories (specifically, quality, improvement activities, or Promoting Interoperability) where we determine, based on information submitted to us on or before November 1st of the year preceding the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because the MIPS eligible clinician delegated submission of the data to their third party intermediary, evidenced by a written agreement between the MIPS eligible clinician and third party intermediary, and the third party intermediary did not submit the data for the performance category(ies) on behalf of the MIPS eligible clinician in accordance with applicable deadlines. We also are proposing that, to determine whether to apply reweighting to the affected performance category(ies), we will consider: whether the MIPS eligible clinician knew or had reason to know of the issue with its third party intermediary's submission of the clinician's data for the performance category(ies); whether the MIPS eligible clinician took reasonable efforts to correct the issue; and whether the issue between the MIPS eligible clinician and their third party intermediary caused no data to be submitted for the performance category(ies) in accordance with applicable deadlines.

(i) Third Party Intermediaries

We are proposing to add a requirement that CMS-approved survey vendors must provide information on the cost of their services beginning with the CY 2026 performance period/2028 MIPS payment year. These costs will only be applicable to the CAHPS for MIPS Survey measure. If this proposal is finalized, the CAHPS for MIPS Survey

Vendor Participation Form and the CAHPS for MIPS Survey Minimum Business Requirements in the QPP Resource Library would be updated to detail the required survey vendor cost information.

(2) Advanced APM Proposals

(a) Overview of the APM Incentive

Eligible clinicians who meet threshold levels of participation in Advanced APMs to become QPs (or partial QPs) are excluded from MIPS reporting requirements and payment adjustments. We assess the level of participation in Advanced APMs based on payment amounts or patient counts as provided in our regulation at § 414.1425 using the threshold percentages specified in § 414.1430. The threshold percentages are calculated using the ratio of attributed beneficiaries to attribution-eligible beneficiaries. A beneficiary is considered attribution-eligible if they meet the six criteria specified in the definition of ''attribution-eligible beneficiary'' under § 414.1305 of our regulations. We are proposing to modify the sixth criterion under the definition of ''attribution-eligible beneficiary.'' Specifically, we are proposing to include as attribution-eligible any beneficiary who has received a covered professional service furnished by the eligible clinician (identified by their National Provider Identifier (NPI)) for the purpose of making QP determinations. We are also proposing to amend § 414.1430 to reflect the statutory QP and Partial QP threshold percentages for both the payment amount and patient count methods under the Medicare Option and the All-Payer Option with respect to payment year 2026 (performance year 2024) in accordance with amendments made by the CAA, 2024. Relatedly, we are proposing to amend § 414.1450 to reflect the statutory APM Incentive Payment amount for the 2026 payment year (performance year 2024) of 1.88 percent of the eligible clinician's estimated aggregate payments for covered professional services in accordance with amendments made by the CAA, 2024.

2. Definitions

At § 414.1305, we are proposing to revise the definition of the following term:

- Attribution-eligible beneficiary

These terms and definitions are discussed in detail in the relevant sections of this proposed rule.

3. Transforming the Quality Payment Program

a. Vision and Strategy Overview

Medicare plays a lead role in transitioning the health care system away from fee-for-service payment, which incentivizes the quantity of care, toward value-based payment, which incentivizes higher-quality care and smarter spending. We continue to focus on transforming health care delivery and our 2030 goal to have all traditional Medicare beneficiaries in an accountable care relationship with their health care provider. Under accountable care, a person-centered care team is responsible for improving quality of care, care coordination, and health outcomes for a defined group of individuals, reducing care fragmentation, and avoiding unnecessary costs for individuals and the health system. We continue to pursue driving higher value care, supporting Advanced APM participation, increasing alignment to reduce burden, and promoting health equity. As stated previously (85 FR 50279 and 50284, 86 FR 65394 through 65396), we envision a full transition to MVP reporting and sunset of traditional MIPS to support movement towards value-based payment. Through this Request for Information (RFI) we seek feedback on policies to support full implementation of MVPs.

We have a cohesive value-based care strategy for Medicare based on three pillars: Alignment, Growth, and Equity.[704] These pillars are inter-related and address the following:

- Aligning key aspects of value-based arrangements across Medicare can help set the stage for broader synchronization of our health system and move health care providers to higher levels of delivery system transformation.
- Growth of accountable care relationships in both traditional Medicare and Medicare Advantage can improve quality and increase savings for Medicare beneficiaries by promoting innovative care delivery that better provides whole-person care.
- The design of value-based arrangements in Medicare can be an important tool for advancing health equity by encouraging the movement of care upstream to address the health-related social needs and disparities that can lead to/exacerbate poor health outcomes.

We intend to continue our efforts to align the Quality Payment Program with the three pillars and broader CMS initiatives. One of our CMS National Quality Strategy goals is to improve quality and health outcomes across the health care journey through the implementation of a ''Universal Foundation'' of impactful measures across all our quality and value-based programs.[705] [706] [707] Adoption of the Universal Foundation will focus clinician attention on specific quality measures, reduce burden, help identify disparities in care, prioritize development of interoperable digital quality measures, allow for cross-comparisons across programs, and help identify measurement gaps. We have identified adult and pediatric measures for the Universal Foundation to be used across CMS programs and populations to the extent they are applicable. For example, we finalized in the CY 2024 PFS final rule our proposal to consolidate the previously finalized Promoting Wellness and Optimizing Chronic Disease Management MVPs into a single consolidated Value in Primary Care MVP which aligns with the adult Universal Foundation core set of quality measures (88 FR 80042 through 80047). In section IV.A.4.c.(2) of this proposed rule we are proposing the creation of a new Alternative Payment Model (APM) Performance Pathway (APP) Plus quality measure set that incrementally adopts all ten of the Adult Universal Foundation measures starting in the CY 2025 performance period/2027 MIPS payment year. In section IV.A.4.e.(1)(b)(i) of this proposed rule, we are proposing MIPS eligible clinicians, groups, and APM Entities have the option to report such measures starting the 2025 performance period/ 2027 MIPS payment year. We are launching the Making Care Primary (MCP) Model in July 2024 to increase the number of primary care providers in value-based care and beneficiaries in accountable care relationships in eight States.[708] [709] The MCP model supports

[704] Update On The Medicare Value-Based Care Strategy: Alignment, Growth, Equity, Health Affairs Forefront, March 14, 2024. *https://www.healthaffairs.org/content/forefront/update-medicare-value-based-care-strategy-alignment-growth-equity.*

[705] CMS National Quality Strategy. (Centers for Medicare & Medicaid Services, April 2022). *https://www.cms.gov/files/document/cms-national-quality-strategy-fact-sheet-april-2022.pdf.*

[706] The CMS National Quality Strategy: A Person-Centered Approach to Improving Quality. Centers for Medicare & Medicaid Services, June 2022). The CMS National Quality Strategy: A Person-Centered Approach to Improving Quality | CMS (*https://www.cms.gov/blog/cms-national-quality-strategy-person-centered-approach-improving-quality#_ftn4*).

[707] Quality in Motion, Acting on the CMS National Quality Strategy, April 2024. *https://www.cms.gov/files/document/quality-motion-cms-national-quality-strategy.pdf.*

[708] *https://www.cms.gov/priorities/innovation/innovation-models/making-care-primary.*

care integration including expected strengthening of primary care clinicians' connections with specialists while using evidence-based behavioral health screening and evaluation to improve patient care coordination. This will include implementation of new model-specific billing codes that we expect to result in greater use of e-consults and expanded ongoing communication among clinicians with a shared patient. The quality performance measures included in the MCP model reflect our Universal Foundation work to streamline measures across programs and test new and innovative measures. We are proposing in section II.G.2. of this proposed rule to adopt specific coding and payment policies for advanced primary care management (APCM) services for use by practitioners who are providing services under this specific model of ''advanced primary care'', beginning January 1, 2025. These services would be furnished under the direction of a physician or other qualified health care professional who is responsible for all primary care (*e.g.,* physicians and non-physician practitioner, including nurse practitioner, physician assistant, certified nurse midwife and clinical nurse specialist), and serve as the continuing focal point for all needed health care services, during a calendar month. We are proposing three new APCM codes that would recognize the resources involved in furnishing ongoing, beneficiary-centered care management services under the broad model of advanced primary care without paying for each activity separately while allowing for flexibility in addressing patient needs. APCM payment would incorporate several specific, existing care management and communication technology-based services into a bundle and include performance measurements requirements that could be met by reporting the Value in Primary Care MVP beginning in the CY 2025 performance period/2027 MIPS payment year. Billing practitioners who are not MIPS eligible clinicians (as defined at 42 CFR 414.1305) would not have to report the MVP in order to furnish and bill for APCM services. The Value in Primary Care MVP contains the Adult Universal Foundation quality measure set, which is consistent with the National Quality Strategy goal of using the Universal Foundation measures across as many programs as is feasible.[709] The Shared Savings Program, Innovation Center, and MIPS continue to collaborate strategically to develop and elaborate on the long-term vision and implementation policies for the Quality Payment Program.

This RFI addresses how we can achieve full MVP adoption and subgroup participation as we move toward the sunsetting of traditional MIPS and advancing the three pillars and the National Quality Strategy. We intend to obtain more meaningful comparable performance data and to drive higher value care through MVPs and to provide as much transparency as possible as we believe about the timing for sunsetting traditional MIPS (86 FR 39356). Specifically, we are seeking feedback on clinician readiness to report MVPs, how we should ensure there are applicable MVPs for all clinicians, including the option of creation of broadly applicable MVP(s), and what guidance/parameters are needed for multispecialty groups to place clinicians into subgroups for reporting an MVP relevant to the scope of care provided.

b. The Role of MVPs in Transforming MIPS

(1) Overview

We are moving towards full implementation of MVPs, which are a key component of transforming MIPS. MVPs connect the MIPS performance categories to measure quality and patient experience of care linked to related costs of care, encourage improvement of care, simplify MIPS, and assure accessible health care performance data and interoperability. We are implementing MVPs in MIPS to encourage clinicians to report on measures that are directly relevant to their clinical practice and connect the performance categories to better measure the value of care and support care improvements (86 FR 39351). MVPs may make it easier for MIPS eligible clinicians to select the measures and activities that are most relevant to their practice. Rather than selecting individual measures and activities from large inventories to report under potentially siloed MIPS performance categories under traditional MIPS, eligible clinicians who submit an MVP will have a simplified process of selecting from a smaller, cohesive set of measures and activities focused on the clinician's performance in rendering care for a specialty or clinical condition. MVPs provide a pathway to improve value, reduce burden, help patients compare clinician performance to inform patient choice, and reduce barriers to movement into Advanced APMs (86 FR 65391).

In the CY 2024 PFS final rule, we discussed the potential of developing policies to raise the bar on quality and support continuous improvement for clinicians who consistently perform well in MIPS (88 FR 79322). At this time, we are not proposing any changes related to the continuous improvement based on feedback received. We are mindful of changes clinicians are making to move towards MVP reporting.

MVPs support the measurement and improvement of specialty and primary care practice, through a portfolio of MVPs that address care and clinician conditions of importance to our patients. MVPs align the quality performance category, cost performance category, and improvement activities performance category and a foundational layer of the Promoting Interoperability performance category and population health measures. MVPs encourage the measurement of performance on a cohesive set of measures and activities focused on the clinician's performance, and over time, improvement in performance in rendering care for clinical conditions or patient populations. Widescale adoption of MVPs, using a standardized connected set of measures and activities for a specialty or medical condition, may generate important and meaningful information for patients to be able to compare performance of clinicians on the same or similar sets of measures. As we have greater MVP adoption and subgroup reporting we expect to obtain an expanded set of clinical specialty performance data that will be meaningful to patients as they choose clinicians.

(2) Furthering MVP Adoption

We continue to incrementally develop and maintain MVPs that are relevant and meaningful for all clinicians who participate in MIPS to support a full transition to MVPs. We finalized five new MVPs in the CY 2024 PFS final rule (88 FR 79322 through 79323) and finalized modifications to previously finalized MVPs (88 FR 79323). We refer readers to section IV.A.4.a.(1) of this proposed rule for the discussion of six additional proposed MVPs addressing a range of clinical conditions and specialty care. As we increase the inventory of MVPs, a greater percentage of MIPS eligible clinicians may report MVPs. Based on our internal data the proposed addition of six MVPs, if finalized, would allow approximately

[709] The CMS Innovation Center's Strategy to Support High-quality Primary Care | CMS, *https://www.cms.gov/blog/cms-innovation-centers-strategy-support-high-quality-primary-care.*

[710] *https://www.cms.gov/medicare/quality/cms-national-quality-strategy/aligning-quality-measures-across-cms-universal-foundation.*

80 percent of specialties participating in the program to submit applicable MVPs.

In the CY 2022 PFS final rule, we finalized that voluntary reporting of MVPs would start in the CY 2023 performance period/2025 MIPS payment year and to implement MVPs through a gradual process that allows MVP Participants and third-party intermediaries time to adapt to changes in policy, requirements, and programming updates that would need to occur in technology systems (86 FR 65394 through 65396). We support a gradual movement to MVPs. Existing flexibility allows organizations and clinicians to determine whether they are ready to make the transition to MVP reporting, and time to familiarize themselves with MVP policies and prepare to report MVPs that are relevant to their practice (86 FR 65396). Promisingly, based on internal data, over 750 groups and clinicians registered to report MVPs for the CY 2023 performance period/2025 MIPS payment year. We are interested in learning from early MVP Participants to understand lessons learned and any barriers that they encountered or overcame to enable MVP submission. We are taking steps to encourage MVP adoption and expect additional MIPS eligible clinicians to voluntarily begin reporting MVPs before the eventual sunset of traditional MIPS. To engage clinicians in MVP adoption we provide MVP webinars and outreach, and our *qpp.cms.gov* web page provides information for clinicians related to reporting MVPs, our MVP inventory and MVP development.[711] We have increased our inventory of MVPs annually and we engage interested parties in MVP development, including a 45-day comment period for public input on MVP candidates each year.[712]

We are collaborating with the CMS Innovation Center as new payment models are explored and developed that may incorporate specialist or clinical condition-based MVP reporting. See section III.J. of this proposed rule for a Request For Information which seeks input regarding the design of a future ambulatory specialty model, which may leverage MVPs as a foundation for increasing specialty care provider engagement in value-based payment.

(3) Sunset of Traditional MIPS

We have discussed in previous PFS rules our intention to fully transition to MVPs and sunset traditional MIPS (85 FR 50279 and 50284, 86 FR 65394 through 65396). Continuing to maintain the traditional MIPS submission option may impair MVP adoption by clinicians who have an available MVP. Slow adoption may delay the benefits of MVPs which will simplify MIPS and improve comparable clinician performance data that helps to drive value and inform clinician selection by patients. We solicited public comments in the CY 2022 PFS proposed rule on the length of time MVP reporting should be voluntary and the timing for when we should sunset traditional MIPS (86 FR 39356). Responding interested parties supported MVP goals and a transparent, gradual transition to MVPs with voluntary MVP reporting, with adequate time to prepare for reporting an MVP. Clinicians may take advantage of voluntary MVP reporting now to gain experience. We have not proposed a target year to sunset traditional MIPS; however, it is critical to develop a plan to sunset traditional MIPS for the awareness of all interested parties (such as MVP Participants, third-party intermediaries, and health systems) so they may plan their work accordingly to coincide with this timeline.

We are developing the timeline for the full transition to MVPs and are seeking feedback on clinician readiness for MVP reporting and MIPS policies needed to sunset traditional MIPS in the CY 2029 performance period/2031 MIPS payment year. This timeline would ensure MVPs may be voluntarily reported during a period of 6 to 7 years while traditional MIPS is available, allowing clinicians time to prepare for MVP reporting and to engage in the development of the MVP inventory. As we plan for the full transition to MVPs, we appreciate that we must ensure that any MIPS policies that require rulemaking to sunset traditional MIPS are proposed and finalized, and that adequate prior notice is provided to clinicians who may need to update their systems and work processes to report MVPs. We continue to assess remaining MVP gaps that must be filled and to confirm participation options for MIPS eligible clinicians. We anticipate that we may be ready to fully transition to MVPs by the CY 2029 performance period/2031 MIPS payment year.

Robust MVP availability and clinician coverage would be a precursor to sunsetting traditional MIPS. Ideally, there would be MVPs applicable to a diverse set of specialties, patient populations, and clinical conditions; and we are working towards this. We acknowledge that, even with a robust inventory of MVPs, there may be some clinicians who cannot submit an applicable MVP, as currently structured, due to lack of measures to build a respective MVP or lack of measure case counts or specialization that does not allow reporting of MVP quality measures and calculation of a cost measure.

While we are expanding our MVP portfolio, we are hampered by the limited number of available quality and cost measures for certain patient populations, clinical conditions, and specialties. We refer readers to section IV.A.4.a.(1) of this proposed rule which discusses MVP development and measure gap areas. We recognize that resources for measure development are limited, and measure development must be prioritized to move forward with quality and cost measurement for the greatest impact. We are collaborating with measure developers and providing transparency on measure gaps and the limitations around quality and cost measure development.

(4) Potential Path Forward

We are aiming to have sufficient MVPs to meet the goals of the MVP Framework, allow reporting by all clinicians in MIPS, sunset traditional MIPS, and transition fully to MVPs. Additionally, in the CY 2026 performance period/2028 MIPS payment year, when subgroup reporting becomes mandatory for multispecialty groups that participate in MIPS as MVP Participants (§ 414.1305; 86 FR 65394 through 65397), we want to ensure there are opportunities for specialists within the multispecialty group to submit MVPs. This will allow us to better assess the scope of care provided by the group and provide a wider scope of clinician performance data to patients. While we endeavor to create a robust set of MVPs allowing for participation by all MIPS eligible clinicians as we sunset traditional MIPS in the future, we acknowledge there are constraints, including measure availability, hindering attainment of this goal. We refer readers to section IV.A.4.a.(1). of this proposed rule for a discussion of measure gaps and MVP development. We continue to explore different ways to increase MVP coverage for as many MIPS eligible clinicians as possible. The current MIPS quality and cost measure inventories contain gaps which affect both traditional MIPS and MVPs, with MVPs requiring fewer measures to meet requirements. Therefore, we are examining approaches to developing MVPs to ensure that all MIPS eligible clinicians have MVPs to report.

Currently, MVPs include performance measures and activities that are broadly applicable across specialties in addition

[711] MIPS Value Pathways (MVPs) (*cms.gov*), *https://qpp.cms.gov/mips/mips-value-pathways.*

[712] MVP Candidate Development & Submission. *https://qpp.cms.gov/mips/mips-value-pathways/submit-candidate.*

to quality measures that are specialty/subspecialty specific. When subspecialty specific or more focused measures are implemented, they are considered for addition to the corresponding MVP. As stated earlier, we have made progress with developing MVPs for the majority of specialties and priority clinical conditions. However, we are exploring options of how MVPs can be further developed to facilitate greater reporting rates for clinicians with fewer measures available for their specialty. We refer readers to the 2025 MVP Needs and Priorities document,[713] which identifies measurement gaps and specialties with limited quality measures, and often limited outcomes and high priority measures, and cost measures.

We are considering approaches that would assist in making MVPs available to all MIPS eligible clinicians, however, all approaches to be more inclusive of clinicians are hindered by the existing gaps in quality and cost measures. We seek comment on approaches that include expanding finalized MVPs to include more specialties or subspecialties related to a care condition; developing new, broader MVPs with a different emphasis from current MVPs focused on a single specialty or clinical condition; and developing MVPs for non-patient facing MIPS eligible clinicians.

- Expand previously finalized MVPs to include different specialties included in care delivery for patient population. The applicability of an MVP could be expanded through embedding measures and activities specific to additional specialties in a relevant MVP, which may allow a broader array of clinicians to report the MVP. For example, in future program years, we may be interested in expanding the Advancing Cancer Care MVP to include measures related to non-patient facing MIPS eligible clinicians that would support care to cancer patients, such as pathologists. A benefit of this approach would be the expansion of the clinician specialties who could report a given MVP, without increasing the number of stand-alone MVPs. However, the addition of too many measures and activities could undermine the goal of having a smaller, cohesive set of measures and activities in MVPs.
- Expand previously finalized MVPs to include subspecialties. The applicability of an MVP could be increased by broadening the measures and activities to include additional subspecialties. For example, we do not anticipate the development of MVPs for each surgical subspecialty or type of surgical procedure, but rather maintain broader surgical MVPs inclusive of surgeries that are clinically related yet support multiple subspecialties and/or procedures within the surgery specialty. As an example, lumbar surgical measures may be included within MVPs for orthopedic surgeons and neurosurgeons but would not comprise a standalone MVP solely focused on lumbar surgery. Conversely, an Improving Spine Care MVP could be developed that encompasses multiple procedures and aspects of care that could support use by multiple specialties, such as orthopedic surgeons and neurosurgeons. Similar to an approach that expands MVPs to include additional specialties, this option adheres to our goal of having a meaningful set of MVPs.
- Develop MVPs based on Multiple Specialty Measure Sets. For specialties that currently do not have MVP coverage, we could develop an MVP applicable to multiple conditions or specialties that currently do not have MVP coverage. This approach would serve as a bridge until new applicable measures are developed that allow for creation of individual MVPs for clinicians without an MVP specific to their specialty, patient populations served, or the primary conditions treated. For example, we do not currently have an MVP for many non-patient facing clinicians, but we could develop an MVP geared towards these multiple specialty types as a temporary bridge until more meaningful options can be finalized. The benefit could be allowing clinicians early experience in MVPs until we have additional specifically specific measures to create more robust and meaningful MVPs. However, this approach may replicate traditional MIPS and fall short of our MVP vision and goals of a cohesive set of measures and activities; as clinicians' performance would still be based upon the various measures and activities chosen. Clinicians might repeatedly choose unlinked measures with high performance levels rather than addressing performance areas in need of improvement and may also lesson the comparability of performance measures reported by clinicians providing similar services.
- Develop MVPs based on Cross-Cutting and Broadly Applicable Measures. We may consider building an MVP which applies to multiple specialty types by leveraging frequently reported cross-cutting or broadly applicable measures that can be reported by MIPS eligible clinicians who currently do not have MVPs specific to their scope of care. Cross-cutting quality measures address important health issues with clinical quality actions that can be completed by a multitude of clinician types, such as screening and cessation intervention for tobacco use, screening for high blood pressure and follow-up and screening for social drivers of health. Broadly applicable quality measures can be submitted by multiple specialties, including Screening for Depression and Follow-up Plan; Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling, and Use of High-Risk Medications in Older Adults. Population-based cost measures, such as the Total Per Capital Cost (TPCC) and Medicare Spending per Beneficiary (MSPB) measures, could be used in such an MVP. A benefit of developing new MVPs would be to create a bridge allowing for early experience in MVPs for clinicians that currently have no other MVP reporting options. MVP development would need to include examination of approaches to add additional quality and cost measures to MIPS. We acknowledge this is a temporary step towards either a more robust and meaningful standalone MVP or expansion of an existing MVP once specialty specific measures are developed and finalized for use in MIPS. We also have concerns that the MVP would be duplicative in nature to the Value in Primary Care MVP that represents concepts related to promoting wellness and appropriate chronic disease management, which is of critical importance in driving positive health outcomes. However, the broader, cross-cutting MVP does not appear to solve the concerns of all specialties identified in our 2024 MVPs Needs and Priorities [714] interested in submitting measures and activities related to their specialties. Additionally, if we developed an MVP that relied on entirely cross-cutting and broadly applicable measures, we may need policies to discourage clinicians from choosing this broad MVP when there is a more specifically applicable MVP available. We may explore using claims-based data to ascertain services provided and whether a clinical condition or specialty specific MVP better matches the type of care delivered or if a bridge MVP submission fits,

[713] 2024 MVP Needs and Priorities. *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1803/MIPS%20Value%20Pathways%20(MVPs)%20Development%20Resources.zip.*

[714] 2024 MVP Needs and Priorities. *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1803/MIPS%20Value%20Pathways%20(MVPs)%20Development%20Resources.zip.*

potentially within an auditing activity or tying payment to MVP selection.

• Develop MVPs for Non-Patient Facing MIPS Eligible Clinicians. We are considering exploring statutory flexibilities that could help address future challenges related to a lack of an applicable MVP for some clinicians. Any flexibilities we explore must support our overall MIPS goals. Reweighting a performance category, for example, would mean that the quality performance category or cost performance category could be reweighted in an MVP, and this would not support performance measurement to drive value or provide comparable information for patient use in selecting clinicians or care teams.

We believe one such flexibility exists at section 1848(q)(2)(C)(iv) of the Act, which provides that we must consider the circumstances of professional types that typically furnish services that do not involve face-to-face interaction with a patient. We refer to these clinicians as non-patient facing MIPS eligible clinicians as defined at § 414.1305. Section 1848(q)(2)(C)(iv) of the Act further provides that, to the extent feasible and appropriate, we take into account such circumstances and apply to such non-patient facing MIPS eligible clinicians ''alternative measures or activities that fulfill the goals of the applicable performance category.'' In doing so, section 1848(q)(2)(C)(iv)(II) of the Act requires that we consult with non-patient facing MIPS eligible clinicians of such professional types or subcategories. We note that measure gaps for some non-patient facing MIPS eligible clinicians, for example diagnostic radiologists and pathologists, present challenges in developing a respective MVP. We refer readers to section IV.A.4.a.(1) of this proposed rule for discussion of MVP portfolio development and specialties with measure gaps. We are interested in exploring alternative measures and activities that would allow us to measure the performance of non-patient facing MIPS eligible clinicians.

As we explore various approaches to enable all MIPS eligible clinicians to report MVPs, we seek comment on options, such as expanding previously finalized MVPs, developing more global MVPs with broadly applicable measures as an interim bridge for those clinicians with too few specialty-specific quality measures and the potential use of statutory flexibilities, as we move to full MVP adoption and sunsetting traditional MIPS.

(5) Consideration of MVP Policies and Requirements

A component of sunsetting traditional MIPS is examining requirements and policy that may require revision to ensure a smooth transition into MVP reporting. For example, we intend to assess our current policy which does not allow virtual groups and opt-in [715] reporters to submit an MVP (§ 414.1305). We want to understand additional barriers preventing clinicians from reporting MVPs, and when possible, examine MVP policies that might need to be revised to remove the barriers. We may undertake these policy proposals in future rulemaking. We are interested in feedback on potential changes required as part of an effort to accommodate clinicians with few applicable and available quality and cost measures, who currently do not have an MVP available.

We have established a policy which states that, starting in the CY 2026 performance period/2028 MIPS payment year, multispecialty groups must form subgroups to report MVPs (86 FR 65394 through 65397). This policy will enable a subset of clinicians in a group to submit measures and activities in an MVP relevant to the scope of care provided by the subgroup and will lead to a more comprehensive evaluation of services provided by groups. As described in section IV.A.3.d. of this proposed rule, we are interested in feedback on how to balance the MVP requirement for multispecialty groups to form multiple subgroups with the ability of the program to evaluate specialty care and for patients to have meaningful information to use when making care decisions.

c. Mandatory Subgroup Reporting Requirement

(1) Overview

We have established a voluntary subgroup participation option for clinicians choosing to report an MVP beginning in the CY 2023 performance period/2025 MIPS payment year. We have also finalized a mandatory subgroup reporting requirement for multispecialty groups choosing to report as an MVP Participant beginning in the CY 2026 performance period/2028 MIPS payment year (§ 414.1305; 86 FR 65394 through 65397). Beginning with the CY 2026 performance period/2028 MIPS payment year, a single specialty group may continue to submit data for an MVP at the group level, and a multispecialty group must form subgroups to report an MVP. Under the existing subgroup reporting policies, a group could place clinicians providing similar scope of care into one or more subgroups for reporting a relevant MVP. The remaining clinicians under the group TIN not part of a subgroup could participate as individuals for reporting an MVP or traditional MIPS. The entire group TIN (including the clinicians that are part of the subgroup) could also submit data as a group in traditional MIPS.

Subgroup participation for MVP reporting will allow group practices to comprehensively capture the diverse range of services provided by the clinicians under a group TIN. We anticipate subgroup reporting will also provide clinician information to patients related to a specific condition or care needs. Subgroup reporting will provide specialist information to primary care clinicians allowing relevant patient referrals. We finalized the implementation of the subgroup reporting option to address public comments received that the existing group reporting requirements in MIPS allow a group to report on broadly applicable quality measures that are not representative of the scope of care provided and do not allow reporting of quality measures by only a portion of the clinicians under the group TIN.

(2) Specialty Composition of a Group

We have previously established definitions for a single specialty group and a multispecialty group at § 414.1305 (87 FR 70038 through 70040). Specifically, we stated that a single specialty group means a group as defined at § 414.1305 that consists of one specialty type as determined by CMS using Medicare Part B claims. A multispecialty group means a group as defined at § 414.1305 that consists of two or more specialty types as determined by CMS using Medicare Part B claims. MIPS eligible clinicians can check their eligibility status (individual, group, virtual group, APM Entity, opt-in) on the QPP Participation Status Tool (*https://qpp.cms.gov/participation-lookup*) to determine their MIPS participation options and whether they are subject to MIPS payment adjustment for the applicable performance period. Currently, the QPP Participation Status Tool does not provide information on group specialty designations informing a group whether CMS considers its TIN is composed of a single or multiple specialties. In the CY 2023 PFS final rule (87 FR 70039), we discussed that CMS utilizes different data sources to identify a clinician's specialty. For

[715] Entities that exceed one or two, but not all three elements of the low-volume threshold defined at 42 CFR 414.1305 can opt-in to participate in MIPS (§ 414.1310(b)(1)(iii) and (b)(2)).

purposes of public reporting, we rely on PECOS as the primary data source, and for purposes of MIPS eligibility determination, we use both PECOS and claims data. Additionally, we use the information on Medicare Part B claims to identify clinician specialty when attributing some of the measures in the cost and quality performance categories. Based on CMS analysis of clinician specialty identification using Medicare Part B claims data and PECOS data, we found a variance rate of less than one percent between the two data sources and finalized the use of Medicare Part B claims data as the best data source to use to determine a group's specialty type or types for purposes of participation in MVPs. We refer readers to the CY 2023 PFS final rule (87 FR 70038 through 70040) for additional details on using the Medicare Part B Claims data to determine a group's specialty composition.

We also recognize there are additional nuances to consider for using the Medicare Part B claims data to appropriately implement the current definitions of a single specialty and multispecialty group. We acknowledge a multidisciplinary group practice could consist of clinicians across multiple specialties to provide team-based care in just one clinical area. For example, a group consisting of internists, geriatricians, family medicine practitioners, physician assistants, and nurse practitioners could be focused on providing primary care services to patients, which could be reflected as multiple specialties in Medicare Part B claims. Beginning in the CY 2026 performance period/2028 MIPS payment year, such a group TIN will be considered a multispecialty group using the definition described under § 414.1305. The internists, geriatricians, and family medicine practitioners could inappropriately be identified as unique specialties resulting in the TIN having clinicians with more than one primary specialty designation. Based on our previously established definition of a multispecialty group, this TIN will be required to form subgroups to participate in MVPs even though all the clinicians under the group TIN provide primary care services. This may result in multiple subgroups under the same group TIN submitting data for the same MVP, which would yield redundant quality measure reporting. Based on the scope of care provided, all the clinicians under the TIN could choose to report the measures and activities in the Value in Primary Care MVP. Additional scenarios that we would like to consider include instances when a primary specialty designation of certain clinician types does not accurately reflect the scope of care provided. The physician assistants and nurse practitioners that are part of a cardiology group would potentially be involved in care relevant to stroke, heart failure, and other cardiac related conditions. The physician assistants and nurse practitioners that are part of a large group practice could be involved in a wide array of services. In both these instances, the primary specialty designation of a physician assistant or nurse practitioner would only be representative of their education credentials, and not the scope of care provided.

One approach we could consider is providing flexibility for a group practice to determine and inform CMS of their specialty composition. We anticipate that allowing a group TIN to indicate if they are a single specialty or multispecialty group could mitigate a few of the above concerns. We use the above example of a group consisting of internists, geriatricians, family medicine practitioners, physician assistants, and nurse practitioners focused on providing primary care services to patients. By allowing a group TIN to identify the group's specialty composition, the group TIN could identify as a single specialty group and report the measures and activities in the Promoting Wellness MVP as a group. Providing the ability for groups to determine their specialty composition would provide the opportunity for groups to determine the MVP participation option that is consistent with the scope of care. We anticipate it would eliminate the need for duplicative reporting, support the team-based care approach, and allow groups to comprehensively categorize the care provided by the clinicians in a group.

(3) Establishing Limits on the Composition of a Subgroup

We envision a future state in the Quality Payment Program where specific and highly meaningful clinician information is available for patients to determine their care choices while allowing clinicians to receive targeted feedback relevant to the scope of care provided. We anticipate a future state where a multispecialty group would only participate as subgroups for reporting MVPs. We have stated that one of the long-term goals of MVP and subgroup reporting is to encourage team-based care and therefore, have not established any restrictions on subgroup formation. Specifically, we do not expect a subgroup to include only clinicians from a single specialty as it might be construed as discouraging team-based care. We are also concerned that the absence of limitations on subgroup formation would result in a subgroup mimicking a multispecialty group in traditional MIPS. A subgroup of 100 clinicians under a group TIN could report on an MVP where the quality measures and activities in the MVP are applicable only to a subset of clinicians in the subgroup.

We are considering placing some limits on the composition of a subgroup to make subgroups meaningful and meet the end goals of MVP reporting. We also believe that a multispecialty group TIN could use the subgroup formation criteria as a guidance for placing clinicians into subgroups relevant to the scope of care provided. We recognize that any potential subgroup composition criteria should not interfere with the team-based approach for care provided by clinicians in multispecialty groups. We are considering whether we could establish limits on the number of clinicians per subgroup based on the size of the overall group TIN. For a multispecialty group TIN with less than 100 clinicians, should we consider limiting the maximum size of a subgroup to 50 clinicians? Similarly for a multispecialty group TIN with 100+ clinicians, should we consider placing limits on the minimum size of a subgroup? We are interested in approaches that would encourage multispecialty groups to report more than one MVP.

We are also considering whether we could utilize the information on Medicare claims data to potentially create subgroup composition restrictions. For example, we could identify the care provided by the clinicians in a group based on the specific procedures or services performed by the clinician. We are considering analyzing subgroups based on the volume of services billed by the clinicians in a group practice for a specific medical condition (for example, heart failure, joint replacement, etc.) or a specific procedure (beta blocker therapy, stent placement, hip and/knee surgery, etc.). We anticipate this approach would serve as a guidance for clinicians such as family practitioners, physician assistants, internists, etc. who provide a diverse range of services across specialty types.

(4) Mandatory Subgroup Reporting for Small Practice TINs

At § 414.1305, we define a small practice to mean a TIN consisting of 15 or fewer eligible clinicians during the MIPS determination period. For a group of 15 or fewer clinicians, participation at the group or subgroup level for MVP

reporting would provide similar performance information to clinicians and patients. Therefore, we do not anticipate additional benefits for mandating clinicians in a small practice TIN to split into multiple subgroups for reporting an MVP. One approach we could consider is making an exception for multispecialty small practice TINs from the mandatory subgroup reporting requirement for multispecialty practices beginning in the CY 2026 performance period/2028 MIPS payment year. This would alleviate the additional burden for small practice TINs to form subgroups and continue to participate as a group for reporting an MVP. A multispecialty small practice could voluntarily participate as subgroups for comprehensively capturing the diverse range of services provided by the group.

d. RFI Questions

We request public comment on specifically the following questions:

- For those clinicians who submitted an MVP for the CY 2023 performance period/2025 MIPS payment year, what practice level barriers did you overcome to successfully submit an MVP? How did you overcome any stated barriers? For those who did not submit an MVP, what key barriers impacted your decision to continue to report traditional MIPS?

++ For those clinicians who participated as a subgroup for reporting an MVP for the CY 2023 performance period/2025 MIPS payment year, we are interested to hear the technological barriers, if any, that impacted the ability to successfully submit subgroup level data. We are also interested to hear feedback from groups on any technical issues with de-aggregating data (specifically, the eCQM quality measure data) at the subgroup level.

- What does meaningful MIPS participation look like for clinicians who in the future with the sunset of traditional MIPS may not have an applicable MVP, *e.g.,* clinician types without an MVP due to having less than four applicable quality performance measures and less than one cost measure identified in the 2025 MVP Needs and Priorities. Should CMS consider developing a more global MVP with broadly applicable measures as an interim bridge for those clinicians with too few specialty-specific quality measures, knowing that the measures may not be as highly relevant to the clinicians' scope of care as we would like? Should flexibilities or alternative policies such as non-patient facing clinician policy changes be considered for clinicians with limited performance measures that allow them to participate in MIPS?

- As subgroup participation becomes mandatory for multispecialty groups reporting an MVP beginning in CY 2026, how can we balance the increase in burden for groups while allowing comprehensive reporting on the diverse range of services provided by the clinicians in a group? For example, should we consider limiting the number of subgroups that a group must form based on group size and composition?

++ Are there alternative approaches we could consider for setting limits on the minimum and maximum number of subgroups per group TIN?

- Could we consider establishing a process during MVP registration for groups to self-identify if the group is considered a single specialty or multispecialty group? Are there any barriers that CMS should be aware of if we established a process for a group practice to identify the overall specialty composition of a group TIN?

- Is it meaningful for a small practice to form subgroups? What additional performance information would it provide to patients and clinicians?

- Are there additional approaches we should consider for providing guidance to groups on appropriately placing clinicians into subgroups based on the scope of care provided?

Please note, this is an RFI only.

In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

Respondents are encouraged to provide complete but concise responses. This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. Not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. Please note that CMS will not respond to questions about the policy issues raised in this RFI. CMS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to this notice are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. CMS may publicly post the comments received, or a summary thereof.

a. CY 2025 MVP Development and Maintenance

(1) Development of New MIPS Value Pathways (MVPs)

In the CY 2023 PFS final rule (87 FR 70035 through 70037), we finalized modifications to the MVP development process to broaden opportunities for the general public to provide feedback on new candidate MVPs prior to the notice and comment rulemaking process. We refer readers to the Quality Payment Program website to review the public feedback we received for each 2025 MVP candidate (*https://qpp.cms.gov/mips/candidate-feedback*).

Through our development processes for new MVPs (85 FR 84849 through 84856, 87 FR 70035 through 70037), we aim to gradually develop new MVPs that are relevant and meaningful for all MIPS eligible clinicians. In this proposed rule, we are proposing the inclusion of six new MVPs titled:

- Complete Ophthalmologic Care;
- Dermatological Care;
- Gastroenterology Care;
- Optimal Care for Patients with Urologic Conditions;
- Pulmonology Care; and
- Surgical Care.

We refer readers to Appendix 3 in this proposed rule for a detailed description of each proposed new MVP. With the proposed addition of the six new MVPs, we estimate approximately 80 percent of specialties will have applicable MVPs available for reporting.

Although our intended goal has been to offer MVPs for all specialties and subspecialties during the transition from traditional MIPS to full MVP implementation (84 FR 40732 through 40740), we acknowledge our existing portfolio of quality and cost measures may not be applicable to all specialties and/or subspecialties. For quality measures, while most specialties and subspecialties can report on broadly applicable quality measures to meet the reporting requirements for the quality performance category within an MVP, some specialties/subspecialties do not have sufficient robust quality measures that are specific to their scope of care. Thus, we continue to explore options for overcoming challenges to develop MVPs for those specialties/subspecialties with limited quality measures.

For cost measures, while most specialties have at least one applicable episode-based cost measure and/or population-based cost measure, these measures may not encompass the full array of care that could be covered by a given specialty and, in some instances, some specialties/subspecialties may not have an applicable cost measure. For example, the following specialties have limited cost measures available and applicable based on the current MIPS cost measure inventory:

- Diagnostic Radiology;
- Interventional Radiology;
- Optometry;
- Pathology;
- Radiation Oncology; and
- Speech Language Pathology.

Additionally, some specialties have one or more applicable cost measures, but subspecialists may not be captured under these measures. In the case of the Melanoma Resection measure, it applies to individual MIPS eligible clinicians, groups, and subgroups that perform a sufficient number of melanoma excision procedures to meet the measure's case minimum. Although this measure is applicable to many dermatologists, whether a dermatologist is scored on this measure depends on multiple factors, including whether they submit claims on, and are attributed a sufficient number of qualifying melanoma excision procedures (minimum of 10 cases as specified under § 414.1350(c)(4)) to receive a score on this cost measure as set forth in § 414.1380(b)(2). While there are existing policies to reweight the cost performance category for individual, groups, and subgroups of MIPS eligible clinicians that cannot be scored on cost measures in accordance with § 414.1380(b)(2), an MVP cannot be developed for a specialty/subspecialty if there is not at least one applicable cost measure, as finalized in the CY 2021 PFS final rule (85 FR 84472). The intent of MVPs is to assess MIPS eligible clinicians, groups, and subgroups across all performance categories, and additional cost measures would support this intent.

We use prioritization criteria from the CY 2022 PFS final rule (86 FR 65456) to determine which cost measures to develop:

- Clinical coherence of measure concept (to ensure valid comparisons across clinicians).
- Impact and importance to MIPS (including cost coverage, clinician coverage, and patient coverage).
- Opportunity for performance improvement.
- Alignment with quality measures and improvement activities to ensure meaningful assessments of value.

The CY 2022 PFS final rule (86 FR 65457) also established the following standards for cost measure construction:

- Measures must assign services that accurately capture the role of attributed clinicians.
- Measures must have clear, ex ante attribution to clinicians.
- Measures must be based on episode definitions that have clinical face validity and are consistent with practice standards.
- Measures' construction methodology must be readily understandable to clinicians.
- Measures must hold clinicians accountable for only the costs they can reasonably influence.
- Measures must convey clear information on how clinicians can alter their practice to improve measured performance.
- Measures must demonstrate variation to help distinguish quality of care across individual clinicians.
- Measure specifications must allow for consistent calculation and reproducibility using Medicare claims data.

As of the CY 2024 performance period/2026 MIPS payment year, we have developed and implemented 29 MIPS cost measures, which reflect the prioritization criteria and input from interested parties about potential clinical topics, measure scope, clinically related services, and potential challenges or barriers to measurement. This is a substantial achievement in building out the cost measure portfolio since MIPS began with only two population-based cost measures, the Total Per Capita Cost (TPCC) measure and the Medicare Spending Per Beneficiary (MSPB) measure.

However, there are still MIPS eligible clinicians that do not have cost measures that apply to the major aspects of their care practice. For example, there are specialties or clinical topics where clinically coherent measure concepts have not yet been identified or where impact in terms of cost, clinician, or patient coverage is lower than that of other measure concepts that were prioritized for development. Therefore, we continue to encourage interested parties to utilize our established pre-rulemaking processes, such as the Call for Measures (*https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/overview*), to develop and submit candidate quality and cost measures relevant to their specialty. Furthermore, we continue to develop MVPs based on needs and priorities, as described in the MVP Needs and Priorities document (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1803/MIPS%20Value%20Pathways%20(MVPs)%20Development%20Resources.zip*). In section IV.A.3. of this proposed rule, we discuss our request for information on Transforming the Quality Payment Program and solicit feedback on challenges to adopting MVPs and a potential path forward for developing MVPs for MIPS eligible clinicians with limited measures.

(2) MVP Maintenance Process

In the CY 2023 PFS final rule (87 FR 70037), we finalized a modification to the annual maintenance process for MVPs previously finalized in the CY 2022 PFS final rule (86 FR 65410). We communicated that if we identified any potentially feasible and appropriate submitted maintenance recommendations, we would host a public facing webinar open to interested parties and the general public through which they could offer their feedback on the potential maintenance updates we have identified.

In this proposed rule, because we have had a low volume of submitted maintenance recommendations in past years, we are proposing to modify the MVP maintenance webinar process to provide us more flexibility in how we communicate submitted maintenance recommendations prior to proposing them formally in rulemaking. Allowing flexibility in communicating

recommendations through alternative webinar formats or other public communication channels would offer similar opportunities for public review and feedback as a live public webinar. For example, in lieu of a live webinar, we could choose to communicate submitted maintenance recommendations via a pre-recorded webinar, which will encourage interested parties to submit their feedback on the submitted recommendations in writing by email before maintenance updates are formally proposed in rulemaking. It is important to reiterate this public webinar process supports our commitment to consider interested parties' feedback when determining which maintenance updates are appropriate for inclusion in formal notice and comment rulemaking. We request comment on this proposal.

(3) MVP Maintenance Updates to Previously Finalized MVPs

Between the CY 2022 PFS final rule (86 FR 65998 through 66031) and the CY 2023 PFS final rule (87 FR 70037), we finalized 12 MVPs available for reporting beginning with the CY 2023 performance period/2025 MIPS payment year:

- Adopting Best Practices and Promoting Patient Safety within Emergency Medicine;
- Advancing Cancer Care;
- Advancing Care for Heart Disease;
- Advancing Rheumatology Patient Care;
- Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes;
- Improving Care for Lower Extremity Joint Repair;
- Optimizing Chronic Disease Management;
- Optimal Care for Kidney Health;
- Optimal Care for Neurological Conditions;
- Patient Safety and Support of Positive Experiences with Anesthesia;
- Promoting Wellness; and
- Supportive Care for Cognitive-Based Neurological Conditions.

In the CY 2024 PFS final rule (88 FR 79978 through 80047), we consolidated Promoting Wellness and Optimizing Chronic Disease Management MVPs into a single primary care MVP titled ''Value in Primary Care MVP'' as well as finalized five additional MVPs available for reporting beginning with the CY 2024 performance period/2026 MIPS payment year:

- Focusing on Women's Health;
- Prevention and Treatment of Infectious Disorders Including Hepatitis C and Human Immunodeficiency Virus (HIV);
- Quality Care for the Treatment of Ear, Nose, and Throat Disorders;
- Quality Care in Mental Health and Substance Use Disorder; and
- Rehabilitative Support for Musculoskeletal Care.

In this proposed rule, we are proposing modifications to all 16 MVPs with the addition and removal of measures and improvement activities based on the MVP development criteria (85 FR 84849 through 84854). Through these modifications, we can expand upon the clinical concepts, advance health equity, address maintenance requests from the public, and remove measures and activities that would either be finalized for removal from their respective MIPS Inventory or replaced by more robust measures. In addition, through the MVP maintenance process, we are proposing to consolidate the previously finalized Optimal Care for Patients with Episodic Neurological Conditions MVP and the Supportive Care for Neurodegenerative Conditions MVP into a single consolidated neurological MVP titled Quality Care for Patients with Neurological Conditions MVP. We refer readers to Appendix 3 of this proposed rule for the proposed modifications and detailed descriptions to the previously finalized MVPs.

b. MVP Requirements and Scoring

In the CY 2022 PFS final rule (86 FR 65411 through 65415), we finalized policies for MVP reporting requirements, including subgroup requirements, which took effect beginning in the CY 2023 performance period/2025 MIPS payment year, at § 414.1365(c)(1) through (4). We noted that MVP reporting requirements are based on the reporting requirements of traditional MIPS but have some differences, such as reporting fewer measures, to reduce MVP reporting burden and allow for measurement that is more meaningful by requiring clinicians to report on measures and activities that comprehensively reflect an episode of care or clinical condition (86 FR 65411).

In the CY 2022 PFS final rule, we finalized policies for MVP scoring that took effect beginning in the CY 2023 performance period/2025 MIPS payment year. We refer readers to 86 FR 65419 through 65427 for the details of those finalized policies. We previously finalized at § 414.1365(d)(2) that, unless otherwise indicated in § 414.1365(d), the performance standards described at § 414.1380(a)(1)(i) through (iv) apply to the measures and activities included in the MVP (86 FR 65419 through 65421). We noted that in general, we have adopted the scoring policies from traditional MIPS for MVP Participants unless there is a compelling reason to adopt a different policy to further the goals of the MVP framework (86 FR 65419). In this proposed rule, we are proposing to update the registration process and scoring policies for population health measures in the quality performance category, clarify the alignment between scoring cost measures in MVPs and traditional MIPS, update requirements and scoring policies for improvement activities in the improvement activities performance category, and update the requirements for subgroup reporting in the Promoting Interoperability performance category.

We refer readers to section IV.A.4.d. of this proposed rule for proposed policies on data submission requirements; IV.A.4.e.(1)(c)(i) of this proposed rule for proposed policies on the data completeness threshold, IV.A.4.f.(1)(b) of this proposed rule for proposed policies on scoring of topped out measures, and scoring virtual groups and APM Entities (including SSP ACOs) in the quality performance category; IV.A.4.f.(1)(d)(ii)(B) of this proposed rule for proposed benchmarking policies for scoring the cost performance category; IV.A.4.e.(3)(b)(iv) of this proposed rule for proposed policies for requirements and scoring that remove medium- and high-weighting from improvement activities in the improvement activities performance category; and IV.A.4.e.(4) of this proposed rule for current requirements and a Request for Information (RFI) for the Promoting Interoperability performance category.

(1) Quality Performance Category in MVPs

(a) Background on Population Health Administrative Claims-Based Measures

In the CY 2021 PFS final rule, we discussed the inclusion of population health measures as a part of the foundational layer of MVPs, to improve patient outcomes, reduce reporting burden and costs, and better align with clinician quality improvement efforts (85 FR 84856 and 84857). In the CY 2022 PFS final rule we defined a population health measure as a quality measure that indicates the quality of a population or cohort's overall health and well-being, such as, access to care, clinical outcomes, coordination of care and community services, health behaviors, preventive care and screening, health equity, or utilization of health services (86 FR 65408). We also discussed in the CY 2022 PFS final rule the importance of currently adopted population health measures,

noting that they capture outcomes important to patients and thus provide meaningful information to clinicians so they can improve their practice, and discussed the use of population health measures as the foundational layer in MVPs to ensure that important areas of measurement are reflected within all MVPs (86 FR 65408).

We finalized in the CY 2022 PFS final rule (86 FR 65414) at § 414.1365(c)(4)(ii) that an MVP Participant is scored on one population health measure in accordance with § 414.1365(d)(1). Since the MVP population health measures are administrative claims-based, they do not require data submission from clinicians and do not contribute to reporting burden. To track which population health measure an MVP Participant intends to report, we finalized in the CY 2022 PFS final rule (86 FR 65417) at § 414.1365(b)(2)(i) that MVP Participants are required to select one population health measure at the time of MVP registration.

(b) Proposal To Use the Highest Score of All Available Population Health Measures

In the CY 2022 PFS final rule (86 FR 65421 and 65422) we finalized scoring rules for population health measures in MVPs. We finalized at § 414.1365(d)(3)(i)(A) that, except as provided in paragraph (d)(3)(i)(A)(*1*), each selected population health measure that does not have a benchmark or meet the case minimum requirement is excluded from the MVP Participant's total measure achievement points and total available measure achievement points. In cases where an MVP Participant selects a population health measure that cannot be scored because it does not have a benchmark or meet the case minimum requirement, we do not score any other population health measures that may be applicable and available.

Population health measures are included in the MVP foundational layer because they capture outcomes important to patients (that is, hospitalizations for acute illness) and thus provide meaningful information to clinicians so they can improve their practice (86 FR 65408). Under the current policy, we cannot score an MVP Participant on a population health measure if the MVP Participant selects a measure at registration that lacks a benchmark or if their case volume does not meet the case minimum requirement for the selected measure, even if another measure is applicable and available. In the CY 2022 PFS final rule (86 FR 65414) we discussed calculating each population health measure and applying the higher score to the quality score, however, we ultimately proposed and finalized the current policy to score only one selected population health measure to mitigate concerns from interested parties that not all population health measures are applicable to all specialties (86 FR 65414). We now realize that at the time of registration, an MVP Participant will not be able to determine if they will have enough cases to meet the case minimum required for scoring the selected population health measure and will not know, in advance, how the measure will score compared to a benchmark. Requiring an MVP participant to select the population health measure to be scored at the time of registration may penalize an MVP Participant who selects a population health measure at MVP registration.

To increase the likelihood that a population health measure can be scored, we had considered several options, including calculating the population health measure score by using an average score of all population health measures that have a benchmark and meet the case minimum requirement and using the score of the population health measure with the highest number of cases in order to score the population health measure that represents the most care provided by an MVP Participant. However, we determined these approaches could result in a lower score for an MVP Participant that did not correlate to the MVP Participant's performance. We also considered whether an MVP Participant could select a population health measure at the time of data submission when all other measures are reported. However, population health measures are calculated by CMS using administrative claims-based data and therefore do not require data submission from clinicians, and administrative claims-based data is not available for CMS calculation until at least 60 days after the end of the reporting period. Therefore, the MVP Participant would not know whether they would meet the case minimum requirement for the selected population health measure at the time of data submission.

Because population health measures in the MVP capture outcomes important to patients (that is, for example, hospitalizations for acute illness) and thus, provide meaningful information to clinicians so they can improve their practice, we want to avoid scenarios where MVP Participants may inadvertently select a measure that cannot be scored. As described for traditional MIPS at § 414.1380(b)(1)(i), CMS calculates all administrative claims-based quality measures and scores the clinician on each measure for which there is a benchmark and the clinician meets the case minimum requirement. Calculating all population health measures in MVPs would more closely align with the policy to calculate all administrative claims-based quality measures. Additionally, we have developed MVPs with a smaller, more cohesive set of measures and streamlined reporting requirements. A policy to take the highest population health score would increase the likelihood that an MVP Participant is scored on a population health measure and would ensure that MVP Participants receive the highest possible population health score that correlates to their performance.

We are proposing to revise § 414.1365(d)(3)(i)(A) to state that for the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, MVP Participants will be scored on the selected population health measure and beginning in the CY 2025 performance period/2027 MIPS payment year, we would use the highest score of all available population health measures. If no population health measure has a benchmark or meets the case minimum requirement, then the population health measure is excluded from the MVP Participant's total measure achievement points and total available measure achievement points. To apply this policy to subgroups reporting an MVP, we also propose to update § 414.1365(d)(3)(i)(A)(*1*) to provide that for the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, subgroups will be scored on the selected population health measure based on its affiliated group score, if available, and beginning in the CY 2025 performance period/2027 MIPS payment year, a subgroup is scored on the highest scoring of all available population health measures based on its affiliated group score, if available. If the subgroup's affiliated group score is not available, each such measure is excluded from the subgroup's total measure achievement points and total available measure achievement points.

We are also proposing to remove the requirement for an MVP Participant to select a population health measure at the time of MVP registration. If we implement our proposal to calculate each population health measure for an MVP Participant and use the participant's highest score for population health measures in MVPs, there would be no need for the MVP Participant to select a measure during registration. We propose to revise

§ 414.1365(b)(2)(i) to provide that for the CY 2024 performance period/2026 MIPS payment year, each MVP Participant must select an MVP, one population health measure included in the MVP, and any outcomes-based administrative claims-based measure on which the MVP Participant intends to be scored. Beginning in the CY 2025 performance period/2027 MIPS payment year, each MVP Participant must select an MVP and any outcomes-based administrative claims-based measure on which the MVP Participant intends to be scored. We seek comment on these proposals.

(2) Cost Performance Category in MVPs

In the CY 2022 PFS final rule, we finalized at § 414.1365(d)(3)(ii) to use the methodology established at § 414.1380(b)(2)(i) through (v) to score the cost performance category for MVPs using the cost measures included in the MVP that MVP Participants select and report. The finalized policies at § 414.1380(b)(2) score cost measures based on achievement and improvement when the case minimum specified under § 414.1350(c) is met or exceeded and CMS has determined a benchmark (86 FR 65422 and 65423). We discussed in the CY 2022 PFS final rule that aligning MVP scoring policies with existing MIPS scoring policies balances the statutory requirements and goals of the program with ease of use, stability, and meaningfulness to MIPS eligible clinicians (86 FR 65419). We refer readers to section IV.A.4.f.(1)(d)(ii)(B) of this proposed rule for proposals to modify the cost performance category's scoring methodology.

To ensure alignment between MVP and MIPS scoring policies, it is important that MVP cost performance category scoring policies refer to the MIPS policy on how cost measures are scored. We remind readers that cost measures are scored based on the clinician's performance on the measure during the performance period compared to the measure's benchmark, as stated at § 414.1380(b)(2). Currently, § 414.1365(d)(3)(ii) provides that the cost performance category score is calculated for an MVP Participant using the methodology at § 414.1380(b)(2)(i) through (v) and the cost measures included in the MVP that they select and report. To ensure continued alignment, we propose to modify § 414.1365(d)(3)(ii) to replace the reference to § 414.1380(b)(2)(i) through (v) with a broader reference to the cost performance category scoring policies at § 414.1380(b)(2).

We also propose to similarly revise § 414.1365(d)(3)(ii)(A). This regulation currently provides that a subgroup is scored on each cost measure included in the MVP that it selects and reports based on its affiliated group score for each such measure, if available. In addition, § 414.1365(d)(3)(ii)(A) provides that, if the subgroup's affiliated group score is not available for a measure, the measure is excluded from the subgroup's total measure achievement points and total available measure achievement points, as described under § 414.1380(b)(2)(i) through (v). We propose to modify § 414.1365(d)(3)(ii)(A) to replace the reference to § 414.1380(b)(2)(i) through (v) with a broader reference to the cost performance category scoring policies at § 414.1380(b)(2).

We seek comment on these proposals.

(3) Improvement Activities Performance Category in MVPs

The improvement activities performance category should provide clinicians with an opportunity to select from a subset of improvement activities within an MVP that are relevant to the clinical topic. In the CY 2022 final PFS rule (86 FR 65412 and 64513) we finalized at § 414.1365(c)(3), that an MVP Participant who reports an MVP must report one of the following: two medium-weighted improvement activities; one high-weighted improvement activity; or participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice as described at § 414.1380(b)(3)(ii). We established that MVP Participants submitting MVPs would report fewer improvement activities than eligible clinicians reporting traditional MIPS to support MVP adoption.

Additionally, in the CY 2022 final PFS rule (86 FR 65423 and 65424) we finalized at § 414.1365(d)(3)(iii) that the improvement activities performance category score for MVP Participants is calculated based on the submission of high- and medium-weighted improvement activities. We finalized that MVP Participants would receive 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325 or for participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice, as described at § 414.1380(b)(3)(ii). Therefore, to receive a score of 40 points, or full credit, an MVP Participant would be required to submit one high-weighted improvement activity, or two medium-weighted improvement activities included in the MVP. We stated that these requirements would provide an incentive for reporting MVPs, since fewer improvement activities are required to receive a full score for the improvement activities category in an MVP compared to traditional MIPS (86 FR 65423).

We refer readers to section IV.A.4.e.(3)(b)(iv) of this proposed rule for proposals to remove the medium- and high-weighting for improvement activities in traditional MIPS starting in the CY 2025 performance period/2027 MIPS payment year. We now propose to align MVP policies with the traditional MIPS proposal regarding the weighting of improvement activities and to reduce the number of improvement activities an MVP Participant must submit for an MVP. Maintaining a lower reporting burden would encourage reporting MVPs. We finalized that incentives for reporting MVPs, including reduced reporting requirements, allow MVP Participants to report on a smaller, more cohesive subset of measures and activities that are relevant to a given clinical topic, condition, or episode of care (86 FR 65419 and 65420). Therefore, starting in the CY 2025 performance period/2027 MIPS payment year, MVP Participants would be required to submit one improvement activity to achieve 40 points, or full credit, whereas in traditional MIPS clinicians would be required to submit two improvement activities to achieve full credit for the improvement activities performance category. We propose to update reporting requirements and scoring rules related to the improvement activities performance category for MVPs accordingly.

We propose to revise § 414.1365(c)(3) to reflect reporting requirements for the CY 2023 and 2024 performance periods/ 2024 through 2026 MIPS payment years and the reporting requirements beginning in the CY 2025 performance period/2027 MIPS payment year. The revisions proposed at § 414.1365(c)(3)(i) introductory text and additions proposed at paragraphs (c)(3)(i)(A) through (C) would require that an MVP Participant who reports an MVP, in the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, report one of the following: two medium-weighted improvement activities; one high-weighted improvement activity; or participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice as described at § 414.1380(b)(3)(ii). Additionally, we propose at § 414.1365(c)(3)(ii) introductory text and (c)(3)(ii)(A) and (B), beginning in the CY 2025 performance period/2027 MIPS

payment year an MVP Participant who reports an MVP must report either one improvement activity or participation in a certified or recognized patient-centered medical home (PCMH), or comparable specialty practice as described at § 414.1380(b)(3)(ii). We seek comment on the proposals.

We also propose to align MVP scoring with proposed modifications to traditional MIPS scoring that would remove the reference to high- and medium-weighted improvement activities for scoring and assign 40 points for each improvement activity submitted by MVP Participants. We propose at § 414.1365(d)(3)(iii) that in the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, the improvement activities performance category score is calculated based on the submission of high- and medium-weighted improvement activities. MVP Participants would receive 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325 or for participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice, as described at § 414.1380(b)(3)(ii). Beginning in the CY 2025 performance period/2027 MIPS payment year, MVP Participants would receive 40 points for each improvement activity that is submitted or participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice. We seek comment on this proposal.

(4) Promoting Interoperability Performance Category in MVPs

In the CY 2022 PFS final rule, we finalized at § 414.1365(c)(4)(i) that an MVP Participant is required to meet the Promoting Interoperability performance category's reporting requirements. We also finalized at § 414.1365(c)(4)(i)(A) the requirements for a subgroup participating in MVP reporting (86 FR 65413 and 65414). Specifically, we stated that for the CY 2023 and 2024 MIPS performance periods/2025 and 2026 MIPS payment years, an MVP Participant that is a subgroup is required to submit its affiliated group's data for the Promoting Interoperability performance category. The submission of the affiliated group's data will be on the subgroup's behalf. If the affiliated group chooses to report as a group for the Promoting Interoperability performance category, the group will still be required to submit its own data separately and in accordance with the reporting rules for groups. We refer readers to the CY 2022 PFS final rule for additional details (86 FR 65413 and 65414).

We acknowledge the existing language under § 414.1365(c)(4)(i)(A) establishes the requirement for a subgroup to submit its affiliated group's data for the Promoting Interoperability performance category in the foundational layer of an MVP for only the CY 2023 and 2024 performance periods/2025 and 2027 MIPS payment years. In the CY 2022 PFS final rule, we stated our intent to assess the performance of clinicians participating in subgroups in the Promoting Interoperability performance category using subgroup level data to the extent that it is operationally feasible (86 FR 39371 and 39372). However, as discussed in the CY 2022 PFS final rule (86 FR 39371), we heard from interested parties through the MVP Town Hall (85 FR 84846), that some clinicians would need additional time to resolve operational challenges, including challenges related to configuration of EHR systems for reporting Promoting Interoperability data at the subgroup level. We recognize that clinicians and interested parties may need additional time to resolve the technical challenges related to configuration of EHR systems for capturing and submitting data at the subgroup level. We propose that this subgroup reporting policy for the Promoting Interoperability performance category in the MVP they select apply beyond the CY 2023 performance period/2025 MIPS payment year and CY 2024 performance period/2026 MIPS payment years currently specified at § 414.1365(c)(4)(i)(A). Specifically, we propose to modify § 414.1365(c)(4)(i)(A) by removing the references to the specific performance periods/MIPS payment years and provide that an MVP Participant that is a subgroup is required to submit its affiliated group's data for the Promoting Interoperability performance category. The proposed change would allow a subgroup to continue to submit the affiliated group's data for the MVP Promoting Interoperability performance category for the CY 2025 performance period/2027 MIPS payment year and beyond. We note CMS will continue to monitor the operational challenges with the EHR systems and reassess whether subgroups should be required to submit subgroup level performance data for the Promoting Interoperability performance category.

We request public comment on this proposal.

We refer readers to section V.B.8. of this proposed rule for discussion on the burden estimates for these proposals.

c. APM Performance Pathway

(1) Overview

In the CY 2021 PFS final rule (85 FR 84859 through 84866), we finalized the APM Performance Pathway (APP) at § 414.1367 beginning in CY 2021 performance period/2023 MIPS payment year, which was designed as a reporting and scoring pathway available only to MIPS APM participants in order to provide a predictable and consistent MIPS reporting option to reduce reporting burden for, and encourage continued APM participation, by these clinicians. We also established that, beginning with the Shared Savings Program performance year 2021 (CY 2021 performance period/2023 MIPS payment year), ACOs were required to report quality data for purposes of the Shared Savings Program via the APP (42 CFR 425.512(a)(3); 85 FR 84722).

In that same rule, we finalized a quality measure set (85 FR 84860 and 84861) for purposes of quality performance category scoring for the APP. For those MIPS eligible clinicians, groups, or APM Entities for whom a given measure is unavailable due to the size of the available patient population or who are otherwise unable to meet the minimum case threshold for a measure, we established that such measure would be removed from the quality performance category score for such MIPS eligible clinician, group, or APM Entity (85 FR 84861). The complete existing APP quality measure set is shown in Table 53. As indicated in Table 53, the current APP quality measure set includes six quality measures, of which five also are Universal Foundation measures. Further, for MIPS eligible clinicians, groups, and APM Entities reporting through the APP, we established that we would not apply the quality measure scoring cap at § 414.1380(b)(1)(iv) in the event that a measure in the APP quality measure set is determined to be topped out. Because the APP quality measure set is fixed, we noted that it would not be appropriate to limit the maximum quality performance category score available to APP reporters. Should an APP quality measure be determined to be topped out, we would at that time consider amending the APP quality measure set through future rulemaking, if appropriate.

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TABLE 53: Existing APM Performance Pathway Quality Measure Set

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type	Universal Foundation Measure
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient's Experience	Patient Engagement/ Experience	Yes
:001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM (all APP reporters) Web Interface/ Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Mgt. of Chronic Conditions	Intermediate Outcome	Yes
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM (all APP reporters) Web Interface/ Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Treatment of Mental Health	Process	Yes
236	Controlling High Blood Pressure	eCQM/MIPS CQM (all APP reporters) Web Interface/ Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Mgt. of Chronic Conditions	Intermediate Outcome	Yes
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible MIPS Clinician Groups	Administrative Claims	N/A	Admissions & Readmissions	Outcome	Yes
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Admissions & Readmissions	Outcome	No

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We stated when finalizing the APP that the goal of the APP quality measure set is not necessarily to reflect the specific quality goals of clinicians within their respective APMs, but rather to reduce the burden of reporting on quality measures twice: once to MIPS and once to their APMs. We believed that by using this broadly applicable population-health-based measure set, we would enable MIPS APM participants to focus more of their energy and attention on the quality measures being reported through their APMs, while relying on a consistent measure set within the APP from one year to the next (85 FR 84862).

We also finalized the Web Interface measure set for the CY 2021 MIPS performance period within the APP for Shared Savings Program ACOs only (85 FR 84720 through 84723), and in the CY 2022 PFS final rule, extended this collection type through CY 2024 (86 FR 65429). In the CY 2024 PFS final rule, we established the Medicare Clinical Quality Measure for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQM) collection type in the APP quality measure set and finalized that the Medicare CQM collection type would be available to only ACOs participating in the Shared Savings Program. Beginning with the 2024 performance year, ACOs in the Shared Savings Program have the option to report the Medicare CQM under the APP on only ''beneficiaries eligible for Medicare CQMs as defined at § 425.20,

instead of their all payer/all patient population'' (88 FR 79329).

(2) Establishment of the APP Plus Quality Measure Set To Align With the Universal Foundation

Under the goals of the CMS National Quality Strategy to improve the quality and safety of healthcare for everyone,[716] CMS is implementing a building-block approach to streamline quality measures across CMS quality programs for measuring primary care clinician performance in the adult and pediatric populations by leveraging the Universal Foundation of quality measures. The Universal Foundation of quality measures focuses clinicians' attention on measures that are meaningful for the health of broad segments of the population; reduces provider burden by streamlining and aligning measures; advances equity with the use of measures that will help CMS recognize and track disparities in care among and within populations; aids the transition from manual reporting of quality measures to seamless, automatic digital reporting; and permits comparisons among various quality and value-based care programs to help the Agency better understand what drives quality improvement and what does not.[717] The Universal Foundation, which identifies a set of key quality measures for use where relevant throughout CMS programs, is already reflected in the Medicaid Core Sets and the Marketplace Quality Rating System.[718] In addition, in the CY 2024 PFS final rule (88 FR 79321 and 80043), CMS consolidated the previously finalized Promoting Wellness and Optimizing Chronic Disease Management MIPS Value Pathways (MVPs) into a single consolidated primary care MVP (Value in Primary Care MVP) that aligns with the adult Universal Foundation quality measures. In the Announcement of CY 2024 Medicare Advantage (MA) Capitation Rates and Part C and D Payment Policies, we also solicited comment on adding the Universal Foundation measures to Medicare Advantage and the Part D Star Ratings Program. We noted that we would take these comments into consideration in the future, and that any additional measures added to the Star Ratings Program would need to be added through rulemaking.[719] Alignment of quality measures across CMS programs allows practitioners to better focus their quality efforts, reduces administrative burden, and drives digital transformation and stratification of a focused quality measure set to assess impact on disparities.[720]

To further advance Medicare's overall value-based care strategy, which emphasizes preventive care and primary care and to promote greater alignment within and across CMS's quality programs, we are proposing to create the APP Plus quality measure set within the APP specifically to incorporate all of the Adult Universal Foundation measures. Five of the ten adult Universal Foundation measures already are represented in the existing APP quality measure set for the CY 2025 performance period/2027 MIPS payment year under policies finalized in the CY 2024 PFS final rule (88 FR 79113 through 79114). The Universal Foundation measures included in the APP quality measure set are listed in Table 53. The inclusion of half of the measures in the Universal Foundation in the existing APP quality measure set and the recognition that a significant number of current and potential users of the APP—those clinicians participating in MIPS APMs—practice in primary and preventive care areas that are relevant to the Universal Foundation make the APP a meaningful addition to CMS's efforts at quality alignment by bringing in MIPS reporting by MIPS APM participants and in turn by providing feedback in the form of their MIPS quality score to those participants as they also continue to work towards advancing the care they provide within the context of their respective MIPS APMs.

We note that we are not proposing to modify the existing APP quality measure set or the overall framework for the APP as a reporting and scoring pathway. For example, the APP will continue to be available to MIPS eligible clinicians, groups, and APM Entities participating in MIPS APMs, meaning that only these clinician types will be able to report and be scored on the APP Plus quality measure set. We are proposing that, within the APP, the APP Plus quality measure set would be a second measure set distinct from the existing APP quality measure set that MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of an APM Entity participating in a MIPS APM may optionally choose to report. Under the proposal, when an applicable MIPS eligible clinician, group, or APM Entity chooses to report the APP beginning in the CY 2025 performance period/2027 MIPS payment year, they will then choose whether to report the APP quality measure set or the APP Plus quality measure set. For the CY 2025 performance period/2027 MIPS payment year, the APP Plus quality measure set would include the current APP quality measures and two additional quality measures from the Adult Universal Foundation measure set. The measure set would incrementally add the remaining three Adult Universal Foundation measures by the CY 2028 performance period/2030 MIPS payment year. Specifically, we are proposing to adopt one new quality measure beginning with the CY 2026 performance period/2028 MIPS payment year, and two new quality measures beginning with the CY 2028 performance period/2030 MIPS payment year.

We are proposing to revise § 414.1367(c)(1) such that each MIPS eligible clinician, group, or APM Entity APM that elects to report the APP would choose to report either the APP quality measure set or the APP Plus quality measure set. A MIPS eligible clinician, group, or APM Entity that chooses to report the APP Plus quality measure set for a performance period would be required to report all available measures in the APP Plus quality measure set for that performance period and would be scored on all such measures. For example, with respect to the CY 2026 performance period/2028 MIPS payment year, a MIPS eligible clinician, group, or APM Entity that chooses to report the APP Plus quality measure set would be required to report all nine MIPS quality measures (to the extent applicable and available): the nine measures are the six measures incorporated from the APP quality measure set and the three additional Universal Foundation measures we are proposing to incrementally adopt in the APP Plus quality measure set in the CY 2025 and 2026 performance periods/2027 and 2028 MIPS payment years.

[716] *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy.*

[717] Jacobs D, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher L. Aligning Quality Measures across CMS—The Universal Foundation. New England Journal of Medicine, March 2, 2023, available at *https://www.nejm.org/doi/full/10.1056/NEJMp2215539.*

[718] ''Update On The Medicare Value-Based Care Strategy: Alignment, Growth, Equity'', Health Affairs Forefront, March 14, 2024. *DOI: 10.1377/forefront.20240311.141546.*

[719] Centers for Medicare and Medicaid Services (2023). Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. Retrieved March 22, 2024 from Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (*https://www.cms.gov/files/document/2024-announcement-pdf.pdf*).

[720] ''Update On The Medicare Value-Based Care Strategy: Alignment, Growth, Equity'', Health Affairs Forefront, March 14, 2024. *DOI: 10.1377/forefront.20240311.141546.*

The clinician would also be scored on all nine of these measures.

The proposal would incrementally incorporate into the APP Plus measure set the Universal Foundation measures that are not already included in the APP measure set beginning in the CY 2025 performance period/2027 MIPS payment year. The Universal Foundation measure set aligns quality measures used across CMS programs and initiatives and is relevant to a significant subset of the clinicians who are eligible to report the APP. The APP Plus quality measure set will allow MIPS eligible clinicians, groups, and APM Entities eligible to report the APP to report Universal Foundation quality measures, which are used across CMS programs and initiatives.

The APP Plus quality measure set would be separate from the APP quality measure set and would be optional for a MIPS eligible clinician, group, or APM Entity to report.[721] Although we want to promote greater familiarity with the Universal Foundation measures and to encourage clinicians to use the Universal Foundation measures through their MIPS participation, it is important to continue to allow the APP to serve its original purpose of offering a streamlined, stable reporting and scoring pathway for MIPS APM participants, who are already performing practice transformation and are reporting and being scored on quality measures within their APMs. Further, we recognize that while the Adult Universal Foundation quality measures are relevant to a significant portion of clinicians who are eligible to report the APP, they are not relevant for all such clinicians. For example, there are specialists for whom few, if any, of these measures may be relevant, and we do not wish to effectively exclude these clinicians from accessing the benefits of the APP when they otherwise are eligible. Moreover, we recognize that as CMS continues to evolve APM offerings for specialists, there may be more clinicians in the future who are participating in MIPS APMs and would therefore be eligible for the APP, which could shift the proportion of clinicians for whom the Universal Foundation measures are relevant as compared to today. For these reasons, we believe it is important to maintain the existing APP quality measure set and to continue to offer it as an option alongside the proposed APP Plus quality measure set.

[721] That said, we note that the Shared Savings Program is proposing in section [B–G pages].4.(2).a to require that an ACO report the APP Plus quality measure set starting with PY 2025.

For the reasons specified above, we are proposing to amend § 414.1367(c)(1) to establish the APP Plus quality measure set and provide MIPS eligible clinicians, groups, and APM Entities the option to report the APP quality measure set or the APP Plus quality measure set beginning with the CY 2025 performance period/2027 MIPS payment year. We request comment on this proposal.

(3) Measures Proposed for Use in the APP Quality Measure Set and APP Plus Quality Measure Sets

In the CY 2021 PFS final rule, we adopted the current APP quality measure set (85 FR 84860 and 84861). Table 53 contains the current APP quality measure set. We are not proposing any changes to the existing APP quality measure set for the CY 2025 performance period/2027 MIPS payment year or successive years.

We are proposing a phased approach to establish the APP Plus quality measure set over four years. By the CY 2028 performance period/2030 MIPS payment year, the APP Plus quality measure set would consist of the measures currently contained in the APP quality measure set and five additional quality measures from the Universal Foundation measure set. We are proposing to phase in these new measures over time to allow for both the eCQM and, for Shared Savings ACOs, Medicare CQM collection types to be developed and become available. Specifically, we are proposing that the APP Plus quality measure set will consist of the six measures currently contained in the APP quality measure set and the following five new measures, which will be added incrementally:

- Beginning with the CY 2025 performance period/2027 MIPS payment year and subsequent performance periods: The Breast Cancer Screening (Quality #: 112) and Colorectal Cancer Screening (Quality #: 113) measures. These measures are currently available as eCQMs, MIPS CQMs, and Medicare Part B Claims measures. If this proposal is finalized, we would make the Medicare CQM collection type available for these measures prior to the start of performance year 2025 only for Shared Savings Program ACOs.
- Beginning with the CY 2026 performance period/MIPS payment year 2028 and continuing for subsequent performance periods: The Initiation and Engagement of Substance Use Disorder Treatment (Quality #: 305) measure. This measure is currently available as an eCQM. If this proposal is finalized, we would make the Medicare CQM collection type available for this measure prior to the start of performance year 2026 and only for Shared Savings Program ACOs.
- Beginning with the CY 2028 performance period/2030 MIPS payment year and continuing for subsequent performance periods: The Screening for Social Drivers of Health (Quality #: 487) and Adult Immunization Status (Quality #: 493) measures. These measures are currently available as MIPS CQMs, but are not currently available as eCQMs or Medicare CQMs. Because developing eCQM specifications typically takes three years, we are proposing to add these measures to the APP Plus quality measure set in the CY 2028 performance period/2030 MIPS payment year. If this proposal is finalized, we would make these measures available prior to the start of CY 2028 performance period/2030 MIPS payment year to report as eCQMs and, for Shared Savings Program ACOs only, Medicare CQMs.

As discussed above, we intend to incorporate the Adult Universal Foundation measures in the APP Plus quality measure set. We note that the additional Universal Foundation measures that we propose to include in the APP Plus quality measure set align with national condition-specific initiatives and CMS priorities. Below, we briefly discuss each new Universal Foundation measure that would be added to the APP Plus quality measure set and that is not already included in the APP quality measure set: Breast Cancer Screening and Colorectal Cancer Screening Measures.

Our proposed addition of the Breast Cancer Screening (Quality #: 112) and Colorectal Cancer Screening (Quality #: 113) measures to the APP Plus quality measure set for CY 2025 performance period and subsequent performance periods aligns with the President and First Lady's Cancer Moonshot initiative, of which a key objective is to ''make sure everyone has access to cancer screenings—so more Americans can catch cancer early, when outcomes are best.'' [722] Breast cancer and colorectal cancer are two of the most common types of cancers, accounting for an estimated 23 percent of all new cancer diagnoses in the United States in 2023.[723] Because the risk of developing

[722] The White House (n.d.). The President and First Lady's Cancer Moonshot. Accessed March 28, 2024. *https://www.whitehouse.gov/cancermoonshot/.*

[723] Siegel, R.L., Miller, K.D., Wagle, N.S., & Jemal, A. (2023). Cancer statistics, 2023. *CA: a cancer journal for clinicians, 73*(1), 17–48. *https://doi.org/10.3322/caac.21763.*

these types of cancers increases with age, the Breast Cancer Screening measure focuses on mammogram screening for breast cancer every 24 months starting at age 50 and the Colorectal Cancer Screening measure focuses on appropriate screening for colorectal cancer once per performance period, also starting at age 50. Additionally, the February 2024 preliminary measure specifications for the eCQM version of Colorectal Cancer Screening lower the starting age for screenings to 45, an update that aligns with United States Preventive Services Task Force recommendation that colorectal cancer screening begin at age 45 to reduce risk of death.[724]

(ii) Initiation and Engagement of Substance Use Disorder Treatment Measure

An estimated 48.7 million Americans aged 12 or older (17.3 percent of the population) were classified as having had a substance use disorder (SUD) in the past year in 2022.[725] These individuals are at an increased risk for having major medical conditions, injury, overdose, and death.[726] Outcomes for individuals with SUDs are improved through early and regular treatment.[727] The Initiation and Engagement of Substance Use Disorder Treatment (Quality #: 305) measure ensures patients 13 years of age and older with a new SUD episode have the initiation of intervention or medication within 14 days of the new SUD episode or engage in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication within 34 days of the initiation of treatment. This measure also supports CMS efforts to reduce deaths related to opioid overdoses, which have significantly increased in recent years,[728] and the CMS Behavioral Health Strategy.[729]

(iii) Screening for Social Drivers of Health Measure

In the CY 2023 PFS proposed rule, we sought comment on the potential future inclusion of the Social Drivers of Health measure in the APP quality measure set (87 FR 46154 through 46155). While the majority of commenters were generally supportive of adding the Screening for Social Drivers of Health measure, several raised concerns related to the undue burden on collection, cost and resources of implementation, and holding providers accountable for the collection of data which could be beyond their scope or ability. Some supportive commenters appreciated that the Screening for Social Drivers of Health measure could drive the standardization of measures that examine social drivers of health in Federal health care quality and payment systems, and that this would ultimately drive the health of our patients and our Nation, maximize the use of limited Government resources to support vulnerable patients, and achieve quality improvement and equity in health outcomes. Commenters further stated that the Screening for Social Drivers of Health measure is crucial in recognizing the impact of Social Drivers of Health-related issues on patients and providers, in laying the foundation to invest in those communities, and in avoiding fragmentation and provider/patient burden by supporting alignment across public and private quality and payment programs. Some commenters opposed the addition of the measure and cautioned CMS to test it before it would be required. Other opposed commenters voiced their concern about the undue burden on data collection among patients and providers and the costs and resources associated with implementing new Social Drivers of Health measures, and that gathering Social Driver of Health measure data would lead to holding providers accountable for addressing social needs of patients that is beyond a provider's scope or ability.

We believe that the benefits of adding the measure to the APP Plus quality measure set outweigh these concerns. For example, while the challenges and concerns noted previously in this section associated with implementing screening for social drivers of health are voiced by family medicine clinicians, social workers, and clinical staff, including the potential negative impact screening could have on the patient-clinician relationship, screening for social drivers of health uncovers patient needs, allows clinicians to provide their patients with resources or referrals, results in appropriately adapting patient care, and prioritizes patient safety.[730] The addition of the Screening for Social Drivers of Health (Quality #: 487) measure also is consistent with our priorities to advance health equity and move toward whole-person care throughout our various programs, including the MIPS and the Hospital Inpatient Quality Reporting (HICR) programs. This measure addresses five social and economic determinants—namely, food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety[731]—that are central to the Health Equity strategic plan pillar (*https://www.cms.gov/pillar/health-equity*) and have been identified as both a measurement priority and a performance gap among CMS programs.

The movement to address socioeconomic, environmental, and behavioral health factors (referred to as drivers of health) has gained traction after a study estimated that only 20 percent of a person's health outcomes are linked to their medical care with the remaining 80 percent attributable to drivers of health.[732] Because of the strong relationship between Social Drivers of Health and physical health outcome, screening for Social Drivers of Health would support the goals of improving health outcomes by providing clinicians with a more comprehensive understanding of each patient's circumstances to inform

[724] eCQI Resource Center (2023). Colorectal Cancer Screening. Accessed March 29, 2024. *https://ecqi.healthit.gov/ecqm/ec/2024/cms0130v12?compare=2024to2023.* United States Preventative Task Force (2021). Final Recommendation on Screening for Colorectal Cancer. *https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/file/supporting_documents/colorectal-cancer-screening-final-rec-bulletin.pdf.*

[725] Substance Abuse and Mental Health Services Administration. (2023). Key substance use and mental health indicators in the United States: Results from the 2022 National Survey on Drug Use and Health (HHS Publication No. PEP23–07–01–006, NSDUH Series H–58). Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. *https://www.samhsa.gov/data/report/2022-nsduh-annual-national-report. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5291754/.*

[726] Bahorik, A.L., D.D. Satre, A.H. Kline-Simon, C.M. Weisner, C.L. Campbell. 2017. ''Alcohol, Cannabis, and Opioid Use Disorders, and Disease Burden in an Integrated Health Care System.'' J Addiction Medicine 11(1),3–9. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5291754/.*

[727] Kampman, K., K. Freedman. 2020. ''American Society of Addiction Medicine (ASAM) National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update.'' Journal of Addiction Medicine 14, no. 2S: 1–91, *https://doi.org/10.1097/ADM.0000000000000633.*

[728] National Institute on Drug Abuse (2023). Drug Overdose Deaths. Accessed March 28, 2024. *https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates.*

[729] Centers for Medicare and Medicaid Services (2024). CMS Behavioral Health Strategy. Accessed April 19, 2024. *https://www.cms.gov/cms-behavioral-health-strategy.*

[730] Porterfield, L., Jan, Q.H., Jones, F., Cao, T., Davis, L., Guillot-Wright, S., & Walcher, C.M. (2024). Family Medicine Team Perspectives on Screening for Health-Related Social Needs. Journal of the American Board of Family Medicine: JABFM, jabfm.2023.230167R3. Advance online publication. *https://doi.org/10.3122/jabfm.2023.230167R3.*

[731] *https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2023_Measure_487_MIPSCQM.pdf.*

[732] Hood, C.M., K.P. Gennuso, G.R. Swain, and B.B. Catlin. 2016. County health rankings: Relationships between determinant factors and health outcomes. *American Journal of Preventive Medicine* 50(2):129–135. *https://doi.org/10.1016/j.amepre.2015.08.024.*

clinical decision making and ensure high-quality care.

In addition, many of these drivers of health are not only linked to poorer health, but disproportionately impact communities of color and underserved populations. Through screening, once per performance period, of patients 18 years and older for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety, screening for Social Drivers of Health and appropriate referrals can potentially improve health outcomes and reduce health disparities. As we indicated when we proposed to adopt Screening for Social Drivers of Health in MIPS in the CY 2023 PFS proposed rule, we believe that consistently addressing drivers of health will have two significant benefits. First, because drivers of health disproportionately impact individuals and communities that are disadvantaged and/or underserved by the healthcare system, the promotion of screening for these factors would support clinician practices and health systems in actualizing an expressed commitment to address disparities in care, implementing associated equity measures to track progress, and improving overall health equity.[733] Second, patient-level driver of health data through screening is essential in the long-term to encourage meaningful collaboration among clinicians and community-based organizations, and implement and evaluate related innovations in healthcare and social service delivery. (87 FR 46280)

(iv) Adult Immunization Status Measure

The Adult Immunization Status measure (Quality #: 493) ensures that adults are up to date with the recommended routine vaccines: influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal. This robust measure supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease.

(v) Maintaining the Use of the Clinician and Clinician Group Risk-Standardized Hospital Admission Rates for Patients With Multiple Chronic Conditions Measure in the APP Quality Measure Set and Including It in the APP Plus Quality Measure Set

We note that Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Quality # 484) is an administrative claims-based measure that is in the APP quality measure set for the MIPS CY performance period 2025/2027 payment year under policies finalized in the CY 2024 PFS final rule (88 FR 79113 and 79114) but is not one of the ten Adult Universal Foundation measures. Our proposal would continue to maintain this measure in the APP quality measure set, and therefore also include it in APP Plus quality measure set, for the CY 2025 performance period/2027 MIPS payment year and subsequent performance periods. We continue to believe that hospital admission rates are an effective marker of ambulatory care quality. As noted in our rationale for adopting the measure in the measure specifications, ''Hospital admissions from the outpatient setting reflect a deterioration in patients' clinical status and as such reflect an outcome that is meaningful to both patients and providers.[734] Patients receiving optimal, coordinated high-quality care should use fewer inpatient services than patients receiving fragmented, low-quality care. Thus, high population rates of hospitalization may signal poor quality of care or inefficiency in health system performance. Furthermore, these effects may be exacerbated in disadvantaged areas.[735] Patients with multiple chronic conditions are at high risk for hospital admission, often for potentially preventable causes, such as exacerbation of pulmonary disease.'' [736] Maintaining this measure in the APP quality measure set and, as a consequence, including it in the APP Plus quality measure set also is consistent with our previously stated goals in the CY 2021 PFS final rule to align the APP with the Meaningful Measures framework, an initiative to remove lower value quality measures across CMS programs while keeping measures that have less burden and are the most meaningful with the greatest impact on patient outcomes. This measure supports the framework's goals as it is identified among the highest priorities for quality measurement and improvement while also reducing burden, promoting alignment, moving payment toward value, and identifying key quality performance metrics for consumers (85 FR 84726).

(vi) The APP and APP Plus Quality Measure Sets Beginning With the CY 2025 Performance Period/2027 MIPS Payment Year

Table 54 identifies the measures in the Adult Universal Foundation measure set, crosswalks them to corresponding MIPS measures, and lists the proposed timeline for their incorporation into the APP Plus quality measure set between the CY 2025 and 2028 performance periods/2027 and 2030 MIPS payment years as they become available for both the eCQM and Medicare CQM collection types. We note that Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Quality # 484) is not one of the ten Adult Universal Foundation measures and is not listed in Table 19; however, we are maintaining reporting of this measure in the APP quality measure set, and, as such, also proposing to include it in the APP Plus quality measure set for the CY 2025 performance period/2027 MIPS payment year and subsequent performance periods.

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[733] American Hospital Association. (December, 2020). Health Equity, Diversity & Inclusion Measures for Hospitals and Health System Dashboards. Available at *https://ifdhe.aha.org/system/files/media/file/2020/12/ifdhe_inclusion_dashboard.pdf.*

[734] Centers for Medicare and Medicaid Services—Quality Payment Program (2023). Measure information for the Multiple Chronic Care Conditions (MCC) Risk-standardized Hospital Submission Rate for Patients for the Merit-based incentive Payment System (MIPS) Groups, Performance Year (PY)2023 MCC Measure Code Specifications, Retrieved March 22, 2024 from 2023 Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions—QPP. *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2202/2023%20MIPS%20Multiple%20Chronic%20Conditions%20Measure%20Specifications.zip.*

[735] Jencks, S.F., et al. (2019). ''Safety-Net Hospitals, Neighborhood Disadvantage, and Readmissions Under Maryland's All-Payer Program: An Observational Study.'' Ann Intern Med. *doi: 10.7326/M16–2671.*

[736] Abernathy, K., Zhang, J., Mauldin, P., Moran, W., Abernathy, M., Brownfield, E., & Davis, K. (2016). Acute Care Utilization in Patients With Concurrent Mental Health and Complex Chronic Medical Conditions. *Journal of primary care & community health, 7*(4), 226–233. *https://doi.org/10.1177/2150131916656155.*

TABLE 54: Alignment of the APP Plus Measure Set with the Adult Universal Foundation Measure Set [a]

Quality #	Identification Number and Name	Measure Title	Domain [b]	Performance Period Measure Added to the APP Plus Measure Set
321	158 (varies by program): Consumer Assessment of Healthcare Providers and Systems overall rating measures	CAHPS for MIPS	Person-centered care	2025
479	561 or 44: Plan all-cause readmissions or all-cause hospital readmissions	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Seamless care coordination	2025
001	204: Hemoglobin A1c poor control (>9%)	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	Chronic conditions	2025
134	672: Screening for depression and follow-up plan	Preventive Care and Screening: Screening for Depression and Follow-up Plan	Behavioral health	2025
236	167: Controlling high blood pressure	Controlling High Blood Pressure	Chronic conditions	2025
112	93: Breast cancer screening	Breast Cancer Screening	Wellness and prevention	2025
113	139: Colorectal cancer screening	Colorectal Cancer Screening	Wellness and prevention	2025
305	394: Initiation and engagement of substance use disorder treatment	Initiation and Engagement of Substance Use Disorder Treatment	Behavioral health	2026
487	Identification number undetermined: Screening for social drivers of health	Screening for Social Drivers of Health	Equity	2028
493	26: Adult immunization status	Adult Immunization Status	Wellness and prevention	2028

[a] Jacobs D, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher L. Aligning Quality Measures across CMS – The Universal Foundation. New England Journal of Medicine, March 2, 2023, available at *https://www.nejm.org/doi/full/10.1056/NEJMp2215539.* Domains are from Meaningful Measures 2.0. Identification numbers are CMS Measures Inventory Tool measure family identification numbers; names reflect the descriptions associated with those numbers.

[b] Domains are from Meaningful Measures 2.0. Identification numbers are CMS Measures Inventory Tool measure family identification numbers; names reflect the descriptions associated with those numbers.

We refer readers to Table 53 for the APP quality measure set for the CY 2025 performance period/2027 MIPS payment year and subsequent years. The proposed APP Plus quality measures for the CY 2025 performance period, the CY 2026 and 2027 performance periods, and the CY 2028 performance period and subsequent performance periods are displayed in Tables 55, 56, and 57, respectively. Under our proposal, there would be eight measures in the APP Plus quality measure set in the CY 2025 performance period (Table 55), nine measures in the CY 2026 and 2027 performance periods (Table 56), and eleven measures in the CY 2028 and subsequent performance periods (Table 57). We refer readers to Appendix 1 of this proposed rule for additional measure specification information.

TABLE 55: APP Plus Quality Measure Set for the CY 2025 Performance Period

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient's Experience	Patient Engagement/ Experience
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Mgt. of Chronic Conditions	Intermediate Outcome
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Treatment of Mental Health	Process
236	Controlling High Blood Pressure	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Mgt. of Chronic Conditions	Intermediate Outcome
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible MIPS Clinician Groups	Administrative Claims	N/A	Admissions & Readmissions	Outcome
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Admissions & Readmissions	Outcome
113	Colorectal Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process
112	Breast Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process

TABLE 56: APP Plus Quality Measure Set for the CY 2026 and 2027 Performance Periods

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient's Experience	Patient Engagement/ Experience
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Mgt. of Chronic Conditions	Intermediate Outcome
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Treatment of Mental Health	Process
236	Controlling High Blood Pressure	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Mgt. of Chronic Conditions	Intermediate Outcome
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible MIPS Clinician Groups	Administrative Claims	N/A	Admissions & Readmissions	Outcome
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Admissions & Readmissions	Outcome
113	Colorectal Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process
112	Breast Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process
305	Initiation and Engagement of Substance Use Disorder Treatment	eCQM (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Behavioral health	Process

TABLE 57: APP Plus Quality Measure Set for the CY 2028 Performance Period and Subsequent Performance Periods

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient's Experience	Patient Engagement/ Experience
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Mgt. of Chronic Conditions	Intermediate Outcome
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Treatment of Mental Health	Process
236	Controlling High Blood Pressure	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Mgt. of Chronic Conditions	Intermediate Outcome
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible MIPS Clinician Groups	Administrative Claims	N/A	Admissions & Readmissions	Outcome
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Admissions & Readmissions	Outcome
113	Colorectal Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process
112	Breast Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process
305	Initiation and Engagement of Substance Use Disorder Treatment	eCQM (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Behavioral health	Process
487	Screening for Social Drivers of Health	eCQM/MIPS CQM (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Equity	Process
493	Adult Immunization Status	eCQM/MIPS CQM (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process

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Under our proposal, scoring for the APP quality performance category scoring methodology at § 414.1367(c)(1) would continue to be performed in

accordance with § 414.1380(b)(1). For the APP quality measure set, this means that the scoring methodology would not change. For the APP Plus quality measure set, we are proposing to calculate the MIPS quality performance category score for a MIPS eligible clinician, group, or APM Entity that chooses to report the APP Plus quality measure set via the APP by summing the scores for all of the measures, as applicable, included in the APP Plus quality measure set for a given year. Scoring clinicians on all measures, as applicable, in the APP Plus quality measure set will promote the best, safest, and most equitable care and provide a comprehensive assessment of the performance of those who choose to report the measure set.

Because we are proposing that a MIPS eligible clinician, group, or APM Entity that chooses to report the APP Plus quality measure set would be scored on all of the measures in that set, we are also proposing a conforming change to MIPS data submission requirements in § 414.1335(b) to require that a MIPS eligible clinician, group, or APM Entity that reports the APP Plus quality measure set via the APP would be required to report on all measures included in the APP Plus quality measure set, except for administrative claims-based measures, which are calculated using data from claims submissions. We solicit comment on this proposal. For further discussion on the data submission proposal for the APP Plus quality measure set, see section IV.A.4.e.(1)(b) of this proposed rule.

d. Data Submission for the Performance Categories

(1) Overview

For previously established policies relevant to data submission for the MIPS performance categories, we refer readers to § 414.1325 and the CY 2017 Quality Payment Program final rule (81 FR 77087 through 77097), CY 2018 Quality Payment Program final rule (82 FR 53619 through 53626), CY 2023 PFS final rule (86 FR 65438 through 65441) and CY 2024 PFS final rule (88 FR 79330 through 79332). Specifically, we finalized at § 414.1325(a)(1) that individual MIPS eligible clinicians, groups, virtual groups, subgroups, and Advanced Payment Model (APM) Entities must submit data on measures and activities for the quality, improvement activities, and Promoting Interoperability performance categories in accordance with § 414.1325. We note, that under the current policies described at § 414.1325(a)(2), there are no data submission requirements for the cost performance category or administrative claims-based quality measures.

In this section, we are proposing to adopt minimum criteria for a qualifying data submission for a MIPS performance period for the quality, improvement activities, and Promoting Interoperability performance categories, which we propose to codify at § 414.1325(a)(1)(i) through (iii). We are also proposing to codify our existing policies governing our treatment of multiple data submissions received for the quality and improvement activities performance categories at § 414.1325(f)(1). We are also proposing to modify our policy governing our treatment of multiple data submissions received for the Promoting Interoperability performance category, which we propose to codify at § 414.1325(f)(2).

Proposals in this section of this proposed rule are intended to eliminate certain issues with the scoring of an unintended data submission affecting payment adjustments for individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities. We are proposing these changes to be effective beginning with the CY 2024 performance period/2026 MIPS payment year for the data submission period in CY 2025. Additionally, we refer readers to section V.B.8.e. of this proposed rule for discussion on the burden estimates for these proposals.

(2) Proposed Minimum Criteria for a Qualifying Data Submission for the MIPS Quality, Improvement Activities, and Promoting Interoperability Performance Categories

(a) Background

CMS uses the data submitted by (or on behalf of) individual MIPS eligible clinicians, groups, virtual groups, subgroups, or APM Entities in the quality, improvement activities, and Promoting Interoperability performance categories to assess their performance on the measures and activities in these three categories and to determine their MIPS payment adjustments. Under the previously established data submission policies at § 414.1325, individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities generally submit data on measures and activities for the quality, improvement activities, and Promoting Interoperability performance categories in accordance with the data submission deadlines at § 414.1325(e)(1). Currently, we consider any submission of data received for a MIPS performance category during the designated data submission period for a MIPS performance period in accordance with § 414.1325(e)(1) to be a data submission for the corresponding MIPS performance period and assign a score for the submission.

For the quality and improvement activities performance categories, under the current reweighting policies at § 414.1380(c)(2)(i)(A)(*6*) through (*8*) for an extreme and uncontrollable circumstance (EUC) or other type of exception based on certain circumstances, we score any data submitted by (or on behalf of) a MIPS eligible clinician with an approved reweighting application. This includes MIPS eligible clinicians with an approved application-based EUC reweighting or an approved reweighting for a clinician identified in a CMS-designated region affected by an automatic EUC event. Under this current policy, in the event that a MIPS eligible clinician submits any data for the quality or improvement activities performance category, such submission overrides the approved reweighting for the applicable performance category and we will score the performance categories for which data was submitted, and include the performance category scores in the MIPS eligible clinician's final score as otherwise provided in § 414.1380(c).

Similarly, for the Promoting Interoperability performance category, under the current reweighting policies at § 414.1380(c)(2)(i)(C) for a significant hardship or other type of exception based on certain circumstances, we score any data submitted by (or on behalf of) a MIPS eligible clinician with an approved reweighting application, except as provided in § 414.1380(c)(2)(i)(C)(*10*) and (*11*). Under this current policy, in the event that a MIPS eligible clinician submits any data for the Promoting Interoperability performance category, such submission overrides the approved reweighting for the performance category and we will score the Promoting Interoperability performance category and include the category score in the MIPS eligible clinician's final score as otherwise provided in § 414.1380(c).

We have received inquiries from MIPS eligible clinicians that highlight unintended consequences associated with our current data submission requirements. Several MIPS eligible clinicians have notified us that there have been instances where they unintentionally submitted non-scorable data for a MIPS performance category, which overrode an approved

reweighting or a previously scorable data submission for the MIPS quality, improvement activities, or Promoting Interoperability performance categories. Data submissions without any scorable data (non-scorable data submissions) generally only include limited data that cannot be scored such as a practice ID, date, activity ID, measure ID, or CMS Electronic Health Record (EHR) Certification ID (CEHRT ID). MIPS eligible clinicians have also notified us that, in some instances, the data submission overriding the prior approved reweighting or prior scorable submission was performed by a third party intermediary or a practice representative.

The MIPS eligible clinician, group, virtual group, subgroup, APM Entity, or third party intermediary acting on behalf of a MIPS eligible clinician, group, virtual group, subgroup, APM Entity, as applicable, that submits data on measures and activities under MIPS is defined at § 414.1305 as the submitter type.

The mechanism by which a submitter type submits data to CMS (including, as applicable: Direct, log in and upload, log in and attest, Medicare Part B claims, and the CMS Web Interface) is defined at § 414.1305 as the submission type. The direct submission type allows users to transmit data through a computer-to-computer interaction, such as an API. The log in and upload submission type allows users to upload and submit data in the form and manner specified by CMS with a set of authenticated credentials. The log in and attest submission type allows users to manually attest that certain measures and activities were performed in the form and manner specified by CMS with a set of authenticated credentials. We refer readers to § 414.1325(b) and (c) for available data submission types individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities may utilize to submit data for the quality, improvement activities, and Promoting Interoperability performance categories.

To submit data, a submitter must gain access to the Quality Payment Program website (*https://qpp.cms.gov/login*) for submitting or viewing data for the associated individual MIPS eligible clinician, group, subgroup, virtual group, or APM Entity. We refer readers to the Quality Payment Program Resource Library (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/335/QPP%20Access%20User%20Guide.zip*) for additional information on the MIPS data submission process and obtaining access to submit data during the designated submission period under § 414.1325(e)(1).

After gaining access to the Quality Payment Program website for the associated individual MIPS eligible clinician, group, subgroup, virtual group, or APM entity, a submitter can navigate to the ''Eligibility and Reporting'' tab and view whether there is any reweighting applied for one or more of the MIPS performance categories for the associated individual MIPS eligible clinician, group, virtual group, subgroup, or APM Entity. In addition, at the time of submission, the system generates warnings to the submitter (for all the available submission types) if there is an existing approved reweighting for the performance category in which the data is being submitted or an existing data submission for an individual MIPS eligible clinician, group, virtual group, subgroup, or APM Entity. For example, if a group has an approved reweighting for the Promoting Interoperability performance category, the system alerts the submitter prior to completing the data submission with a message stating: ''This Action Will Impact Your Category Weights. Currently, Promoting Interoperability does not count towards your final score. By choosing to report Promoting Interoperability data, your score for this category will be included in your final score. This action cannot be undone.'' The submitter must check the ''Yes, I agree'' box prior to confirming the data submission in the performance category. We refer readers to the Quality Payment Program Resource Library (*https://qpp.cms.gov/resources/resource-library*) for additional details on the process to submit MIPS data for MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities.

Under the current process, we assign a score for any submission received from an individual MIPS eligible clinician, group, virtual group, subgroup or APM Entity for a performance period during the designated MIPS submission period regardless of whether the submission included data on the MIPS measures and activities. We implemented the process to recognize any data submitted as an extension of the policy that submission of any data overrides reweighting of the MIPS performance categories as described at § 414.1380(c)(2). We assign a score for submissions with data on MIPS measures and activities, and also for submissions that only include non-scorable data, such that they do not include any data that allows us to measure a clinician's performance on the applicable measures and activities. For example, if we receive a submission for a MIPS performance category without any measure or activity data (for example, without numerator and denominator data for any quality measures, without a response of ''yes'' for any improvement activities, without a ''yes'' or ''no'' response for an attestation, or responses for the required objectives and associated measures and attestation statements for the Promoting Interoperability performance category), and the data submission includes only non-scorable data (such as the practice ID, measure ID and TIN/NPI information), we assign a zero score for the applicable MIPS performance category in the event we do not receive a subsequent submission with measure or activity data.

Despite implementing these system warnings to alert the submitter of a potential impact of their entry on the reweighting status or existing data submission, we continue to receive non-scorable data submissions, which override an approved reweighting, or a previously scored data submission, for the MIPS quality, improvement activities, or Promoting Interoperability performance categories. To help address the unintentional overriding of an existing scorable data submission or an approved reweighting for the MIPS performance categories, we are proposing a narrower set of minimum criteria of what would qualify as a data submission under our existing policies. We note that we are not proposing to change our existing policies to assign a score for a data submission (meeting the proposed narrower minimum criteria) for the applicable MIPS performance categories, including our policy governing data submissions from a third party intermediary, even if the submission overrides an approved reweighting or a prior scorable submission for the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity.

We have identified that we could potentially avoid submissions without any scorable data on MIPS measures or activities from overriding previously approved reweighting or a prior submission for the MIPS performance categories if we require a submission to include certain data on measures or activities in the MIPS quality, improvement activities, or Promoting Interoperability performance categories in order to assign a score. Therefore, we are proposing to adopt minimum criteria for what we would consider to be a qualifying data submission for which CMS can assign a score.

Specifically, we are proposing to consider a submission valid and

scorable (including, potentially, a score of zero) for the applicable MIPS performance category only if the data submission includes: numerator and denominator data for at least one MIPS quality measure in the quality performance category; a response of ''yes'' for at least one improvement activity in the improvement activities performance category; and all required elements to report objectives and associated measures and attestation statements for the Promoting Interoperability performance category.[737] We discuss the details of these proposed data submission criteria for each performance category in sections IV.A.4.d.(2)(b), IV.A.4.d.(2)(c), and IV.A.4.d.(2)(d) of this proposed rule.

We note that we are not proposing any changes to the existing scoring or reweighting policies described under § 414.1380 for the MIPS performance categories in this section of this proposed rule. If the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity does not have an approved reweighting for one or more of the MIPS performance categories and we do not receive a data submission for a performance category that has not been reweighted, we will assign a score of zero for the applicable performance category.

(b) Quality Performance Category

We refer readers to §§ 414.1325 and 414.1330 through 414.1340 and the CY 2017 Quality Payment program final rule (81 FR 77097 through 77162) and CY 2018 Quality Payment Program final rule (82 FR 53626 through 53641), the CY 2019 PFS final rule (83 FR 59754 through 59765), CY 2020 PFS final rule (84 FR 63949 through 62959), CY 2021 PFS final rule (85 FR 84866 through 84877), CY 2022 PFS final rule (86 FR 65431 through 65445), CY 2023 PFS final rule (87 FR 70047 through 70057), and CY 2024 PFS final rule (88 FR 79329 through 79338) for a description of previously established policies related to the quality performance category. The data submitted from the final list of MIPS quality measures are used to assess the performance of an individual MIPS eligible clinician, group, virtual group, subgroup, or APM Entity for the quality performance category, to contribute to their overall score, and to help determine the payment adjustment for MIPS eligible clinicians.

We are proposing that a data submission in the quality performance category must include numerator and denominator data for at least one quality measure from the list of MIPS quality measures to be assigned a score in the quality performance category. Under the current policies described at § 414.1325, we finalized data submission types for MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities. In the CY 2018 Quality Payment Program final rule (82 FR 53780), we stated that we will determine a quality performance category percent score whenever a MIPS eligible clinician has submitted at least one quality measure. As described previously in this section of this proposed rule, we currently assign a score for any data submitted for the MIPS performance categories and have implemented operational measures to limit unintentional overriding of an approved reweighting or existing scorable data submitted for a MIPS performance category. However, we continue to receive unintentional submissions without data that can be scored resulting in the overriding of an approved reweighting application or a prior data submission that can be scored for the quality performance category. We note that this proposal does not include any changes to the current scoring policies described under § 414.1380(b)(1) for the quality performance category. Therefore, we will still assign a score of zero for the quality performance category if an individual MIPS eligible clinician, group, virtual group, subgroup, or APM Entity does not submit at least one available quality measure unless the performance category has been reweighted as defined at § 414.1380(c)(2).

We propose to specify what we consider to be a data submission at § 414.1325(a)(1)(i) to state that, for the quality performance category, a data submission must include numerator and denominator data for at least one MIPS quality measure from the final list of MIPS quality measures. We anticipate the proposed change would potentially avoid unintentional overriding of an approved reweighting or a prior data submission for the quality performance category due to submissions without any quality measure data. We are not proposing any changes to the data submission requirements, data submission criteria, data completeness criteria, and scoring for the quality performance category described under §§ 414.1325, 414.1335, 414.1440, and 414.1380(b)(1) respectively. We request public comments on this proposal.

(c) Improvement Activities Performance Category

We refer readers to §§ 414.1355 and 414.1360 and the CY 2017 Quality Payment Program final rule (81 FR 77177 and 77178), CY 2018 Quality Payment Program final rule (82 FR 53648 through 53661), CY 2019 PFS final rule (83 FR 59776 and 59777), CY 2020 PFS final rule (84 FR 62980 through 62990), CY 2022 PFS final rule (86 FR 65462) and the CY 2024 PFS final rule (88 FR 79328) for a description of previously established policies related to the improvement activities performance category.

We previously finalized at § 414.1360(a)(2) that MIPS eligible clinicians, groups, virtual groups, or subgroups must submit a yes response for each improvement activity that is performed for at least a continuous 90-day period during the applicable performance period to receive points in the improvement activities performance category described under § 414.1360(b)(3). We currently assign a score for any submission or attestation received in the improvement activities performance category via the submission types described under § 414.1325(a)(1) regardless of whether the submission or attestation included a yes response or not. In the event of a submission without yes responses, we currently assign a score of zero.

Data submitted in the improvement activities performance category is used to assess the performance of an individual MIPS eligible clinician, group, virtual group, subgroup, or APM Entity on the attestation or data submission for the improvement activities and to determine the payment adjustment for MIPS eligible clinicians. We are proposing to specify for clinicians what we consider to be a data submission and that we would score a data submission only if the submission includes a response of ''yes'' for at least one improvement activity included in the improvement activities inventory for the MIPS performance period. We anticipate the proposed change would potentially avoid unintentional overriding of an approved reweighting or a prior data submission for the improvement activities performance category due to submissions or attestations without a response of ''yes'' for any of the improvement activities.

We propose to specify what we consider to be a data submission at

[737] Attestation is one possible way to for MIPS eligible clinicians participating in APMs to earn credit in the improvement activities performance category but is not required to earn credit. Consistent with our regulation at § 414.1380(b)(3)(i), we automatically award 50 percent credit for the improvement activities performance category to MIPS eligible clinicians participating in APMs when they attest to having completed an improvement activity or submit data for the quality or Promoting Interoperability performance categories. We are not proposing to change this.

§ 414.1325(a)(1)(ii) to state that for the improvement activities performance category, a data submission must include a response of ''yes'' for at least one activity in the MIPS improvement activities inventory. We note that we are not proposing any changes to the data submission criteria and scoring for the improvement activities performance category described under §§ 414.1360 and 414.1380(b)(3) respectively. We request public comments on this proposal.

(d) Promoting Interoperability Performance Category

We refer readers to § 414.1375 for our previously established policies regarding reporting for the Promoting Interoperability performance category. We also refer readers to § 414.1305 for the definition of attestation, § 414.1325 for data submission requirements, and § 414.1380(b)(4) for Promoting Interoperability performance category scoring. We refer readers to § 414.1380(c)(2)(i)(C) for our previously finalized policies regarding scoring of data submission in the Promoting Interoperability performance category after an approved reweighting for the performance category. We also refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77199 through 77245), CY 2018 Quality Payment Program final rule (82 FR 53663 through 53688), CY 2019, CY 2021, CY 2022, CY 2023, and CY 2024 PFS final rules (83 FR 59785 through 59820, 84 FR 62991 through 63006, 85 FR 84886 through 84895, 86 FR 65466 through 65490, 87 FR 70060 through 70087, and 88 FR 79351 through 79365, respectively) for a description of previously established policies related to the Promoting Interoperability performance category.

We currently consider any information received for the Promoting Interoperability performance category in the Quality Payment Program Submission environment a data submission and assign a performance category score based on the submission. We assign a score of zero for incomplete submissions in the Promoting Interoperability performance category, for example, submissions that include only a date and CMS CEHRT ID without any data that can be scored with respect to the required objectives, measures, or attestations, as specified by CMS. Under § 414.1375, if we receive a complete data submission for the Promoting Interoperability performance category with responses included for all the required Promoting Interoperability objectives, associated measures, and attestation statements as specified by CMS and utilizing the CEHRT (meeting the definition at § 414.1305) as required, we score the data submission under our established scoring policies for the performance category.

We previously finalized at § 414.1380(c)(2)(i)(C) that, if a MIPS eligible clinician with an approved reweighting for the Promoting Interoperability performance category submits data, they will be scored in this performance category and the reweighting will not be applied, except as provided in § 414.1380(c)(2)(i)(C)(*10*) and (*11*). We also included in the educational materials available on the Quality Payment Program resource library (*https://qpp-cm-prod content.s3.amazonaws.com/uploads/ 2602/2023MIPSSubmissionGuide.pdf*) that a MIPS eligible clinician will be scored in this performance category if they attest to any data, such as selecting performance period dates or responding to attestation statements during the submission period. As set forth under § 414.1380(c)(2)(i)(C), submission of any data for the Promoting Interoperability performance category overrides reweighting, including reweighting due an approved significant hardship exception and automatic reweighting for clinicians that are Ambulatory Surgical Center (ASC)-based, hospital-based, non-patient facing, and small practices. Similarly, under § 414.1380(c)(2)(i)(A)(*4*)(*iii*), submission of any data also overrides our automatic reweighting of the Promoting Interoperability performance category for clinical social workers.[738]

Furthermore, to earn a performance category score for the Promoting Interoperability performance category, we established at § 414.1375 that, for the performance period established at § 414.1320, individual MIPS eligible clinicians, groups, virtual groups, subgroups, or APM Entities must use CEHRT as defined at § 414.1305, report on objectives and associated measures as specified by CMS, and submit attestations as specified by CMS. Under § 414.1325(b) and (c), individual MIPS eligible clinicians, groups, virtual groups, subgroups and APM entities (or authorized representatives submitting on their behalf) can submit data for the Promoting Interoperability performance category using the direct, login and attest, or login and upload submission types. Specifically, to submit data for the Promoting Interoperability performance category, individual MIPS eligible clinicians, groups, virtual groups, subgroups and APM entities (or authorized representatives submitting on their behalf) must use CEHRT as required (meeting the definition at § 414.1305) for the continuous 180-day performance period (§ 414.1320(i)) to report the applicable objectives, measures, and attestations. We refer readers to section IV.A.4.e.(4) of this proposed rule for additional details on CEHRT requirements (including ONC health IT certification criteria set forth under 45 CFR 170.315) and objectives, measures, and attestations required for the Promoting Interoperability performance category.

Currently, we receive submissions in the Promoting Interoperability performance category without completed responses for all the required objectives, measures, and attestations. For example, if a submission for the Promoting Interoperability performance category includes only a date, practice ID, and/or a CEHRT ID, or the submission does not include all of the required objectives, measures, and attestations, then we consider these to be incomplete data submissions. Currently, an incomplete data submission would void an approved reweighting of the Promoting Interoperability performance category in accordance with § 414.1380(c)(2)(i)(C). As discussed in this section of this proposed rule, we believe that we should not consider data submissions for the Promoting Interoperability performance category if the submission is incomplete, and does not include all necessary required data. We are proposing that the minimum criteria for a qualifying data submission for the Promoting Interoperability performance category must include all required reporting elements for the performance category, as specified below.

We considered whether CMS should accept incomplete submissions for the Promoting Interoperability performance category. If CEHRT is utilized as required to collect and report measure data and submit attestation statements and other requirements, it would generally result in only complete submissions for the Promoting Interoperability performance category. We recognize that some of the measures in the Promoting Interoperability performance category (such as the SAFER Guides measure and security risk analysis) do not directly require the use of CEHRT, whereas some measures (such as e-prescribing) directly require the use of CEHRT. However, all the requirements for the Promoting Interoperability performance category are directly related to a MIPS eligible clinician demonstrating that whether

[738] We note that this automatic reweighting policy for clinical social workers only applies through the CY 2024 performance period/2026 MIPS payment year.

they are a meaningful user of CEHRT in accordance with sections 1848(q)(2)(A)(iv), (B)(iv) and 1848(o)(2)(A) of the Act. Further, section 1848(o)(2)(A) requires that all requirements set forth therein (meaningful use of CEHRT, electronic exchange of health information, and reporting on clinical quality and other measures using CEHRT) be met for a MIPS eligible clinician to be treated as a meaningful EHR user for the applicable performance period. Therefore, accepting an incomplete data submission for the Promoting Interoperability performance category would be counterintuitive to a MIPS eligible clinician demonstrating whether they are a meaningful user of CEHRT in accordance with sections 1848(q)(2)(A)(iv), (B)(iv) and 1848(o)(2)(A) of the Act.

We are proposing to adopt minimum criteria for what we would consider a qualifying data submission for the Promoting Interoperability performance category only if the submission includes all of the required reporting elements for the category, including data on all required measures (including any claim of an applicable exclusion), required attestation statements, the CEHRT ID, and the start and end date for the applicable performance period. This proposal would clarify what counts as a data submission for MIPS eligible clinicians and it would potentially avoid partial data submissions from overriding an approved reweighting or a previously scored submission for the Promoting Interoperability performance category.

Specifically, we propose to specify minimum criteria as a qualifying data submission for the Promoting Interoperability performance category at § 414.1325(a)(1)(iii) to provide that a data submission must include all of the following elements:

- Performance data, including any claim of an applicable exclusion, for the measures in each objective, as specified by CMS;
- Required attestation statements, as specified by CMS;
- CMS EHR Certification ID (CEHRT ID) from the Certified Health IT Product List (CHPL); and
- The start date and end date for the applicable performance period as set forth in § 414.1320.

As discussed previously, we are not proposing any changes to the existing scoring or reweighting policies described under § 414.1380 for the MIPS performance categories in this section of this proposed rule. If the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity does not have an approved reweighting for one or more of the MIPS performance categories and we do not receive a data submission meeting the proposed minimum criteria for a performance category that has not been reweighted, we will assign a score of zero for the applicable performance category. If we receive a qualifying data submission meeting the proposed minimum criteria for reporting, then we will review the data submission and score the Promoting Interoperability performance category in accordance with our applicable scoring policies.

We refer readers to section IV.A.4.e.(4) of this proposed rule for additional details on the reporting requirements and scoring of the objectives, measures, and attestations the Promoting Interoperability performance category.

We request public comments on this proposal.

(3) Treatment of Multiple Data Submissions

(a) Background

Under the current policies described at § 414.1325(d), individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities may submit their MIPS data using multiple data submission types for any performance category in accordance with § 414.1325(a)(1), as applicable; provided, however, that the individual MIPS eligible clinician, group, virtual group, subgroup, or APM Entity uses the same identifier for all performance categories and all data submissions. We established the policy to offer flexibility for individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities with reporting, as it provides more options for submission of data for the applicable performance categories. We refer readers to the CY 2017 and 2018 Quality Payment Program final rules (81 FR 77094 and 77095 and 82 FR 53619 through 53626, respectively) for additional details on the use of multiple data submission mechanisms for any MIPS performance category.

As discussed in this section of this proposed rule, at § 414.1305, we define a submitter type as a MIPS eligible clinician, group, virtual group, subgroup, APM Entity, or third party intermediary acting on behalf of a MIPS eligible clinician, group, virtual group, subgroup, APM Entity, as applicable, that submits data on measures and activities under MIPS. During a submission period, a submitter associated with an organization (for example, registry, practice administrator, or EHR vendor) could submit data for a MIPS eligible clinician, group, subgroup, virtual group, or APM Entity. If needed, the submitter could also review and correct the data submission resulting in multiple data submissions for the MIPS performance categories. Additionally, there could be instances when a submitter unintentionally submits data multiple times. There could also be instances when we receive data for a MIPS eligible clinician, group, subgroup, virtual group, or an APM Entity from multiple organizations. For example, both a registry and a QCDR could submit MIPS data on behalf of a group practice for a performance period. Individual MIPS eligible clinicians, groups, practice representatives, and third party intermediaries benefit from the flexibility to submit data multiple times as it provides opportunities to correct errors in a prior submission and allows clinicians to submit data from multiple sources (qualified registry and group submission) to increase their chances to provide the most clinically relevant data.

For the quality, improvement activities, and Promoting Interoperability performance categories, there is an established policy governing our treatment of multiple data submissions received for a performance period; additional guidance on how we process and score multiple submissions received in the MIPS performance categories via educational and outreach materials is available on the Quality Payment Program Resource Library (*https://qpp.cms.gov/resources/resource-library*). However, we have not codified this policy in prior rules. In this section, we are proposing to codify at § 414.1325(f)(1) our existing policies governing our treatment of multiple data submissions received for the quality and improvement activities performance categories. We are also proposing to modify our policy governing our treatment of multiple data submissions received for the Promoting Interoperability performance category, which we also propose to codify at § 414.1325(f)(2).

(b) Quality and Improvement Activities Performance Categories

In the CY 2018 Quality Payment Program final rule (82 FR 53619 through 53626), we discussed scoring policies for multiple submissions received in the MIPS performance categories. Specifically, we stated that if an individual MIPS eligible clinician or group submits the same measure through two different mechanisms, each submission would be calculated and

scored separately and that we do not have the ability to aggregate data on the same measure across submission mechanisms. We would only count the submission that gives the clinician the higher score, thereby avoiding double counting (82 FR 53620). We refer readers to CY 2019 PFS final rule (83 FR59747 through 59749) for our discussion of previously finalized policies related to the use of the term ''submission mechanism.''

Under the existing process for the quality and improvement performance categories, if we receive multiple submissions for an individual clinician, group, subgroup, or virtual group from submitters from separate organizations (for example, registry, practice administrator, or EHR vendor), we score each submission and assign the highest of the scores for the performance category. If we receive multiple submissions for an individual clinician, group, subgroup, or virtual group from a submitter or submitters from the same organization, we will use the most recent submission. For example, if a qualified registry submits improvement activities for a group on Tuesday and a practice administrator submits improvement activities data for the same group on Wednesday, we will score all the data submissions and assign the highest of the scores. If the practice administrator from a group practice submits improvement activities data for the group on Tuesday and either the practice administrator or another submitter employed by the group practice submits improvement activities data for the group again on Wednesday, we will score only the data submission received on Wednesday because a new data submission received from the same organization on Wednesday will override the prior data submission on Tuesday.

To codify the existing process for multiple data submissions for the quality and improvement activities performance categories, we are proposing to add at § 414.1325(f)(1) that for multiple data submissions received in the quality and improvement activities performance categories in accordance with paragraphs (a)(1)(i) and (ii) for an individual MIPS eligible clinician, group, subgroup, or virtual group from submitters in multiple organizations (for example, qualified registry, practice administrator, or EHR vendor), CMS will calculate and score each submission received and assign the highest of the scores. We are also proposing to modify our policy governing our treatment of multiple data submissions for the quality and improvement activities performance category received for an individual MIPS eligible clinician, group, subgroup, or virtual group from one or multiple submitters in the same organization and score the most recent submission. We request public comments on this proposal.

(c) Promoting Interoperability Performance Category

For the Promoting Interoperability performance category, we explained in the educational materials published on the Quality Payment Program Resource Library (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2602/2023MIPSSubmissionGuide.pdf*) that any data submitted through multiple submission types or multiple submissions submitted through the same submission type will result in a score of zero for the Promoting Interoperability performance category. Additionally, we recommended using a single submission type (file upload, API, or attestation by an individual MIPS eligible clinician, group, virtual group, subgroup or a third party intermediary) to submit data for the Promoting Interoperability performance category. As discussed in section IV.A.4.d.(2)(d) of this proposed rule, the utilization of the CEHRT should not generate conflicting data for measures and objectives in the Promoting Interoperability performance category. However, we have received inquiries from MIPS eligible clinicians that were impacted by the existing process to assign a score of zero for multiple submissions in the Promoting Interoperability performance category. Specifically, we identified scenarios when a complete submission from an individual MIPS eligible clinician or group followed by an incomplete submission resulted in a score of zero, either overriding a previous score greater than zero or voiding an approved reweighting for the performance category.

On this basis, we propose to amend our policy for treatment of multiple data submissions for the Promoting Interoperability performance category. We are proposing that, for multiple data submissions received, CMS would calculate a score for each data submission received and assign the highest of the scores. We also are proposing to codify this proposal at § 414.1325(f)(2).

We believe this proposal is consistent with our existing policy for treatment of multiple data submissions received in the quality and improvement activities performance categories, as discussed previously. Implementing a similar policy for allowing multiple data submissions in the Promoting Interoperability performance category may provide flexibility for individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities to fix errors in a prior data submission. Additionally, we recognize there may be instances when a practice switches EHR vendors during a performance period, potentially resulting in separate data submissions for the Promoting Interoperability performance category. This proposed policy also aligns with our intent to maintain consistency in data submission requirements across all MIPS performance categories, to the extent possible, as it significantly reduces the complexity for MIPS eligible clinicians participating in MIPS.

We request public comments on this proposal.

f. MIPS Performance Category Measures and Activities

(1) Quality Performance Category

(a) Background

Section 1848(q)(1)(A)(i) and (ii) of the Act requires the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician according to certain specified performance standards and, using such methodology, to provide for a final score for each MIPS eligible clinician. Section 1848(q)(2)(A)(i) of the Act provides that the Secretary must use the quality performance category in determining each MIPS eligible clinician's final score, and section 1848(q)(2)(B)(i) of the Act describes the measures that must be specified under the quality performance category.

We refer readers to §§ 414.1330 through 414.1340 and the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77097 through 77162 and 82 FR 53626 through 53641, respectively), and the CY 2019, CY 2020, CY 2021, CY 2022, CY 2023, and CY 2024 PFS final rules (83 FR 59754 through 59765, 84 FR 63949 through 62959, 85 FR 84866 through 84877, 86 FR 65431 through 65445, 87 FR 70047 through 70055, and 88 FR 79329 through 79338, respectively) for a description of previously established policies and statutory basis for policies regarding the quality performance category.

In this proposed rule, we are proposing to:

- Establish the data submission criteria for the Alternative Payment Model (APM) Performance Pathway (APP) quality measure set.
- Maintain the data completeness criteria threshold of at least 75 percent for the CY 2027 and CY 2028

performance periods/2029 and 2030 MIPS payment years.

- Codify previously established criteria pertaining to the removal of MIPS quality measures.
- Modify the MIPS quality measure set as described in Appendix 1 of this proposed rule, including the addition of new measures, updates to specialty sets, removal of existing measures, and substantive changes to existing measures.

(b) Data Submission Criteria

(i) Data Submission Criteria for the Quality Performance Category

In the CY 2021 PFS final rule (85 FR 84859 through 84866), we established the APP in § 414.1367 as an available reporting option starting with the CY 2021 performance period/2023 MIPS payment year, which was designed to provide a predictable and consistent MIPS reporting option to reduce reporting burden and encourage continued APM participation. Additionally, we finalized a quality measure set (85 FR 84860 through 84861) for purposes of the quality performance category scoring for the APP.

The APP and the APP quality measure set were designed to reduce the reporting burden and create new scoring opportunities for MIPS APMs by having a stable, streamlined pathway for reporting and scoring in MIPS while recognizing the reporting burden and performance scoring that MIPS eligible clinicians, groups, and APM Entities already experience in their respective MIPS APMs. We believed that using a broadly applicable population health-based measure set would enable MIPS APM participants to focus on the quality measures being reported through their APMs, while relying on a consistent measure set within the APP from year to year. (85 FR 84862).

In section IV.A.4.c.(3) of this proposed rule, we are proposing to create a second quality measure set as an available option under the APP, specifically the APP Plus quality measure set, which is a set of measures that are included in the Adult Universal Foundation measure set. Of the ten Adult Universal Foundation measures, five of the measures are already included in the APP quality measure set for the CY 2025 performance period/2027 MIPS payment year (88 FR 79113 through 79114). The APP Plus quality measure set would initially consist of all the measures currently within the APP quality measure set (five Adult Universal Foundation measures and a separate quality measure) plus two additional measures from the Adult Universal Foundation measure set. The set would incrementally add the remaining three Adult Universal Foundation measures by the CY 2028 performance period/2030 MIPS payment year. (We refer readers to section IV.A.4.c.(3) of this proposed rule for further discussion regarding the APP Plus quality measure set.) Aligning the APP Plus quality measure set with the Adult Universal Foundation measure set serves to advance Medicare's overall value-based care strategy and maintain alignment within and across CMS's quality programs. The alignment of quality measures across CMS programs allows clinicians to better focus their quality efforts, reduce administrative burden, and drive digital transformation and stratification of a focused quality measure set to assess the impact on disparities.[739]

For the APP Plus quality measure set, we are proposing in § 414.1335(b) to require MIPS eligible clinicians, groups, and APM Entities, including Medicare Shared Saving Program Accountable Care Organizations (ACOs), to report on all measures in the APP Plus quality measure set (with the exception of the administrative claims-based quality measures automatically calculated by CMS) for the applicable performance period. As discussed further in sections IV.A.4.c.(3) of this proposed rule, the APP Plus quality measure set would be optional for MIPS eligible clinicians, groups, and APM Entities (not including Medicare Shared Savings Program ACOs) meeting the reporting requirements under the APP starting with the CY 2025 performance period/2027 MIPS payment year. However, for a Medicare Shared Savings Program ACOs, they would be required to report the APP Plus quality measure set to meet the reporting requirements of the Medicare Shared Savings Program's quality performance standard as discussed in section IV.A.4.c.(2) of this proposed rule. Under the proposal in § 414.1335(b), the requirement to report all measures within the APP Plus quality measure set (with the exception of the administrative claims-based quality measures automatically calculated by CMS) would be the same regardless of whether a MIPS eligible clinicians, group or APM Entity is reporting the APP Plus quality measure set on a mandatory or optional basis. We are proposing conforming amendments in § 414.1335(a).

Having Medicare Shared Savings Program ACOs use the APP Plus quality measure set allows for the comprehensive incorporation of the quality measures in the Adult Universal Foundation measure set by the CY 2028 performance period/2030 MIPS payment year and the better alignment of the quality measures reported by Medicare Shared Savings Program ACOs with the Medicaid Core Sets and the Marketplace Quality Rating System, which have previously adopted the quality measures in the Adult Universal Foundation.[740] Also, the alignment with the Adult Universal Foundation would better align the quality measures reported by Medicare Shared Savings Program ACOs with the Value in Primary Care MIPS Value Pathway (MVP). Alignment would allow clinicians to leverage their familiarity and experience with the Adult Universal Foundation quality measures among primary care clinicians participating in this MVP as they transition to reporting the APP Plus quality measure set in the Medicare Shared Savings Program. Experience and familiarity with the same quality measures, redesigned care processes, and quality improvement activities that are commonplace in ACOs would streamline the pathway for clinicians to join ACOs in the future, which is consistent with our goal to have all beneficiaries in an accountable care relationship by 2030. The Medicare Shared Savings Program has the authority under section 1899(b)(3)(C) of the Act to seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care.

Lastly, we note that the existing reporting requirements and scoring policies established in § 414.1367(c)(1) continue to be applicable to the APP quality measure set. Similarly, the existing scoring policies established in § 414.1367(c)(1) would be applicable to the APP Plus quality measure set. As discussed in more detail in section IV.A.4.c.(3) of this proposed rule we are proposing to require that all measures within the APP Plus quality measure set be reported (with the exception of the administrative claims-based quality measures that are automatically calculated by CMS), and all measures in the APP Plus quality measure set would be scored, unless a measure does not

[739] Update On The Medicare Value-Based Care Strategy: Alignment, Growth, Equity'', Health Affairs Forefront, March 14, 2024. *DOI: 10.1377/forefront.20240311.141546*.

[740] Jacobs D, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher L. Aligning Quality Measures across CMS—The Universal Foundation. New England Journal of Medicine, March 2, 2023, available at *https://www.nejm.org/doi/full/10.1056/NEJMp2215539*.

have a benchmark or meet the case minimum requirements. If a measure within the APP Plus quality measure set does not have a benchmark or meet the case minimum requirements, the measure would still be required to be reported in order to meet the reporting requirements of the APP and for the measure to be excluded from scored (such measure would not contribute to the quality performance category score as long as the measure is reported). If such a measure is not reported, then the measure would fail to meet the reporting requirements of the APP and as a result, it would receive 0 achievement points.

We are seeking public comment on the proposal to establish the data submission criteria for the APP Plus quality measure set, specifically the proposal to require the reporting of all measures within the APP Plus quality measure set (with the exception of the administrative claims-based quality measures automatically calculated by CMS).

(c) Data Completeness Criteria

(i) Data Completeness Criteria for the Quality Performance Category

As described in the CY 2017 Quality Payment Program final rule (81 FR 77125 through 77126), to ensure that data submitted on quality measures are complete enough to accurately assess each MIPS eligible clinician's quality performance, we established a data completeness requirement. Section 1848(q)(5)(H) of the Act provides that analysis of the quality performance category may include quality measure data from other payers, specifically, data submitted by MIPS eligible clinicians with respect to items and services furnished to individuals who are not entitled to benefits under Part A or enrolled under Part B of Medicare. For the CY 2017 performance period/2019 MIPS payment year (first year of the implementation of MIPS), we established the data completeness criteria threshold to reflect a threshold of at least 50 percent (81 FR 77125). The data completeness criteria threshold means the following: an individual MIPS eligible clinician, group, virtual group, or APM Entity submitting measure data on qualified clinical data registry (QCDR) measures, MIPS clinical quality measures (CQMs), or electronic clinical quality measures (eCQMs) must submit data on at least a specific percent (that is, 50 percent as specified above and 60 percent, 70 percent, and 75 percent as specified in the following paragraphs) of their patients that meet the measure's denominator criteria, regardless of payer; an individual MIPS eligible clinician, group, virtual group, or APM Entity submitting quality measure data on Medicare Part B claims measures must submit data on at least a specified percent (*i.e.,* 50 percent as specified above and 60 percent, 70 percent, and 75 percent as specified in the following paragraphs) of their Medicare Part B patients seen during the corresponding performance period; and an APM Entity, specifically a Medicare Shared Savings ACO that meets the reporting requirements under the APP, submitting quality measure data on Medicare CQMs must submit data on at least a specified percent (that is, 70 percent and 75 percent as specified in the following paragraphs) of the APM Entity's applicable beneficiaries eligible for the Medicare CQM, as defined at § 425.20, who meet the measure's denominator criteria.

In the CY 2017 and CY 2018 Quality Payment Program final rules and the CY 2020 PFS final rule, we noted that we would increase the data completeness criteria threshold over time (81 FR 77121, 82 FR 53632, and 84 FR 62951). We increased the data completeness criteria threshold from at least 50 percent to at least 60 percent for the CY 2018 performance period/2020 MIPS payment year (81 FR 77125 and 82 FR 53633) and maintained a threshold of at least 60 percent for the CY 2019 performance period/2021 MIPS payment year (82 FR 53633 and 53634). For the CY 2020 performance period/ 2022 MIPS payment year, we increased the data completeness criteria threshold from at least 60 percent to at least 70 percent (84 FR 62952). We maintained data completeness criteria threshold of at least 70 percent for the CY 2021, CY 2022, and CY 2023 performance periods/2023, 2024, and 2025 MIPS payment years (86 FR 65435 through 65438). For the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years, we increased the data completeness criteria threshold from at least 70 percent to at least 75 percent (87 FR 70049 through 70052). Lastly, we maintained the data completeness criteria threshold of at least 75 percent for the CY 2026 performance period/2028 MIPS payment year (88 FR 79334 through 79337).

We continue to believe that it is important to incrementally increase the data completeness criteria threshold as MIPS eligible clinicians, groups, virtual groups, subgroups, and Alternative Payment Model (APM) Entities gain experience with MIPS. The incorporation of higher data completeness criteria thresholds in future years ensures a more accurate assessment of a MIPS eligible clinician's performance on quality measures and prevents selection bias to the extent possible (81 FR 77120, 82 FR 53632, 83 FR 59758, 86 FR 65436, 87 FR 70049, and 88 FR 79334). In order to improve compliance with the data completeness threshold, we have encouraged all MIPS eligible clinicians to perform the quality actions associated with the quality measures on their patients (82 FR 53632, 86 FR 65436, 87 FR 70049, and 88 FR 79334) such that all applicable cases may be used when calculating a measure. The data submitted for each measure is expected to be representative of the individual MIPS eligible clinician, group, or virtual group's overall performance for that measure.

Increasing the data completeness criteria threshold provides for a more accurate assessment of performance. We want to ensure that an appropriate, yet achievable, data completeness criteria threshold is applied to all eligible clinicians participating in MIPS. Based on our analysis of data completeness rates from data submission for the CY 2017 performance period,[741] it is generally feasible for eligible clinicians and groups to achieve a higher data completeness criteria threshold without jeopardizing their ability to successfully participate and perform well in MIPS. Our approach for increasing the data completeness criteria threshold slowly and incrementally over time enhances the ability for individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities to meet the data completeness criteria threshold as it increases and consequently, enables successful participation under MIPS. Thus, a data completeness criteria threshold of less than 100 percent may reduce clinician burden and accommodate operational issues that may arise during data collection during the initial years of the program (82 FR 53632, 86 FR 65436, 87 FR 70049, and 88 FR 79334).

As MIPS eligible clinicians, groups, virtual groups, and APM Entities have gained experience participating in MIPS, particularly meeting the data completeness criteria threshold over the last 8 years (from the CY 2017 performance period to the CY 2024 performance period), such experience has prepared MIPS eligible clinicians, groups, virtual groups, subgroups (participation option available starting with the CY 2024 performance period),

[741] As described in the CY 2020 PFS final rule (84 FR 62951), the average data completeness rates were as follows: for individual eligible clinicians, it was 76.14; for groups, it was 85.27; and for small practices, it was 74.76.

and APM Entities to meet incremental increases in the data completeness criteria threshold. We have maintained a data completeness criteria threshold of at least 70 percent for 4 years from the CY 2020 performance period through the CY 2023 performance period and as a result, individual MIPS eligible clinicians, groups, virtual groups, and APM Entities had 4 years of a maintained data completeness criteria threshold of at least 70 percent before transitioning to an increased data completeness criteria threshold of at least 75 percent starting with the CY 2024 performance period. We believed that maintaining the data completeness criteria threshold of at least 70 percent for 4 years provided adequate time for individual MIPS eligible clinicians, groups, virtual groups, and APM Entities to adjust to the increase that went into effect at the onset of the COVID–19 public health emergency and account for the implications the COVID–19 pandemic had on the healthcare system.

As we assess the timeframe for a potential future increase to the data completeness criteria threshold, we have determined that maintaining the data completeness criteria threshold of at least 75 percent for a total of 5 years would provide sufficient time for MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities to adjust to the data completeness criteria threshold of at least 75 percent. In response to the proposal in the CY 2023 PFS proposed rule to increase the data completeness criteria threshold to at least 80 percent starting with the CY 2026 performance period/2028 MIPS payment year, interested parties indicated in the public comments that increasing the data completeness threshold from 75 to 80 percent within two years of increasing the threshold from 70 to 75 percent would present various challenges such as the following, which would make it more difficult to meet the data completeness criteria threshold: increased burden (in particular, disproportionately increase burden for smaller and rural practices due to limited resources and staff, and some practices that are continuing to recover from the COVID–19 Public Health Emergency); and exacerbated technical and interoperability challenges pertaining to data aggregation across multiple EHRs, systems (utilizing different registries, and EHR developers and vendors), and sites (including multiple TINs participating in the Medicare Shared Savings Program as an ACO) (88 FR 79337). We accept these concerns, and we thus believe that MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities require more time to adjust and prepare for an increase. We have implemented the data completeness criteria threshold of at least 75 percent for 2 years. Specifically, we previously established that for the CY 2024 performance period through the CY 2026 performance period/2026 MIPS payment year through the 2028 MIPS payment year, we would establish and maintain the data completeness threshold of at least 75 percent (87 FR 70049 through 70052, 88 FR 79334 through 79337). Therefore, for the CY 2027 and CY 2028 performance periods/2029 and 2030 MIPS payment years, we are proposing to maintain the data completeness criteria threshold of at least 75 percent. In establishing data completeness criteria thresholds in advance of an applicable performance period, it is advantageous to delineate the expectations for MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities as it provides sufficient notice of the expectation and subsequently, allows such MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities to prepare for a potential increase in future years.

In this proposed rule, we are proposing to maintain the data completeness criteria threshold of at least 75 percent for 2 additional years. Specifically, in § 414.1340(a), we are proposing the following data completeness criteria thresholds pertaining to QCDR measures, MIPS CQMs, and eCQMs:

- At paragraph (a)(4), for the CY 2027 and CY 2028 performance periods/2029 and 2030 MIPS payment years, a MIPS eligible clinician, group, virtual group, subgroup, and APM Entity submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs must submit data on at least 75 percent of the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's patients that meet the measure's denominator criteria, regardless of payer.

Similarly, in § 414.1340(b), respectively, we are proposing the following data completeness criteria thresholds pertaining to Medicare Part B claims measures:

- At paragraph (b)(4), for the CY 2027 and CY 2028 performance periods/2029 and 2030 MIPS payment years, a MIPS eligible clinician, group, virtual group, subgroup, and APM Entity submitting quality measures data on Medicare Part B claims measures must submit data on at least 75 percent of the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's patients seen during the corresponding performance period to which the measure applies.

Additionally, in § 414.1340(d), respectively, we are proposing the following data completeness criteria thresholds pertaining to Medicare CQMs:

- At paragraph (d)(1), for the CY 2027 and CY 2028 performance periods/2029 and 2030 MIPS payment years, an APM Entity, specifically a Medicare Shared Savings Program ACO that meets the reporting requirements under the APP, submitting quality measure data on Medicare CQMs must submit data on at least 75 percent of the APM Entity's applicable beneficiaries eligible for the Medicare CQM, as defined at § 425.20, who meet the measure's denominator criteria.

Lastly, for the data completeness criteria pertaining to the quality performance category, we are proposing a conforming amendment to recognize that an APM Entity, specifically a Medicare Shared Savings Program ACO that meets the reporting requirements under the APP, must meet the data completeness criteria requirements established at § 414.1340(d)(1).

We are seeking public comment on these proposals.

(d) Selection of Quality Measures

(i) Addition of New Quality Measures

(A) Pre-Rulemaking Process

Prior to introducing a new MIPS quality measure in a proposed rule, CMS receives public input on measures through the pre-rulemaking process (referred to as the Pre-Rulemaking Measure Review (PRMR)) established in accordance with section 1890A of the Act. Although section 1848(q)(2)(D)(viii) of the Act provides that the pre-rulemaking process under section 1890A of the Act is not required to apply to the selection of MIPS quality measures, we have found that the pre-rulemaking process provides a comprehensive review of measures from multi-stakeholder workgroups and have accordingly elected for such measures to be reviewed utilizing the PRMR process (87 FR 70048). Pursuant to the established PRMR process (additional information regarding the PRMR process is available at *https://p4qm.org/PRMR*), CMS has contracted with a Consensus-Based Entity (CBE), which is responsible for convening a multi-stakeholder panel comprised of clinicians, patients, measure experts, and health information technology specialists to provide input on measures CMS is considering for use in Medicare.

The pre-rulemaking process begins with CMS's publication of measures under consideration for use in Medicare (the MUC List). Each measure on the MUC List is reviewed by one of several committees convened by the PQM for the purpose of providing multi-stakeholder input to the Secretary. The PRMR process includes opportunities for public comment through a 21-day public comment period, as well as public listening sessions. The PQM posts the compiled comments and listening session inputs received during the public comment period and the listening sessions within 5 days of the close of the public comment period. More details regarding the PRMR process may be found in the PQM Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review and Measure Set Review.

The final vote of a multistakeholder committee convened by the CBE may result in the following disposition of a measure: recommended, recommended with conditions, do not recommend, or no consensus. A ''no consensus'' recommendation signals continued disagreement among the committee despite being presented with perspectives from public comment, committee member feedback and discussion, and highlights the multi-faceted assessments of quality measures. Quality measures that are considered for potential implementation in MIPS starting with the CY 2025 performance period were included on the 2023 Measures Under Consideration (MUC) List (available at *https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx*). The new MIPS quality measures proposed are described in Table Group A of Appendix 1 of this proposed rule. There may be cases in which the CBE does not recommend for a measure to move forward to the rulemaking process and eventual implementation due to a measure not being endorsed by the CBE or other CBE, but we go forth with proposing a measure. We note that section 1848(q)(2)(D)(iii)(v)(III) of the Act does not preclude the Secretary from proposing and implementing measures that are not endorsed by a CBE as long as the measure is evidence-based.

(ii) Removal of Quality Measures

In this proposed rule, we are codifying previously established criteria for the removal of MIPS quality measures from the MIPS quality measure inventory. In the CY 2017 Quality Payment Program final rule (81 FR 77136 through 77137), we established the following criteria for measure removal to include: If the Secretary determines that the MIPS quality measure is no longer meaningful, such as MIPS quality measures that are topped out; and, if a measure steward is no longer able to maintain the quality measure. In the CY 2019 PFS final rule (83 FR 59763), we expanded the criteria for measure removal to include MIPS quality measures that reached an extremely topped out status (for example, a measure with an average mean performance within the 98th to 100th percentile range); the MIPS quality measure may be proposed for removal in the next rulemaking cycle, regardless of whether or not it is in the midst of the topped-out measure lifecycle, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made, after taking into account any other relevant factors.

Also, in the CY 2019 PFS final rule (83 FR 59764), we established other criteria for measure removal, specifically MIPS quality measures that are: duplicative; not maintained or updated to reflect current clinical guidelines, which are not reflective of a clinician's scope of practice; and low-bar, standard of care process measures. As described in the CY 2019 PFS final rule (83 FR 59765), we established an approach to incrementally remove process measures where prior to removal, consideration will be given to, but will not be limited to the following:

- Whether the removal of the process measure impacts the number of measures available for a specific specialty.
- Whether the MIPS quality measure addresses a priority area highlighted in the Measure Development Plan: *https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/Measuredevelopment.html*.
- Whether the MIPS quality measure promotes positive outcomes in patients.
- Considerations and evaluation of the measure's performance data.
- Whether the MIPS quality measure is designated as high priority or not.
- Whether the MIPS quality measure has reached extremely topped out status within the 98th to 100th percentile range, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made.

Lastly, in the CY 2020 PFS final rule (84 FR 62958 through 62959), we expanded the criteria for measure removal to include MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods and not available for MIPS quality reporting by or on behalf of all MIPS eligible clinicians. For MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods, we noted that we will factor in other considerations (such as, but not limited to: The robustness of the measure; whether it addresses a measurement gap; if the measure is a patient-reported outcome; and consideration of the MIPS quality measure in developing MVPs) prior to determining whether to remove the MIPS quality measure.

We are proposing to codify the aforementioned criteria established for the removal of MIPS quality measures from the MIPS quality measure inventory in § 414.1330(c), respectively.

(iii) Inventory of Quality Measures

Section 1848(q)(2)(D)(i) of the Act requires the Secretary, through notice and comment rulemaking, to establish an annual final list of quality measures from which MIPS eligible clinicians may choose for the purpose of assessment under MIPS. Section 1848(q)(2)(D)(i)(II) of the Act requires that the Secretary annually update the list by removing measures from the list, as appropriate; adding new measures to the list, as appropriate; and determining whether measures that have undergone substantive changes should be included on the updated list.

Previously finalized MIPS quality measures can be found in the CY 2024 PFS final rule (88 FR 79556 through 79964), CY 2023 PFS final rule (87 FR 70250 through 70633), CY 2022 PFS final rule (86 FR 65687 through 65968), CY 2021 PFS final rule (85 FR 85045 through 85377), CY 2020 PFS final rule (84 FR 63205 through 63513), CY 2019 PFS final rule (83 FR 60097 through 60285), CY 2018 Quality Payment Program final rule (82 FR 53966 through 54174), and CY 2017 Quality Payment Program final rule (81 FR 77558 through 77816). We are proposing changes to the MIPS quality measure inventory, as set forth in Appendix 1 of this proposed rule, including the following: the addition of new measures; updates to specialty sets (*i.e.,* creation of new specialty sets; addition and/or removal of measures; and substantive changes to existing measures within specialty sets); removal of existing measures; and substantive changes to existing measures. For the CY 2025 performance

period, we are proposing an inventory of 196 MIPS quality measures.

The new MIPS quality measures that we are proposing to include in MIPS for the CY 2025 performance period and future years can be found in Table Group A of Appendix 1 of this proposed rule. For the CY 2025 performance period, we are proposing 9 new MIPS quality measures, which includes 5 high priority measures, of which 2 are also patient-reported outcome measures.

On January 3, 2024, we announced that we would be accepting recommendations for potential new specialty measure sets or revisions to existing specialty measure sets for year 9 (CY 2017 performance period/2019 MIPS payment year through CY 2025 performance period/2027 MIPS payment year) of MIPS under the Quality Payment Program.[742] The recommendations we received were based on the MIPS quality measures finalized in the CY 2024 PFS final rule and the 2023 MUC List; the recommendations include the addition or removal of current MIPS quality measures from existing specialty sets, and/or the creation of new specialty sets. All specialty set recommendations submitted for consideration were assessed and vetted, and as a result, the recommendations that we agree with are proposed in this proposed rule. We are proposing the addition of a new specialty set and additionally proposing modifications to existing specialty sets as described in Table Group B of Appendix 1 of this proposed rule. Modifications to specialty sets include the addition of new measures and/or existing measures within the MIPS quality measure inventory, removal of measures, and/or substantive changes to previously finalized measures (we refer readers to Table Group D of Appendix 1 in this proposed rule). Specialty and subspecialty sets are not inclusive of every specialty or subspecialty. We develop and maintain specialty measure sets to assist MIPS eligible clinicians with selecting quality measures that are most relevant to their scope of practice.

In addition to establishing new individual MIPS quality measures, modifying existing specialty sets, and creating new specialty sets as described in Tables Group A and Group B of Appendix 1 of this proposed rule, we refer readers to Table Group C of Appendix 1 of this proposed rule for a list of MIPS quality measures proposed for removal and applicable rationale for each measure. We have previously specified certain criteria that will be used when we are considering the removal of a measure (81 FR 77136 and 77137; 83 FR 59763 through 59765; 84 FR 62957 through 62959); and such criteria is outlined in the proposed § 414.1330(c) (as further discussed in section IV.A.4.e.(1)(d)(ii) of this proposed rule). For the CY 2025 performance period, we are proposing to remove 11 MIPS quality measures based on the previously established criteria. Of the 11 MIPS quality measures proposed for removal, 2 MIPS quality measures are duplicative to a proposed new MIPS quality measure; 3 MIPS quality measures are duplicative of current measures; 1 MIPS quality measure has reached the topped out lifecycle; 2 MIPS quality measures are extremely topped out; 1 MIPS quality measure is no longer owned/maintained; and 2 MIPS quality measures have limited adoption and consequently, have not been able to establish benchmarks to provide a meaningful impact to quality improvement. We have continuously communicated to interested parties our desire to reduce the number of process measures within the MIPS quality measure set (*see*, for example, 83 FR 59763 through 59765). Seven of the MIPS quality measures proposed for removal are process measures that would not provide granular information related to disparities. The proposal to remove the MIPS quality measures described in Table Group C of Appendix 1 of this proposed rule would lead to a more parsimonious inventory of meaningful, robust measures in the program, and that our approach to removing measures should occur through an iterative process that includes an annual review of the MIPS quality measures to determine whether they meet our removal criteria.

Also, we are proposing substantive changes to several MIPS quality measures, which can be found in Table Group D of Appendix 1 of this proposed rule. We have previously established criteria that would apply when we are considering making substantive changes to a quality measure (81 FR 77137, and 86 FR 65441 through 65442). We are proposing substantive changes to 66 MIPS quality measures, which includes 2 MIPS quality measures previously retained for utilization only in MVPs (we refer readers to Table Group DD of Appendix 1 of this proposed rule for such measures). On an annual basis, we review the established MIPS quality measure inventory to consider updates to the measures. Possible updates to measures may be minor or substantive. The aforementioned proposed inventory of 196 MIPS quality measures includes 193 MIPS quality measure available for utilization in traditional MIPS and MVPs, and 3 MIPS quality measures available only for utilization in MVPs (as finalized in the CY 2024 PFS final rule (88 FR 79897 through 77902)). In the CY 2024 PFS final rule, we removed the following 3 MIPS quality measures from traditional MIPS, but retained for utilization in MVPs: Quality #112: Breast Cancer Screening; Quality #113: Colorectal Cancer Screening; and Quality #128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (88 FR 79338 and 79897 through 79902). We note that some MIPS quality measures available in traditional MIPS and/or MVPs are measures adopted by the Medicare Shared Savings Program for utilization under the APP, specifically the APP quality measure set and the newly established APP Plus quality measure set, as proposed in section IV.A.4.c.(3) of this proposed rule. For the MIPS quality measures available in the APP quality measure set and APP Plus quality measure set for the CY 2025 performance period, we refer readers to section IV.A.4.c.(1) and section IV.A.4.c.(3) of this proposed rule.

Lastly, it should be noted that in this proposed rule, we are proposing a substantive change to the following administrative claims measure, Quality #492: Risk-Standardized Acute Cardiovascular-Related Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System (we refer readers to Table Group D of Appendix 1 of this proposed rule), that would be applied retroactively starting with the CY 2023 performance period/2025 MIPS payment year. In the CY 2023 PFS final rule, we inadvertently specified the measure was availability at the individual clinician level. The inclusion of the availability of the measure at the individual clinician level is a misrepresentation and erroneously conveys to MIPS eligible clinicians reporting at the individual clinician level that the measure is available to meet the minimum required number of measures to report under traditional MIPS or an MVP. The measure was tested and developed for implementation at the group, virtual group, subgroup via an MVP, and APM Entity levels. Thus, the measure is limited to groups, virtual groups,

[742] Message to the Quality Payment Program listserv on January 3, 2024, entitled ''The Centers for Medicare & Medicaid Services (CMS) is Soliciting Stakeholder Recommendations for Potential Consideration of New Specialty Measure Sets and/or Revisions to the Existing Specialty Measure Sets for the 2025 Performance Year of the Merit-based Incentive Payment System (MIPS).''

subgroups via an MVP, and APM Entities participating in MIPS. We believe that a failure to apply this substantive change retroactively would be contrary to the public interest.

Prior to the finalization of this measure as a new measure available within the MIPS quality measure inventory in the CY 2023 PFS final rule, the measure was initially proposed as a new measure in the CY 2022 PFS proposed rule. Based on the public comments received in response to the initial proposal of this measure in the CY 2022 PFS proposed rule, there were concerns regarding the attribution of certain patients to clinicians, particularly the risk adjustment for clinicians with higher caseloads of patients with more complicated or severe heart failure. As a result, the measure was not finalized as part of the CY 2022 PFS final rule; however, we noted that we would continue to consider how to implement condition-specific measures such as this measure under MIPS (86 FR 65692 through 65694).

In the CY 2023 PFS proposed rule, we re-proposed this measure, which mitigated the concerns regarding the attribution of such patients to clinicians by excluding patients at advanced stages of heart failure and requiring that a group, virtual group, subgroup via an MVP, and APM Entity to include at least 1 cardiologist (and a 21-patient case minimum); and subsequently, the measure was finalized in the CY 2023 PFS final rule (87 FR 70266 through 70271). The intent of the measure is for assessment of performance to be conducted at the group, virtual group, subgroup via an MVP, and APM Entity levels. The measure was not tested, developed, or implemented at the individual clinician level. In order for this measure to be available at the individual clinician level, the measure would need to be tested at the individual clinician level to establish validity, reliability, and risk adjustments at the individual clinician level. It is not appropriate for the measure to be available at the individual clinician level without further testing. Consequently, any assessment of data for this measure at the individual clinician level would produce invalid and unreliable results. By retroactively applying the substantive change to this measure (modifying the measure to remove the individual clinician level as an option) effective starting with the CY 2023 performance period/2025 MIPS payment year, the level of reporting available for the measure would align with the intent, implementation, and operationalization of the measure, and clarify that the measure is not available at the individual clinician level.

We are seeking public comment on the proposals to modify the quality performance category measure inventory, a set of 196 MIPS quality measures for the CY 2025 performance period, which includes the following:

- Implementation of 9 new MIPS quality measures: 5 high priority measures, of which 2 are also patient-reported outcome measures;
- Removal of 11 MIPS quality measures: 2 MIPS quality measure are duplicative to a proposed new quality measure; 3 MIPS quality measures are duplicative to current quality measures; 1 MIPS quality measure has reached the topped-out lifecycle; 2 MIPS quality measures are extremely topped out; 1 MIPS quality measure is no longer owned/maintained; and 2 MIPS quality measures have limited adoption and consequently, have not been able to establish benchmarks to provide a meaningful impact to quality improvement; and
- Substantive changes to 66 MIPS quality measures.

We refer readers to Table Groups A through DD of Appendix 1 of this proposed rule for the proposed modifications to the MIPS quality measure inventory for the CY 2025 performance period.

(e) Quality Performance Category Requests for Information

In this proposed rule, we are seeking public comment on the following two requests for information (RFIs) regarding to the quality performance category (see sections IV.A.4.e.(1)(e)(i) and IV.A.4.e.(1)(e)(ii) of this proposed rule). In accordance with the implementation of regulations pertaining to the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), the general solicitation of public comments for the two RFIs are exempt from the PRA. Facts or opinions submitted in response to general solicitations of public comments published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to themself, other than that which is necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

Respondents are encouraged to provide complete, but concise responses. The following RFIs are issued solely for information and planning purposes; they do not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. The RFIs do not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through the following RFIs and will not accept unsolicited proposals. Respondents are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to the RFIs; all costs associated with responding to the RFIs will be solely at the interested party's expense. Not responding to the RFIs do not preclude participation in any future procurement, if conducted. It is the responsibility of the potential respondents to monitor these RFI announcements for additional information pertaining to the requests. Please note that CMS will not respond to questions about the policy issues raised in the RFIs. CMS may or may not choose to contact individual respondents. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review responses for each RFI. Responses to these notices are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of the RFIs may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. The following RFIs should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. CMS may publicly post the comments received, or a summary thereof.

(i) Survey Modes for the Administration of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey Request for Information

We are seeking public comment on the potential expansion of the survey modes of the CAHPS for MIPS Survey from a mail-phone protocol to a web-mail-phone protocol. The current protocol is to administer the survey first through the mail and then by phone interview with non-respondents. The expansion to the protocol would include an initial administration of the survey by web, followed by mail, and then by phone. During the 2023 CAHPS

for MIPS Web Mode Field Test,[743] adding the web-based survey mode to the current mail-phone protocol of CAHPS for MIPS survey administration resulted in an increased response rate. Surveys for the field test were administered to a random sample of 8,613 survey-eligible patients from 20 Medicare Shared Savings Program ACOs between March 6, 2023, and May 31, 2023, and were compared to survey data collected from the CY 2022 performance period CAHPS for MIPS Survey for the same Medicare Shared Savings Program ACOs. In total, 3,638 patients completed a survey during the field test, resulting in a 43 percent response rate for the web-mail-phone protocol compared to 28 percent for the mail-phone protocol from the CY 2022 performance period CAHPS for MIPS Survey. The percentage of patients with an email address varied by ACO, ranging from 40 percent to 88 percent, and 38 percent of sampled patients had an email address. Evidence from the 2023 field test indicates that the use of the web-mail-phone protocol results in a higher response rate. Analysis of this field test data revealed that 43 percent of surveys completed via the web-based survey mode came from patients who did not have an email address but responded by entering a URL and patient-specific PIN code printed in either the pre-notification letter or web invitation letter. The web-mail-phone protocol also achieved higher response rates among patients of Latino or Hispanic ethnicity; no statistically significant differences in response rates were found by other demographic characteristics, including gender, age, or race. Analysis of the 2023 field test data also showed that adding the web-based survey mode reduced the response by mail from 93 percent during the CY 2022 performance period to 73 percent during the field test timeframe.

Given the potential for an increased response rate by expanding to a web-mail-phone protocol, we are seeking public comment on the following:

- Would the increase in survey response rates (as shown from the results of the 2023 CAHPS field test), outweigh a possible increase in the cost of survey administration that would be associated with a three-mode survey protocol (web-mail-phone) compared to the current two-mode survey protocol (mail-phone)?
- Would providing email addresses to vendors be feasible for groups, virtual groups, subgroups, and APM Entities (including Medicare Shared Savings Program ACOs)?

(ii) Guiding Principles for Patient-Reported Outcome Measures in Federal Models, and Quality Reporting and Payment Programs Request for Information

We are committed to elevating the patient voice in healthcare. One critical approach to elevating the patient voice that is aligned with the CMS National Quality Strategy and strategy of the CMS Innovation Center is to incorporate more Patient-Reported Outcome Measures (PROMs) and Patient-Reported Outcome Performance Measures (PRO–PMs) in CMS quality reporting and payment programs and CMS Innovation Center Models.

CMS had defined a patient-reported outcome (PRO) as any report of the status of a patient's health condition or health behavior coming directly from the patient without interpretation of the patient's response by a clinician or anyone else.[744] PROs are critical for the support of person-centered care, as they provide information from the patient or caregivers perspective and offer important information to improve patient-clinician communication, decision-making, and care delivery. PROMs are structured tools used to collect data on PROs, tested for validity and reliability in the population of interest. PRO–PMs aggregate information collected using PROMs into a reliable, valid measure of performance at the measured entity level (for example, clinician or health system). Often these measures have established benchmarks for assessing risk-adjusted outcomes.

A potential path forward is the development of an accessible and unified database of PROMs/PRO–PMs used in programs and payment systems in health care by Federal, State-based, and commercial payers, and healthcare systems. This database would identify the measure steward and include information on the specifications of the measure. The PROMs in this database could serve as a resource for the subsequent development of PRO–PMs.

Separately, considerations for a data infrastructure that allows PROMs and PRO–PMs to be integrated into clinical workflow with minimal cost and administrative burden, with data seamlessly shared across different healthcare settings and systems is important. Although we recognize there may be important reasons for not restricting PROMs/PRO–PMs to a strictly defined data infrastructure, we seek to avoid the evolution of multiple PROM/PRO–PM repositories that may inhibit the development of these measures and potentially impose additional costs on clinicians and healthcare systems.

One currently existing, unified, non-proprietary PROM repository is the Patient-Reported Outcomes Measurement Information System® (PROMIS®) developed and funded by the National Institutes of Health (NIH). PROMIS tools assess patient-reported health status for physical, social, and mental wellbeing. NIH supported the development of PROMIS, and in 2018 PROMIS was made available to the public through a platform known as HealthMeasures (*www.healthmeasures.net*). Northwestern University stewards HealthMeasures and oversees proprietary and copyright issues, as well as scientific work using PROMIS developed data elements and measures. HealthMeasures also provides several PRO–PMs for PROMIS available at *https://www.healthmeasures.net/implement-healthmeasures/evaluate-quality-of-care/healthmeasures-pro-pms*. As noted previously, this repository of PROMs and PRO–PMs could be used in conjunction with a data infrastructure that integrates PROMs and PRO–PMs into clinical workflow and is able to be shared across multiple healthcare environments.

As we move forward with including more PROMs and PRO–PMs in CMS quality reporting and payment programs and CMS Innovation Center Models, it is important to develop a set of guiding principles and considerations for the selection and implementation of PROMs or PRO–PMs. An illustrative set of guiding principles may include:

- Data Infrastructure—Measures implemented in programs should, to the extent possible, use existing data systems for data collection and reporting to minimize the administrative burden associated with collecting PROMs and deriving PRO–PMs. The PROMs and PRO–PMs should be deployed in a data infrastructure that supports necessary interoperability standards to support sharing across providers, practices, hospitals, health systems, health plans and States.
- Measure Testing—The PROMs have been psychometrically tested and undergone rigorous reliability and validity testing (fully developed PRO–PMs have also been tested for scientific acceptability including reliability as a

[743] Centers for Medicare & Medicaid Services. (June 2024). 2023 CAHPS for MIPS Web Mode Field Test. Available at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2893/2023_CAHPS_for_MIPS_WebMode_Field_Test.pdf*.

[744] Centers for Medicare & Medicaid Services. (December, 2023). Patient Reported Outcome Measures. Available at *https://mmshub.cms.gov/sites/default/files/Patient-Reported-Outcome-Measures.pdf*.

quality measure for the accountable entity). Moreover, PROMs have been tested as digital measures that can be collected and reported electronically, making their adaptation as electronic Patient Reported Outcomes (ePROs) feasible.

- Feasible Clinical Implementation—Measures that will be used for clinical decision making can be integrated into the clinical workflow with minimal cost and administrative burden. Further, the data can be seamlessly shared across different healthcare settings and payer systems. The measures can be expected to have meaningful participation and response rates to draw conclusions from measure score results (based on anticipated sample size from participating providers).
- Accessible—The measures are easily accessible to clinicians and care teams, without the creation of additional administrative or significant financial burdens, or the requirement for additional resources.
- Patient Engagement—The measures have been tested to show that the concept is meaningful to patients. Additionally, there is a validated feedback loop on how their patient-reported data is used to drive performance improvement. and improvement in individual patient outcomes/experience.
- Equity—Measures selection considers how measurement may ameliorate or exacerbate disparities including but not limited to considerations for language concordance and response rates. Measures may be stratified by subgroup to better understand disparities in response rates and outcomes.

Through this RFI, we are seeking comment on principles related to data infrastructure, selection, feasible implementation, and patient engagement of PROMs and PRO–PMs. We request feedback from the public regarding the overarching principles and considerations.

Specifically we are seeking input on the following areas:

- Are the aforementioned guiding principles outlined comprehensive or are there additional guiding principles and considerations we should consider for the selection, and implementation of PROM and PRO–PMs?
- How can CMS accelerate the development of PRO–PMs and advance them more rapidly into use? How can CMS support PRO–PM development while balancing the goal of accessible PRO–PMs with the additional time and resources required to construct PROMs and PRO–PMs from a PROM?
- How should CMS balance the use of broad PRO–PMs that might be applicable across multiple clinical contexts compared to condition-specific PROMs and PRO–PMs measures that can be more tailored to a given clinical situation but lead to a greater number of tools in use across measures and health care providers?
- How can CMS support making PROMs broadly accessible without limiting both innovation and resources committed to developing new tools? Are there other examples (beside PROMIS) of currently existing PROMs/PRO–PMs repositories that make their tools widely available to clinicians and healthcare systems?

(2) Cost Performance Category

Section 1848(q)(2)(A) of the Act includes resource use as a performance category under MIPS. We refer to this performance category as the cost performance category. As required by sections 1848(q)(2) and (5) of the Act, the four performance categories of MIPS are used in determining the MIPS final score for each MIPS eligible clinician. In general, MIPS eligible clinicians are evaluated under all four of the MIPS performance categories, including the cost performance category.

We are proposing to add six new episode-based measures to the cost performance category beginning with the CY 2025 performance period/2027 MIPS payment year. These six measures include:

- Chronic Kidney Disease (CKD), which assesses MIPS eligible clinicians on the risk-adjusted and specialty-adjusted cost to Medicare for patients who receive care to manage and treat CKD stages 4 and 5;
- End-Stage Renal Disease (ESRD), which assesses MIPS eligible clinicians on the risk-adjusted and specialty-adjusted cost to Medicare for patients who receive medical care to manage ESRD;
- Kidney Transplant Management, which assesses MIPS eligible clinicians on the risk adjusted and specialty-adjusted cost to Medicare for ongoing kidney transplant-related care and management starting at least 90 days after transplant surgery;
- Prostate Cancer, which assesses MIPS eligible clinicians on the risk-adjusted and specialty-adjusted cost to Medicare for the management and treatment of prostate cancer;
- Rheumatoid Arthritis, which assesses MIPS eligible clinicians on the risk-adjusted and specialty-adjusted cost to Medicare for the management and treatment of rheumatoid arthritis; and
- Respiratory Infection Hospitalization, which assesses MIPS eligible clinicians on the risk-adjusted cost to Medicare for the inpatient treatment of respiratory infection.

We are proposing modifications to two existing episode-based measures so that their specifications reflect reevaluated versions beginning with the CY 2025 performance period/2027 MIPS payment year. These two measures are:

- Cataract Removal with Intraocular Lens (IOL) Implantation, which assesses MIPS eligible clinicians on the risk adjusted cost to Medicare for cataract removal procedures; and
- Inpatient (IP) Percutaneous Coronary Intervention (PCI), which assesses MIPS eligible clinicians on the risk-adjusted cost to Medicare for the inpatient PCI treatment of patients who present with a cardiac event.

We are proposing that MIPS eligible clinicians must be attributed a minimum of 20 cases for each of the proposed six new measures. In addition, we are proposing to maintain the existing case minimums for the two measures we are proposing to modify in this rulemaking, which are a 20-episode case minimum for the IP PCI measure and a 10-episode case minimum for the Cataract Removal with IOL Implantation measure. We are also proposing to update the operational list of care episode and patient condition groups and codes to reflect these new and modified measures we are proposing.

Finally, we are proposing to adopt criteria to specify objective bases for the removal of any cost measures from the MIPS cost performance category, which we are also proposing to codify at § 414.1350(e).

For a description of the statutory authority for and existing policies pertaining to the cost performance category, we refer readers to § 414.1350 and the CY 2017 Quality Payment Program final rule (81 FR 77162 through 77177), CY 2018 Quality Payment Program final rule (82 FR 53641 through 53648), CY 2019 PFS final rule (83 FR 59765 through 59776), CY 2020 PFS final rule (84 FR 62959 through 62979), CY 2021 PFS final rule (85 FR 84877 through 84881), CY 2022 PFS final rule (86 FR 65445 through 65461), CY 2023 PFS final rule (87 FR 70055 through 70057), and CY 2024 PFS final rule (88 FR 79339 through 79349).

More details on the proposals in this section, which we invite comments on, are provided in section IV.A.4.e.(2)(a) through section IV.A.4.e.(2)(d) of this proposed rule. We also refer readers to section V.B.8.k. of this proposed rule for discussion on the burden estimates for these proposals.

(a) Proposed Updates to MIPS Episode-Based Measure Inventory

(i) Background on Episode-Based Measure Development and Use

Under § 414.1350(a), we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category. There are currently 29 cost measures in the cost performance category for the CY 2024 performance period/2026 MIPS payment year, comprising of 27 episode-based measures covering a range of conditions and procedures and two population-based measures. We worked with the measure development contractor to identify the proposed six new episode-based measures through empirical analyses and public comment. These measures cover clinical topics and MIPS eligible clinicians practicing in certain specialties for whom there are currently limited or no applicable cost measures. As such, these measures would help fill gaps in the cost performance category's measure set.

In addition, these measures would support the transition from traditional MIPS to MVPs by allowing new MVPs to be created and enhancing existing MVPs. Further, the addition of these measures would address interested parties' feedback about the need for more clinically refined episode-based measures in the cost performance category. The measures would also increase the cost coverage of care episode and patient condition groups, moving closer towards the statutory goal of covering 50 percent of expenditures under Medicare Parts A and B, as specified under section 1848(r)(2)(i)(I) of the Act.

At a high level, episode-based measures represent the cost to the Medicare Program and beneficiaries for the items and services furnished to Medicare beneficiaries during an episode. They aim to compare MIPS eligible clinicians on the basis of the cost of care that is clinically related to treatment and management of a Medicare beneficiary and provided during the episode's timeframe. Specifically, for such measures, we define and measure the cost of care for the episode based on the allowed amounts on Medicare claims, which include both Medicare trust fund payments and any applicable beneficiary deductible and coinsurance amounts. The cost of care for these measures includes amounts paid under Medicare Parts A and B, and, on a case-by-case basis, Medicare Part D that have been standardized to remove price variation from non-clinical factors. The Parts A and B payment standardization methodology and the Part D payment standardization methodology are available at *https://resdac.org/articles/cms-price-payment-standardization-overview*. Information about how the Part D standardization methodology incorporates rebates into standardized amounts is available at *https://www.cms.gov/files/document/2023-part-d-rebate-methodology.pdf*. We refer the readers to section IV.A.4.e.(2)(a)(iii) of this proposed rule for more information on the six episode-based measures we are proposing.

In this proposed rule, we provide detail about the six new measures that we are proposing to adopt in the cost performance category beginning with the CY 2025 performance period/2027 MIPS payment year. In section IV.A.4.e.(2)(a)(ii) of this proposed rule, we summarize the timeline for development of these proposed measures, including engagement activities undertaken by the measure development contractor. In section IV.A.4.e.(2)(a)(iii) of this proposed rule, we summarize the proposed new measures that would be included in the cost performance category beginning with the CY 2025 performance period/2027 MIPS payment year. In section IV.A.4.e.(2)(a)(viii) of this proposed rule, we discuss the pre-rulemaking review process these measures underwent. In section IV.A.4.e.(2)(b) of this proposed rule, we discuss our proposal that MIPS eligible clinicians must be attributed a minimum of 20 cases for each of these proposed measures to be assessed and scored on such measure.

(ii) Overview of Measure Development Process for New Episode-Based Measures

In this section, we describe the development process for the six proposed episode-based measures.

Development of episode-based measures for the cost performance category must comply with section 1848(q)(2)(B)(ii) of the Act, which provides that measures and activities specified for a performance period include the measurement of resource use (cost) as provided under section 1848(p)(3) of the Act, using the methodology under section 1848(r) of the Act, to collaborate with physicians, practitioners, and other interested parties, as appropriate. Section 1848(p)(3) of the Act provides that costs shall be evaluated, to the extent practicable, based on a composite of appropriate measures of costs established by the Secretary as further specified therein. We note that the measure development contractor uses a ''wave'' approach to indicate cycles of measure development where clinical expert panels convene to select episode groups to develop into cost measures and to provide input on the measures' specifications. All six of the proposed measures have been developed with extensive engagement from interested parties, including clinicians, persons with lived experience, and the general public. The term ''persons with lived experience,'' as used in this section IV.A.4.e.(2) of this proposed rule, refers to persons and family of persons who have experienced these conditions or diseases. Our approach to engagement is outlined in the CY 2018 Quality Payment Program final rule (82 FR 53644 and 53645), the CY 2019 PFS final rule (83 FR 59767 through 59769), the CY 2022 PFS proposed rule (86 FR 39396 and 39397), and the CY 2024 PFS proposed rule (88 FR 52568 through 52576). These processes have been refined over time to incorporate feedback from interested parties, such as to extend the development timeline from 12 months in Wave 2 to 18 months in Waves 3 and 4, and to integrate conversations between persons with lived experience and clinical experts.

We began development of the six episode-based measures across several of these waves:

- The Prostate Cancer, Rheumatoid Arthritis, and Kidney Transplant Management measures were initiated in Wave 5 in 2022 and followed the typical 18-month process.
- The CKD and ESRD measures were initiated in 2021 as part of an off-cycle development process and were incorporated into Wave 5 in 2022 to be completed along with the other three episode-based measures (that is, Prostate Cancer, Rheumatoid Arthritis, and Kidney Transplant Management).
- The Respiratory Infection Hospitalization measure is a revised version of the Simple Pneumonia with Hospitalization measure that was initially developed in Wave 1 in 2018. The Simple Pneumonia with Hospitalization measure was adopted in MIPS in the CY 2019 PFS final rule (83 FR 59767 through 59773) and then removed from use in MIPS in the CY 2024 PFS final rule (88 FR 79348 and 79349). The measure underwent a comprehensive reevaluation process from 2022–2023 to identify and incorporate refinements based on public feedback, clinical input, and empiric testing. Unlike the other five new measures we are proposing, this measure did not undergo further development as part of Wave 5. Because the Simple Pneumonia with

Hospitalization measure is no longer in use in MIPS, we are proposing the Respiratory Infection Hospitalization measure as a new measure, and not as modifications to an existing measure. More information on the comprehensive reevaluation process that this measure underwent is described in sections IV.A.4.e.(2)(a)(iv) and IV.A.4.e.(2)(a)(v) of this proposed rule.

This section of this proposed rule will provide more details on the development process for the measures that were developed during Wave 5 (CKD, ESRD, Kidney Transplant Management, Prostate Cancer, and Rheumatoid Arthritis measures). We began developing the CKD and ESRD measures in 2021 as priority clinical areas by convening a clinician expert workgroup and gathering feedback from persons with lived experience. However, the clinician expert workgroup recommended that we develop a Kidney Transplant Management measure to fully capture the care continuum of kidney disease care before continuing to move forward with the CKD and ESRD measures. As a result, we halted measure development on the CKD and ESRD measures until 2022, while we gathered public feedback on the development of a Kidney Transplant Management measure, and later incorporated the CKD and ESRD measures into the Wave 5 development process.

The episode-based measures that were developed in the Wave 5 cycle of measure development (CKD, ESRD, Kidney Transplant Management, Prostate Cancer, and Rheumatoid Arthritis measures) underwent an 18-month development process. As a first step, the measure development contractor held a public comment period from February to April 2022 to gather feedback on which clinical areas to prioritize for measure development. The public comment period solicited feedback on the importance and feasibility of prioritizing kidney transplant management, prostate cancer, and rheumatoid arthritis, among other clinical areas, for measure development. During the public comment period, the measure development contractor received 32 comments on the candidate episode groups for development in Wave 5. We used this feedback, in conjunction with empirical testing by the measure development contractor, to inform our decision to develop measures for three specific clinical areas—prostate cancer, rheumatoid arthritis, and kidney transplant management—into episode-based measures. The summary of the public comments is available in this document *https://www.cms.gov/files/document/wave-5-public-comment-summary-report.pdf*. We selected these clinical areas for measure development for several reasons including: representation of high priority clinical areas, potential to improve clinician performance or patient outcomes, potential to capture high costs of care paid by the Medicare Program, and ability to fill measurement gaps in the MIPS cost performance category and MVPs.

Following our decision to develop measures for prostate cancer, rheumatoid arthritis, and kidney transplant management, in addition to continuing to develop the CKD and ESRD measures, the measure development contractor convened four clinician expert panels, comprised of a total of 45 members, affiliated with 36 organizations and specialty societies. The CKD and ESRD measures shared a clinician expert panel due to the close clinical overlap of these diseases. Each panel also incorporated the perspective of persons with lived experience; their input is collected via structured focus groups, interviews, or surveys, and then summarized and presented to the clinical expert panels.

Then, the measure development contractor held a national field testing period from January 17, 2023, to February 14, 2023 for the Wave 5 measures (CKD, ESRD, Kidney Transplant Management, Prostate Cancer, and Rheumatoid Arthritis measures). During this field testing period, individual MIPS eligible clinicians and groups meeting a minimum threshold of 20 episodes for each measure could review field test reports and an episode-level file with detailed information to understand the types of services that comprise a large or small share of their episode costs. Supplemental materials, such as testing information on measures, a Frequently Asked Questions document, and mock field test reports were posted publicly for interested parties' review. The measure development contractor gathered feedback via survey and a summary of this feedback from the field testing period is available at *https://www.cms.gov/files/document/2023-field-testing-feedback-summary-report.pdf*.

The measure development contractor also has a standing technical expert panel (TEP), which is referred to as the Physician Cost Measures and Patient Relationship Codes (PCMP) TEP. The PCMP TEP is composed of 20 members from different clinical areas, academia, health care and hospital administration, and persons with lived experience, which provides overarching input on cross-measure topics, such as testing approaches and methodology. For example, the PCMP TEP discussed general challenges in developing chronic condition episode-based measures and ways that the chronic condition framework can address those challenges, provided feedback on the attribution rules (that is, the algorithms and the types of codes used in each algorithm) that would demonstrate a relationship between a clinician group and a patient with a chronic condition(s), and discussed service assignment, risk adjustment, and exclusions, which support the overall development of episode-based measures, including, but not limited to those episode-based measures being proposed in this rulemaking. This input helped inform the specifications for the chronic condition episode-based measure framework, which serves as the framework for the chronic condition episode-based measures (that is, Prostate Cancer, Rheumatoid Arthritis, CKD, ESRD, and Kidney Transplant Management episode-based measures) developed in Wave 5 and being proposed in this proposed rule.

More information about the measure development and interested parties' engagement process for the six episode-based measures we are proposing for adoption in the cost performance category is available in materials on the QPP Cost Measure Information page at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures*. Summaries of the public comment period and clinician expert workgroup meetings organized by the measure development contractor are also available on the QPP Cost Measure Information page at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures*. Descriptions of the methods through which the measure development contractor gathered expert input during measure development and other interested parties' engagement activities is available in the ''2024 MIPS Summary of Cost Measures'' document at *https://www.cms.gov/files/document/2024-mips-summary-costs-measures.pdf*.

(iii) Description of Six New Episode-Based Measures Proposed for Adoption Beginning With the CY 2025 Performance Period/2027 MIPS Payment Year

In this section of this proposed rule, we discuss the six new episode-based measures, which we propose to add to the cost performance category beginning with the CY 2025 performance period/2027 MIPS payment year.

In conjunction with our measure development contractor, we developed these measures with consideration of the common standards that are described in the CY 2022 PFS final rule (86 FR 65455 through 65459) to ensure consistency across episode-based measures being developed. Specifically, the CY 2022 PFS final rule requires that any episode-based measure for the cost performance category include the following: (1) episode definition based on trigger codes that determine the patient cohort; (2) attribution; (3) service assignment; (4) exclusions; and (5) risk adjustment. The six new episode-based measures we are proposing meet all requirements described in CY 2022 PFS final rule, including these features. We provide more information on the specific requirements for each of the episode-based measures later in this section of this rulemaking.

Generally, for all episode-based measures, we exclude episodes where costs cannot be fairly compared to the costs for the whole cohort in the episode-based measure. These exclusions, like other features of each episode-based measure, are developed with extensive clinician and interested parties' engagement. We have specified exclusions for all six proposed episode-based measures.

We also apply a risk adjustment model to all episode-based measures in the cost performance category. The model includes standard risk adjustors that are applied to all episode-based measures (for example, CMS Hierarchical Condition Category [HCC] variables, comorbidities, age brackets, disability status, ESRD status), and measure-specific risk adjustors (for example, for the Rheumatoid Arthritis episode-based measure, rheumatoid arthritis severity, fractures, frailty, and cognitive status). We assess the risk adjustment model at the level of each stratification to ensure that only like patients are compared to each other. The risk adjustment model we use in development of the cost performance category's episode-based measures is described in detail in CY 2019 PFS final rule (83 FR 59767 through 59773). As mentioned previously in this section, all six proposed episode-based measures have been risk adjusted in accordance with this model.

More information on the episode-based measure development requirements, which were outlined so that external interested parties could develop measures in the future, are available in the Blueprint for the CMS Measures Management System (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint*) and the Meaningful Measures Framework (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page*).

The episode-based measures that we are proposing for adoption beginning with the CY 2025 performance period/2027 MIPS payment year are set forth in Table 58.

TABLE 58: Proposed Episode-Based Measures Beginning with CY 2025 Performance Period/2027 MIPS Payment Year

Measure Name	Episode Type
Chronic Kidney Disease (CKD)	Chronic condition
End-Stage Renal Disease (ESRD)	Chronic condition
Kidney Transplant Management	Chronic condition
Prostate Cancer	Chronic condition
Rheumatoid Arthritis	Chronic condition
Respiratory Infection Hospitalization	Acute inpatient medical condition

The five chronic condition episode-based measures assess outpatient treatment and ongoing management of the following chronic conditions: CKD, ESRD, kidney transplant management, prostate cancer, and rheumatoid arthritis. These measures assess the costs of services related to these conditions, such as physician services, imaging or diagnostic services, emergency room care or hospitalizations, medications, or other services related to ongoing management or post-acute care. The measure construction for these proposed measures follows the approach described in the CY 2022 PFS final rule (86 FR 65445 through 65461), which also includes detailed discussion of the attribution methodology and examples of how episodes are attributed.

To briefly summarize, the attribution methodology that identifies a clinician-patient care relationship for these chronic condition episode-based measures is slightly different at the clinician group and individual MIPS eligible clinician levels, to reflect that care provided at the clinician group and individual MIPS eligible clinician levels, respectively. At a high level, these proposed chronic condition episode-based measures attribute episodes to the clinician group that renders services that constitute a trigger event, which is identified by the occurrence of two claims billed in close proximity by the same clinician group. Both claims must have a diagnosis code indicating the same chronic condition related to the specific episode-based measure. For example, for the Prostate Cancer measure, both claims of the trigger event must have a diagnosis indicating prostate cancer. The services that trigger an event for these chronic condition episode-based measures are identified first by Evaluation and Management (E/M) codes for outpatient services, and then by a second claim with either another E/M code for outpatient services or a condition-related Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) code (CPT/HCPCS) related to the treatment or management of the chronic condition. Note, some measures also use additional CPT/HCPS codes with a relevant diagnosis as the initial trigger service. The trigger event opens a year-long attribution window from the date of the initial E/M outpatient service, during which the same clinician group could reasonably be considered responsible for managing the patient's chronic condition. If we see evidence that the relationship is ongoing, represented by another E/M or condition-related procedure code that we refer to as the reaffirming claim, then this window can be extended.

For individual MIPS eligible clinicians, we would attribute episodes to each individual MIPS eligible

clinician within an attributed clinician group that renders at least 30 percent of trigger or reaffirming codes on Part B Physician/Supplier claim lines during the episode, such as office visits or diagnostic services. We also apply conditions to ensure the MIPS eligible clinicians to whom the episode is attributed are reasonably responsible for the management of the patient's chronic condition. Specifically, the MIPS eligible clinician must have provided condition-related care to this patient prior to or on the episode start date.

Additionally, for some measures, we use provider-level prescription billing patterns to ensure that we are capturing the MIPS eligible clinicians directly involved in providing ongoing chronic care management. Specifically, for some measures, the MIPS eligible clinician must also have prescribed at least two prescriptions claimed under Medicare Part D and/or Medicare Part B related to the management of the condition for two different patients during the measurement period, plus a one-year lookback period. These conditions, which we use to attribute a cost measure to MIPS eligible clinicians, also apply to the attribution methodology at the clinician group level. Specifically, the clinician group would always meet the first condition by construction (that is, there would always be an individual MIPS eligible clinician under the clinician group that has provided care to the patient prior to or on the episode start date). However, the clinician group must have at least one potentially attributable MIPS eligible clinician under it who meets the second condition.

More information about the chronic condition episode-based measures attribution methodology, including a one-page summary and a Frequently Asked Questions (FAQ) document, is available at *https://www.cms.gov/files/zip/mips-chrcondition-episode-based-cost-measures-attribution-methodology-2023-zip.zip*. More general information about the overall chronic condition cost measure framework is available at *https://www.cms.gov/files/document/chronic-condition-cost-measure-framework-poster.pdf*.

The Respiratory Infection Hospitalization measure is an acute inpatient medical condition episode-based measure, which focuses on the inpatient treatment of respiratory infection and is attributed to clinicians and clinician groups treating a patient during the hospitalization. It includes the cost of services related to the inpatient treatment of a respiratory infection, such as initial inpatient services, subsequent outpatient physician visits, and emergency room care or hospitalizations for related complications. As noted in section IV.A.4.e.(2)(a)(ii) of this proposed rule, the Respiratory Infection Hospitalization measure is the reevaluated version of the Simple Pneumonia with Hospitalization measure, adopted for MIPS in CY 2019 PFS final rule (83 FR 59767 through 59773) and removed from MIPS in the CY 2024 PFS final rule (88 FR 79348 and 79349). We developed the Simple Pneumonia with Hospitalization acute inpatient medical condition measure in accordance with the previously established framework for episode-based measures, which we described in detail in the CY 2019 PFS final rule (83 FR 59769 through 59771). The Simple Pneumonia with Hospitalization measure was reevaluated following the process described in sections IV.A.4.e.(2)(a)(iv), IV.A.4.e.(2)(a)(v), and IV.A.4.e.(2)(a)(viii) of this proposed rule. We are proposing the Respiratory Infection Hospitalization measure, the reevaluated version of the Simple Pneumonia with Hospitalization measure, because we continue to believe it is important to capture pneumonia and other respiratory infections, as pneumonia is a leading infectious cause of hospitalization and death among adults in the United States.[745] This new, revised measure addresses the concerns with the previous version of the measure by expanding the patient cohort to include beneficiaries hospitalized for pneumonia and related respiratory infections, reflecting the coding changes as described in the CY 2024 PFS final rule (88 FR 79348 and 79349). The revised measure also incorporates feedback we received from interested parties about appropriate risk adjustment and exclusions during the reevaluation process of the prior Simple Pneumonia with Hospitalization measure.

The specifications for all six episode-based measures we are proposing for adoption in this rulemaking are available at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures*. The specifications documents for each measure consist of a methods document that describes the steps for constructing the measure and a measure codes list file that contains the medical codes used in that methodology. First, the methods document provides detailed methodology describing each step to construct the measure, including: identifying patients receiving care; defining an episode-based measure; attributing episodes to MIPS eligible clinicians and clinician groups; assigning costs; defining exclusions; risk adjusting; and calculating measure score. Second, the measure codes list file contains the codes used in the measure specifications, including the episode triggers, attribution, stratification, assigned items and services, exclusions, and risk adjustors.

More information about the episode-based measures is available in the measure justification forms, which were posted to support Pre-rulemaking Measure Review (PRMR) discussions. These documents provide a comprehensive characterization of the measures, their justification, and testing results of the measures' specifications at this time. These documents are available through the QPP Cost Measure Information page at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures*.

(iv) Background on Episode-Based Measure Reevaluation and Maintenance

In this section, we describe the measure maintenance process we use, in conjunction with our measure development contractor, to monitor, evaluate, and potentially modify cost measures. Using this maintenance process, we holistically reviewed, and evaluated whether to modify or take other actions with respect to, certain measures in the cost performance category. As a result of this process, we propose to modify two episode-based measures currently in use (the Routine Cataract Removal with Intraocular Lens (IOL) Implantation and ST-Elevation Myocardial Infarction (STEMI) Percutaneous Coronary Intervention (PCI) measures), and propose the reevaluated Respiratory Infection Hospitalization as a new measure, replacing the Simple Pneumonia with Hospitalization measure previously removed from the cost performance category.

The measure development contractor routinely conducts three types of measure maintenance: measure monitoring, annual measure specifications updates, and comprehensive reevaluation. Comprehensive reevaluation occurs every 3 years after a measure is implemented in MIPS. The purpose of comprehensive reevaluation is to ensure that measures continue to meet criteria for importance, scientific acceptability, and usability in line with the CMS Measures Management System Blueprint (*https://mmshub.cms.gov/*

[745] Regunath, Hariharan, and Yuji Oba. ''Community-Acquired Pneumonia.'' National Library of Information, August 8, 2022. *https://www.ncbi.nlm.nih.gov/books/NBK430749.*

blueprint-measure-lifecycle-overview). In this process, we holistically review the measure, seek public comment, and consider whether any changes need to be made to measure specifications. A new version of the measure may be considered for implementation in MIPS in future years, after undergoing the pre-rulemaking and the notice-and-comment rulemaking processes. For more information on recent reevaluation efforts, please refer to the documents under the ''Wave 1 cost measure comprehensive reevaluation (2022–2023)'' section of the QPP Cost Measure Information page at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/prior*.

For the purpose of assessing performance of MIPS eligible clinicians in the cost performance category, we finalized, in the CY 2019 PFS final rule (83 FR 59767 through 59773), the Routine Cataract Removal with Intraocular Lens (IOL) Implantation, ST-Elevation Myocardial Infarction (STEMI) Percutaneous Coronary Intervention (PCI), and Simple Pneumonia with Hospitalization measures to be included in MIPS beginning with the CY 2019 performance period/2021 MIPS payment year. In this section, we are proposing to modify the Routine Cataract Removal with IOL Implantation and STEMI PCI measures based on input from interested parties from prior public comment periods and recommendations from Clinician Expert Workgroups.

We also propose to modify the measure titles. Routine Cataract Removal with Intraocular Lens (IOL) Implantation would be revised to Cataract Removal with Intraocular Lens (IOL) Implantation to reflect substantive changes to the measure exclusions. ST-Elevation Myocardial Infarction (STEMI) Percutaneous Coronary Intervention (PCI) would be revised to Inpatient (IP) Percutaneous Coronary Intervention (PCI) to reflect the inclusion of patients with a non-STEMI PCI diagnosis and patients with a PCI diagnosis but neither STEMI nor non-STEMI diagnoses.

The episode-based measures that we propose to modify beginning with the CY 2025 performance period/2027 MIPS payment year are listed in the Table 59.

TABLE 59: Proposed Reevaluated Episode-Based Measure Modifications Beginning with CY 2025 Performance Period/2027 MIPS Payment Year

Original Measure Name	Revised Measure Name	Episode Type
Routine Cataract Removal with Intraocular Lens (IOL) Implantation	Cataract Removal with Intraocular Lens (IOL) Implantation	Procedural
ST-Elevation Myocardial Infarction (STEMI) Percutaneous Coronary Intervention (PCI)	Inpatient (IP) Percutaneous Coronary Intervention (PCI)	Acute inpatient medical condition

(v) Overview of Measure Reevaluation Process for Episode-Based Measures

As part of the reevaluation process, we worked with the measure development contractor to gather feedback from interested parties on potential refinements to the measures. The measure development contractor worked with a standing TEP, Clinician Expert Workgroups, and held two public comment periods.

Initially, a public comment period was held from February to May 2022 to gather feedback on which of the Wave 1 measures implemented in MIPS in 2019 that the measure developer should prioritize reevaluating. A summary of public comments from the 2022 public comment period can be found in the Wave 1 Comprehensive Reevaluation Public Comment Summary Report at *https://www.cms.gov/files/document/wave-one-public-comment-summary-report.pdf*.

The measure development contractor then convened the TEP for a meeting in August 2022 to provide input on the comprehensive reevaluation process for all Wave 1 episode-based measures. In October 2022, the measure development contractor convened the Cataract Removal with IOL Implantation Clinician Expert Workgroup, the IP PCI Clinician Expert Workgroup, and the Respiratory Infection Hospitalization Clinician Expert Workgroup, to provide detailed clinical input on measure specifications for each reevaluated measure. This input was informed by empiric testing conducted by the measure development contractor. The workgroup discussions from October 2022 can be found in the Summary of Wave 1 Comprehensive Reevaluation Workgroup meetings at *https://www.cms.gov/files/zip/summary-wave-1-comprehensive-reevaluation-workgroup-meetings.zip*.

After this, a second public comment period was held in February 2023 to gather feedback on the draft revisions the measure developer made to the Cataract Removal with IOL Implantation, IP PCI, and Respiratory Infection Hospitalization measures. A summary of public comments from the 2023 public comment period can be found in the 2023 Revised Cost Measure Feedback Period Summary Report at *https://www.cms.gov/files/document/2023-revised-cost-measure-feedback-period-summary-report.pdf*.

The measure-specific expert workgroups then reviewed the feedback received through public comments and provided input on proposed decisions regarding the measure specifications. The workgroup discussions from Spring 2023 are available in the Summary of Wave 1 Post-Feedback Period Workgroup meetings at *https://www.cms.gov/files/zip/summary-wave-1-post-feedback-period-pfr-workgroup-meetings-23.zip*. After the proposed specifications for each measure were finalized, we submitted the three revised measures (Cataract Removal with IOL Implantation, IP PCI, and Respiratory Infection with Hospitalization measures) to the 2023 MUC list and underwent review by the PRMR Clinician Committee and Clinician Committee Recommendation Group, which reviewed the measures for use in MIPS. We provide more information about this discussion in section IV.A.4.e.(2)(a)(viii) of this proposed rule.

(vi) Description of Proposed Modifications to the Routine Cataract Removal With Intraocular Lens (IOL) Implantation Measure With the Newly Titled Cataract Removal With IOL Implantation Measure

We finalized the Routine Cataract Removal with Intraocular Lens (IOL) Implantation cost measure in the CY 2019 PFS final rule (83 FR 59767 through 59773) for use in MIPS as an important measure of clinician cost performance, as cataract surgery is the most common surgical procedure in the United States.[746] We continue to believe that the existing measure is appropriate to use in MIPS. When we finalized this measure for use in MIPS, we noted that as with all the cost measures, we would maintain this measure and update its specifications as appropriate (83 FR 59766 and 59767). As a part of our routine measure maintenance, we reevaluated the Routine Cataract Removal with IOL Implantation measure with consideration of input from interested parties and testing. This feedback from interested parties included:

- The patient cohort for the measure should be expanded, while still accounting for patient heterogeneity, to expand clinician and beneficiary coverage.
- The measure should account for patients with ocular conditions that impact case complexity to account for patient heterogeneity.
- Certain Medicare Part B medication costs related to cataract procedures should be included in the measure, while Medicare Part D medication costs should remain excluded to better account for more clinically-related medication costs.
- The measure should more broadly capture services associated with cataract removal.

In response to this feedback, CMS and the measure development contractor conducted additional empirical analyses and discussed potential modifications with the measure-specific expert workgroup. Summaries of these discussions are available here: *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/prior*. Based on these testing results and the clinician expert input, we are proposing to replace the Routine Cataract Removal with IOL Implantation with the revised Cataract Removal with IOL Implantation cost measure. The modifications that we are proposing to incorporate into the revised Cataract Removal with IOL Implantation measure and our rationale is outlined as follows.

First, we propose to modify this cost measure by expanding the patient cohort based on changes to the exclusion criteria. Testing has shown that many episodes excluded due to ocular conditions had similar cost profiles, compared to episodes included in the measure, and represented a significant portion of triggered episodes. The measure-specific expert workgroup discussed the appropriateness of the original exclusion criteria and recommended potential revisions. The proposed revised measure includes patients with certain previously excluded ocular conditions, such as glaucoma and macular degeneration, in the measure cohort because of their similar cost profiles. In response to expanding the measure cohort, we also propose updates to the risk adjustment model to risk adjust for ocular conditions that are no longer excluded but may still impact case complexity and episode costs. We believe that these changes are appropriate as they further account for patient heterogeneity in the more clinically diverse patient cohort. However, the proposed revised measure continues to exclude episodes for patients with significant ocular conditions impacting surgical complication rate or visual outcomes because testing did not suggest they had similar enough cost profiles for any expected cost differences to be accounted for through risk adjustment.

Second, we propose to modify this cost measure's service assignment specifications in two ways, to include: (1) certain clinically-related telehealth services, pre-operative testing, emergency department (ED) visits for ocular complaints, and postoperative durable medical equipment (DME); and (2) certain additional clinically-related Medicare Part B medication costs that were not initially included in the measure. The previous version of the measure included a smaller subset of these services. However, testing showed that additional clinically-related services within these categories occur during Cataract Removal episodes and exclusion of these services from the measure could result in failure to capture important costs. We are proposing to include the additional services because we believe this change would retain the original intent of the measure while capturing a more complete picture of cost performance variation. Additionally, we are proposing to expand the types of Part B medications assigned to the measure because we believe it would be appropriate to use similar service assignment rules for all clinically-related Part B medications.

Further details about the revised Cataract Removal with IOL Implantation measure are available in the measure specifications documents, which are available at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures.*

(vii) Description of the Proposed Modifications to the ST-Elevation Myocardial Infarction (STEMI) With Percutaneous Coronary Intervention (PCI) Measure With the Newly Titled Inpatient (IP) Percutaneous Coronary Intervention (PCI) Measure

Similar to the Cataract Removal with IOL Implantation measure, we finalized the ST-Elevation Myocardial Infarction (STEMI) Percutaneous Coronary Intervention (PCI) measure in the CY 2019 PFS final rule (83 FR 59767 through 59773) for use in MIPS as an important measurement of clinician cost performance, due to the high frequency and cost of PCI procedures in the United States. PCI is one of the most common procedures for cardiac events (AMIs) and is associated with $10 billion in health care costs annually.[747] We continue to believe that the existing measure is appropriate for use in MIPS. However, when we finalized this measure for use in MIPS, we noted that, as with all the cost measures, we would maintain this measure and update its specifications as appropriate (83 FR 59766 and 59767). As a part of our routine measure maintenance, we reevaluated the STEMI PCI measure with consideration of input from interested parties and testing. This feedback from interested parties included:

- The patient cohort for the measure should be expanded, while still accounting for patient heterogeneity to increase clinician coverage and capture more clinically-related services.
- The measure should account for patients with cardiac arrest and patients who smoke tobacco to reduce factors outside of clinician control that influence measure performance.

In response to this feedback, CMS and the measure development contractor conducted additional empirical analyses

[746] Pershing, S., D.E. Morrison, and T. Hernandez-Boussard. ''Cataract Surgery Complications and Revisit Rates among Three States.'' [In eng]. Am J Ophthalmol 171 (Nov 2016): 130–38.

[747] Amin, Amit P., Patterson, Mark, House, John A., Giersiefen, Helmut, Spertus, John A., Baklanov, Dmitri V., Chhatriwalla, Adnan K., Safley, David M., Cohen, David J., Rao, Sunil V., Marso, Steven., ''Cost Associated With Access Site and Same-Day Discharge Among Medicare Beneficiaries Undergoing Percutaneous Coronary Intervention: An Evaluation of the Current Percutaneous Coronary intervention Care Pathways in the United States,'' JACC Cardiovasc Interv 10, no. 4 (2017): 342–351.

and discussed potential modifications with the measure-specific Clinician Expert Workgroup. Summaries of these discussions are available here: *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/prior*. Based on these testing results and the clinician expert input, CMS is proposing to replace the STEMI PCI measure with the revised IP PCI measure. The modifications that we are proposing to incorporate into the revised IP PCI measure and our rationale is outlined as follows.

First, we propose to modify this cost measure by expanding the patient cohort based on changes to the triggering logic. The previous version of the measure narrowly defined a subset of STEMI PCI patients to promote homogeneity of the patient cohort. However, testing demonstrated that PCI episodes with and without STEMI appear to have similar cost profiles and involve similar clinician types. Therefore, it is appropriate to expand the patient cohort in the proposed revised measure to include episodes beyond those with STEMI diagnoses, such as PCI for non-STEMI diagnoses and PCI without either STEMI or non-STEMI diagnoses. As such, we would no longer use ICD–10 diagnosis information to restrict assessment of costs under this measure to only inpatient PCI procedures with a STEMI diagnosis. This change would increase the number of clinicians and beneficiaries for whom this cost measure would be applicable.

Second, we are proposing to modify this cost measure to include additional sub-groups to stratify the patient cohort based on diagnosis to account for variations in cost and treatment pathways for inpatient procedures. While there are overall similarities between the diagnosis for inpatient PCI episodes (that is, STEMI, non-STEMI, and other inpatient PCI episodes), there are still expected differences in observed costs between these cohorts. This modification would allow us to assess variation in clinician cost performance rather than expected cost differences due to patient diagnoses. We believe this is appropriate as testing shows differences in observed episode costs among STEMI, non-STEMI, and other inpatient PCI episodes are neutralized via sub-grouping and risk adjustment.

Third, we are proposing that the proposed revised measure excludes episodes with cardiac arrest and risk adjusts for patients with a history of tobacco use to further address heterogeneity in the patient cohort, as these cases can result in more complex treatment and higher observed costs for reasons outside of the control of the attributed clinician. This was supported by testing on the expanded patient cohort.

Further detail about the revised IP PCI measure is included in the measure specifications documents, which are available at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures*.

(viii) Pre-Rulemaking Measure Review Process

After these extensive measure development and refinement activities, we included the six proposed new episode-based measures and two modified episode-based measures on our 2023 Measures Under Consideration (MUC) List (available for download at *https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx*) to be considered for potential use in MIPS. The measures then underwent PRMR during the 2023–2024 review cycle. This process involved reviews by the PRMR Clinician Committee advisory and recommendation workgroups, as well as two public comment periods. More details on the PRMR process are available at *https://p4qm.org/PRMR*.

Although we may pursue endorsement by the consensus-based entity (CBE), contracted in accordance with section 1890 of the Act, for the proposed measures at a later time, we are not required to use only CBE endorsed measures in MIPS. We emphasize that cost measures undergo extensive review and testing before they are implemented in MIPS. As described in section IV.A.4.e.(2)(a)(ii), the proposed new and revised cost measures in this proposed rule were vetted by clinicians, specialty societies, persons with lived experience, consensus panels, and the public at large without going through the CBE endorsement process. Cost measures are developed through a rigorous process with a Clinician Expert Workgroup providing detailed input on each aspect of the specifications, reviewing iterative empirical testing, and considering the input from persons with lived experience. The cost measures undergo field testing during the development process where MIPS eligible clinicians can download feedback reports to review their performance before measure implementation, and share input with the developer to help finalize the measure specifications. In addition, the proposed new and revised cost measures in this proposed rule were reviewed through the pre-rulemaking process described in this section of this proposed rule. We continue to believe in the strength of the episode-based measures, proposed for adoption and modification in this rulemaking, based on valid and reliable testing results and extensive review from interested parties as part of the measure development and implementation process.

The PRMR Clinician Committee and Clinician Committee Recommendation Group reviewed the measure information, a preliminary analysis of the measures and their testing information developed by the CBE, and public comments. The PRMR Clinician Committee Recommendation Group met in January 2024 to discuss the measures in more detail and vote on their recommendations for the appropriateness of these measures' use in MIPS. The final result from the committee's vote can be: Recommend, Recommend with conditions, Do not recommend, or Consensus not reached. Consensus not reached signals continued disagreement among the committee despite being presented with perspectives from public comment, committee member feedback and discussion, and highlights the multi-faceted assessments of measures. More details regarding the CBE PRMR voting procedures may be found in Chapter 4 of the Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review and Measure Set Review at *https://p4qm.org/sites/default/files/2023-09/Guidebook-of-Policies-and-Procedures-for-Pre-Rulemaking-Measure-Review-%28PRMR%29-and-Measure-Set-Review-%28MSR%29-Final_0.pdf*.

The PRMR had mixed recommendations for the episode-based measures we are proposing to adopt and modify (in section IV.A.4.e.(2)(a)(ix)) in this rulemaking.

The PRMR Clinician Committee Recommendation Group voted to ''recommend with conditions'' for the revised Cataract Removal with IOL Implantation and IP PCI measures. For the Cataract Removal with IOL Implantation measure, while the committee did not provide or explain its conditions, they generally suggested further examination of how implementation of cost measures may impact patient outcomes. We plan to examine patient outcomes in more detail as part of routine measure monitoring. For the IP PCI measure, the committee recommended with the two conditions: CBE endorsement and additional testing to gather performance data over a longer period. As previously discussed, CBE endorsement is not required for measures to be adopted and used in MIPS. We plan to address these

conditions by monitoring the IP PCI measure's performance over time.

The PRMR Clinician Committee Recommendation Group did not reach consensus on the CKD, ESRD, Kidney Transplant Management, Prostate Cancer, and Respiratory Infection Hospitalization measures. Overall, there was varied levels of support of the measures across the PRMR Clinician Committee Recommendation Group. The main concerns raised were related to scientific acceptability (for example, testing results suggesting low reliability for the CKD, ESRD and Kidney Transplant Management measures), appropriateness of risk adjustment, and potential unintended consequences. We recognize the Recommendation Group's concerns, but emphasize the tradeoffs between accuracy and reliability, as described in the CY 2022 PFS final rule (86 FR 65453 through 65456). However, we did work with the measure development contractor to conduct additional testing to address these concerns. We identified non-substantive updates to existing outlier exclusions applied to cost measures that would address concerns about measure reliability for the CKD, ESRD, and Kidney Transplant Management measures. These adjusted outlier exclusions substantially improve reliability and are reflected in Table 60 of this proposed rule. We note that all the proposed new and revised measures meet the 0.4 mean reliability threshold that CMS typically applies for measures' use in MIPS. The Recommendation Group also expressed a strong interest in the measures undergoing CBE endorsement. As noted above, we may pursue CBE endorsement of these measures in the future, but it is not a requirement for measures to be adopted and used in MIPS.

The voting results of the PRMR Clinician Committee Recommendation Group for the Rheumatoid Arthritis measure were ''do not recommend.'' The PRMR final recommendations state that the Recommendation Group supported the measure concept, but ultimately had reservations about its use in MIPS and concerns about measure performance. These concerns aligned with the concerns the Recommendation Group raised about cost measures overall, such as concerns around how cost measures impact patient outcomes. More information on the PRMR recommendations is available in the PRMR 2023 Final Recommendation Report: *https://p4qm.org/sites/default/files/2024-02/PRMR-2023-MUC-Recommendations-Report-Final-.pdf.*

We acknowledge the feedback from the Recommendation Group regarding the Rheumatoid Arthritis measure, but we disagree that the measure should not be used in MIPS. We agree with the Recommendation Group's feedback regarding the importance of this measure to assess and address wide variation in cost performance for rheumatoid arthritis treatment and management. Literature states that rheumatoid arthritis is highly prevalent and is most common among older adults.[748] [749] Given this high prevalence, rheumatoid arthritis is costly to the healthcare system and individual patients, though costs vary based on treatment regimen.[750] Over the past decade, Medicare costs associated with disease-modifying treatments have increased substantially.[751] Additionally, certain treatment choices for Rheumatoid Arthritis are associated with increased costs due to adverse outcomes associated with these choices, suggesting room for improvement in cost performance and patient care. For example, chronic glucocorticoid use among rheumatoid arthritis patients is associated with higher health care costs due to increased occurrence of adverse events (*e.g.,* developing diabetes or osteoporosis, cardiovascular events such as thrombotic stroke, myocardial infarction, or death).[752] [753] [754] We believe that the cost of these adverse events are important to assess in terms of Medicare spending and impact on the patient population. In line with these findings, the Recommendation Group did express support for the intent of this measure from a clinician and patient perspective.

The Recommendation Group stated that public comments submitted during the PRMR process suggest the Rheumatoid Arthritis measure does not have support by certain rheumatology associations. However, the comments received during PRMR did not include comments from a major rheumatologic association that has called for the development of an episode-based measure for rheumatologists. Members of this organization were also involved in the development of the Rheumatoid Arthritis measure through the participation in the Rheumatoid Arthritis Clinician Expert Workgroup. As described in section IV.A.4.e.(2)(a)(ii) of this proposed rule, the Rheumatoid Arthritis episode-based cost measure was developed with extensive engagement from interested parties (that is, clinicians who treat this disease, persons with lived experience with Rheumatoid Arthritis, and the general public) through several mechanisms including a TEP, public comment periods, a clinician expert workgroup, person and family engagement opportunities, and national field testing. During the public comment period for determining which measures to prioritize for development, we received feedback from rheumatology professional societies that they supported the development of a Rheumatoid Arthritis measure, as the current MIPS cost measure inventory does not include cost measures specific to care typically provided by rheumatologists. Additionally, the Rheumatoid Arthritis Clinician Expert Workgroup that advised on the measure specifications included representatives from 11 professional societies, including key rheumatology societies.

The Recommendation Group also expressed concerns with the scientific acceptability of the Rheumatoid Arthritis measure. However, national field testing indicates the measure is valid and has high reliability at the group level, with a mean reliability of 0.74, and has moderate reliability at the individual level with a mean reliability of 0.52. At both the group and individual levels, the measure passes the 0.4 reliability threshold we typically apply for a cost measure's use in MIPS, as discussed in CY 2022 PFS final rule (86 FR 65453 through 65455). Additionally, several commenters expressed concerns with the Rheumatoid Arthritis measure, such as the measure could hold clinicians accountable for costs that they cannot control (for example, medications), the risk adjustment methodology may not account for differences in the patient

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[748] Centers for Disease Control and Prevention, ''Rheumatoid Arthritis (RA),'' 2020, *https://www.cdc.gov/arthritis/basics/rheumatoid-arthritis.html.*

[749] Hunter TM, Boytsov NN, Zhang X, Schroeder K, Michaud K, Araujo AB. Prevalence of rheumatoid arthritis in the United States adult population in healthcare claims databases, 2004–2014. *Rheumatol Int.* 2017;37(9):1551–1557. *doi:10.1007/s00296–017–3726–1.*

[750] Hunter et al., Prevalence of rheumatoid arthritis.

[751] Stolshek BS, Wade S, Mutebi A, De AP, Wade RL, Yeaw J. Two-year adherence and costs for biologic therapy for rheumatoid arthritis. Am J Manag Care. 2018;24(8 Spec No.): SP315–SP321.

[752] Black, R.J. et al., ''A Survey of Glucocorticoid Adverse Effects and Benefits in Rheumatic Diseases: The Patient Perspective,'' *Journal of Clinical Rheumatology* 23, no. 8 (December 2017): 416–420, *https://doi.org/10.1097/rhu.0000000000000585.*

[753] Wilson, J.C. et al., ''Incidence and Risk of Glucocorticoid-Associated Adverse Effects in Patients With Rheumatoid Arthritis,'' *Arthritis Care & Research,* 71, no. 4, (April 2019): 498–511, *https://doi.org/10.1002/acr.23611.*

[754] Best, J.H. et al., ''Association Between Glucocorticoid Exposure and Healthcare Expenditures for Potential Glucocorticoid-related Adverse Events in Patients with Rheumatoid Arthritis,'' *Journal of Rheumatology* 45, no. 3 (March 2018): 320–328, *https://doi.org/10.3899/jrheum.170418.*

population, and the measure is not tied directly to patient outcomes. Testing also indicates that the cost measure reflects the cost related to treatment choices and the cost of adverse outcomes resulting from care and that the risk adjustment model is working as intended. There has not been evidence to suggest that this cost measure would impact patient outcomes negatively. More information is available in the Measure Justification Form available for download at *https://www.cms.gov/files/zip/2023-wave-5-measure-justification-forms-zip.zip*. The Recommendation Group also acknowledged that the measure is already specified to adjust for expected differences in medication costs based on whether a patient is enrolled in Medicare Part D (that is, stratifying the measure by Part D enrollment), furthering supporting the scientific acceptability of this measure.

The Recommendation Group suggested the measure should undergo endorsement review and receive CBE endorsement. As discussed previously, we may pursue CBE endorsement of these measures in the future, but CBE endorsement is not a requirement for measures to be adopted and used in MIPS.

We are continuing to propose this measure despite the ''do not recommend'' vote from the PRMR committee because we continue to believe in the use of this measure based on the empiric testing results discussed in this section, including indications of moderate to high reliability, and because of the importance of capturing this clinical area of care. We originally selected this measure for development because of its high impact in terms of patient population, clinician coverage, and Medicare spending, and the opportunity to build a chronic condition measure that would address a condition not captured by other episode-based measures in the MIPS cost performance category. We believe that there is a strong rationale for including this measure in the cost performance category for these same reasons.

(ix) Proposal To Adopt Six Episode-Based Measures and Modify Two Episode-Based Measures

In consideration of the extensive development, reevaluation, and pre-rulemaking review processes described in sections IV.A.4.e.(2)(a)(i) through IV.A.4.e.(2)(a)(viii), we are proposing to make the following updates to the MIPS cost performance category:

We are proposing to adopt the six new episode-based measures in the cost performance category, outlined in Table 58 and described in section IV.A.4.e.(2)(a)(iii) of this rulemaking, beginning with the CY 2025 performance period/2027 MIPS payment year.

We are proposing to replace the original Routine Cataract Removal with Intraocular Lens (IOL) Implantation with the revised Cataract Removal with Intraocular Lens (IOL) Implantation measure, with the modifications described in section IV.A.4.e.(2)(a)(vi) of this rulemaking, in the cost performance category beginning with the CY 2025 performance period/2027 MIPS payment year.

We are proposing to replace the ST-Elevation Myocardial Infarction (STEMI) Percutaneous Coronary Intervention (PCI) with the revised Inpatient (IP) Percutaneous Coronary Intervention (PCI) measure, with the modifications described in section IV.A.4.e.(2)(a)(vii) of this rulemaking, in the cost performance category beginning with the CY 2025 performance period/2027 MIPS payment year.

We invite comments on the proposals in this section.

(b) Reliability and Case Minimum

In this section of this proposed rule, we discuss the case minima we are proposing for the episode-based measures we are proposing to adopt and modify (in section IV.A.4.e.(2)(a)(ix)) in this rulemaking.

Reliability is a metric that evaluates the extent that variation in a measure comes from clinician performance (''signal'') rather than random variation (''noise''). Higher reliability suggests that a measure is effectively capturing meaningful differences between clinicians' performance. However, we continued to caution against using reliability as the sole metric to evaluate a measure because of the tradeoffs between accuracy and reliability, and the role of service assignment in reducing noise. These and other considerations are detailed in the CY 2022 PFS final rule (86 FR 65453 through 65455). We also noted that increasing case minima necessarily reduces the number of clinicians who meet the case minimum for a given measure. Because these are clinically refined measures, we aim to have as many MIPS eligible clinicians as possible to be able to have their costs evaluated by them. Therefore, we considered that a mean reliability of 0.4 represents moderate reliability because it accounts for these considerations and is a sufficient threshold to ensure that the measure is performing as intended when assessed in conjunction with other testing.

We previously established at § 414.1350(c)(5) a case minimum of 20 episodes for acute inpatient medical condition episode-based measures and at § 414.1350(c)(4) a case minimum of 10 episodes for procedural episode-based measures in the CY 2019 PFS final rule (83 FR 59773 through 59774). We also established at § 414.1350(c)(6) a case minimum of 20 episodes for chronic condition episode-based measures in the CY 2022 final rule (86 FR 65453 through 65455).

We examined the reliability of the eight episode-based measures (six new and two modified) we are proposing in this rulemaking, and Table 60 presents the percentage of tax identification numbers (TINs) and TIN/National Provider Identifiers (NPIs) that meet the 0.4 reliability threshold and the mean reliability for TINs and TIN/NPIs at our case minimum of 20 for each of the chronic condition and acute inpatient medical condition episode-based measures. At a 20-episode case minimum, the mean reliability for the measures exceeds 0.4 for both groups and individual clinicians, and the majority of groups and individual clinicians meet the 0.4 reliability threshold. For the procedural measure, Cataract Removal with Intraocular Lens (IOL) Implantation, we applied the case minimum of 10 episodes. At a 10-episode case minimum, the mean reliability for the measure exceeds 0.4 for both groups and individual clinicians, and all groups and individual clinicians meet the 0.4 reliability threshold.

TABLE 60: Percent of TINs and TIN/NPIs that Meet 0.4 Reliability Threshold and TIN and TIN/NPI Mean Reliability

Measure name	% TINs meeting 0.4 reliability threshold	Mean reliability for TINs	% TIN/NPIs meeting 0.4 reliability threshold	Mean reliability for TIN/NPIs
Prostate Cancer	87.4%	0.68	84.1%	0.62
Rheumatoid Arthritis	95.0%	0.74	97.3%	0.76
Chronic Kidney Disease	88.8%	0.63	82.3%	0.57
End-Stage Renal Disease	92.5%	0.65	90.0%	0.59
Kidney Transplant Management	91.2%	0.64	95.8%	0.68
Respiratory Infection Hospitalization	100.0%	0.74	100.0%	0.53
Cataract Removal with Intraocular Lens (IOL) Implantation	100.0%	0.97	100.0%	0.96
Inpatient (IP) Percutaneous Coronary Intervention (PCI)	100.0%	0.63	100.0%	0.52

We believe that calculating these proposed episode-based measures with these case minimums would accurately and reliably assess the performance of clinicians and clinician group practices. Therefore, we are proposing to adopt a case minimum of 20 episodes for the chronic condition (CKD, ESRD, Kidney Transplant Management, Prostate Cancer, Rheumatoid Arthritis) and acute inpatient medical condition (Respiratory Infection Hospitalization and IP PCI) measures and a case minimum of 10 episodes for the procedural measure (Cataract Removal with IOL Implantation) listed in Table 60. For the IP PCI and Cataract Removal with IOL Implantation, these case minimums remain consistent with the case minimums for the original measures (that is, STEMI PCI and Routine Cataract Removal with IOL Implantation) that are currently in use. These proposals are also consistent with our regulation at § 414.1350(c)(4) through (6). We do not propose to modify these regulations establishing the case minima for these types of cost measures.

We invite comments on the proposals in this section.

(c) Proposed Revisions to the Operational List of Care Episode and Patient Condition Groups and Codes

We are proposing revisions to the operational list of care episode and patient condition groups and codes to reflect the proposal of any new episode-based measures. This section of this proposed rule provides context on the statutory requirements for care episode and patient condition groups and proposes changes to the operational list.

Section 1848(r) of the Act specifies a series of steps and activities for the Secretary to undertake to involve physicians, practitioners, and other interested parties in enhancing the infrastructure for cost measurement, including for purposes of MIPS and APMs. Section 1848(r)(2) of the Act requires the development of care episode and patient condition groups, and classification codes for such groups, and provides for care episode and patient condition groups to account for a target of an estimated one-half of expenditures under Medicare Parts A and B (with this target increasing over time as appropriate). Sections 1848(r)(2)(E) through (G) of the Act require the Secretary to post on the CMS website a draft list of care episode and patient condition groups and codes for solicitation of input from interested parties, and subsequently, post an operational list of such groups and codes. Section 1848(r)(2)(H) of the Act requires that not later than November 1 of each year (beginning with 2018), the Secretary shall, through rulemaking, revise the operational list of care episode and patient condition codes as the Secretary determines may be appropriate, and that these revisions may be based on experience, new information developed under section 1848(n)(9)(A) of the Act, and input from physician specialty societies and other interested parties.

For more information about past revisions to the operational list that we made as we developed and proposed episode-based measures, we refer readers to the CY 2023 PFS final rule (87 FR 70056 through 70057) and CY 2024 PFS final rule (88 FR 79348). The current operational list and prior operational lists are available at the QPP Cost Measure Information page at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/about*.

Additionally, as required by section 1848(r)(2)(I) of the Act, information on resource use (or cost) measures currently in use in MIPS, cost measures under development and the time-frame for such development, potential future cost measure topics, a description of engagement with interested parties, and the percent of expenditures under Medicare Parts A and B that are covered by cost measures must be provided on the website of CMS not later than December 31 of each year.

In accordance with section 1848(r)(2)(H) of the Act, we are proposing to revise the operational list beginning with the CY 2025 performance period/2027 MIPS payment year to include six new care episode and patient condition groups, based on input from clinician specialty societies and other interested parties, as discussed in section IV.A.4.e.(2)(a) of this proposed rule. We propose including Respiratory Infection Hospitalization as a care episode group and CKD, ESRD, Kidney Transplant Management, Prostate Cancer, and Rheumatoid Arthritis as patient condition groups. These care episode and patient condition groups serve as the basis for the six new episode-based

measures that we are proposing in section IV.A.4.e.(2)(a)(ix) of this proposed rule for the cost performance category. The codes that define these six care episode and patient condition groups align with the trigger codes of the proposed episode-based measures in section IV.A.4.e.(2)(a)(ix) of this proposed rule. As described in section IV.A.4.e.(2)(a)(ii), these specifications are developed with extensive input from interested parties.

Additionally, we propose to revise the care episode group codes listed to align with the modifications proposed for Cataract Removal with Intraocular Lens (IOL) Implantation and Inpatient (IP) Percutaneous Coronary Intervention (PCI) measures.

Our proposed revisions to the operational list are available on our QPP Cost Measure Information page at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/about.*

We invite public comment on our proposals in this section.

(d) Proposed Removal Criteria for MIPS Cost Measures

Once adopted, cost measures are retained in the cost performance category measure inventory, except when we specifically propose to remove a measure. We have identified a need to establish and codify objective criteria that can be used to inform the removal of a cost measure from the MIPS cost performance category. Specifically, when removing the Simple Pneumonia with Hospitalization episode-based measure from the CY 2024 PFS final rule (88 FR 79348 through 79349), we confirmed that, unlike the MIPS quality performance category, the MIPS cost performance category did not have clear guidelines for removing a measure established through the notice-and-comment rulemaking process. Establishing such criteria would allow for more consistency in our evaluation of the cost measures and our decision on whether to propose that a cost measure be removed from the MIPS cost performance category.

Therefore, we are proposing to adopt the following factors that can be used to guide the removal of a cost measure:

- *Factor 1:* It is not feasible to implement the measure specifications.
- *Factor 2:* A measure steward is no longer able to maintain the cost measure.
- *Factor 3:* The implementation costs or negative unintended consequences associated with a cost measure outweigh the benefit of its continued use in the MIPS cost performance category.
- *Factor 4:* The measure specifications do not reflect current clinical practice or guidelines.
- *Factor 5:* The availability of a more applicable measure, including a measure that applies across settings, applies across populations, or is more proximal in time to desired patient outcomes for the particular topic.

We selected these factors because they outline instances that we anticipate based on previous experience where a cost measure may not be appropriate to maintain in a program, but not limited to these instances. We also worked to align these criteria with the MIPS quality removal considerations and criteria outlined in the CY 2019 PFS final rule (83 FR 59763 through 59765) and CY 2020 PFS final rule (84 FR 62957 through 62959), where possible, and, in part, the Hospital Value-Based Purchasing (HVBP) Program's removal factors that are codified in our regulations at 42 CFR 412.164(c)(3). We are proposing these specific criteria to encourage a degree of alignment between existing measure removal policies within MIPS and across Medicare programs, where appropriate, for cost measures.

There were some instances where certain removal criteria used by the MIPS quality performance category and the HVBP Program would not be applicable for cost measures and, in those instances, we are not proposing to adopt those factors. For example, we did not propose to adopt the removal criterion for measures that do not reach appropriate reporting volumes. This is because MIPS eligible clinicians do not separately report or submit data for cost measures. Instead, we assess and score cost measures based on administrative claims data. In addition, our existing scoring policies for the cost performance category at § 414.1380(b)(2) already address situations where there are insufficient number of MIPS eligible clinicians meeting the case minimum, such that the cost measure is not scored. If we were to determine that a cost measure would be unlikely to be scored moving forwards due to insufficient number of MIPS eligible clinicians meeting the case minimum, we believe that the first factor we are proposing (that is, it is not feasible to implement the measure specifications) would be applicable for removal.

We note that these factors are criteria that would be used as guidance when considering whether or not to propose to remove a measure, rather than firm requirements. Specifically, there could be instances when a measure meets one or multiple measure removal factors, but would be retained in the cost performance category regardless, provided that we determine that the benefit of keeping the measure in the cost performance category would outweigh the benefit of removing it. Prior to proposing a measure for removal in accordance with this policy, we would carefully review the specifications of the cost measures by conducting necessary literature reviews, empirical testing, or other information gathering.

Additionally, we propose to codify this proposed measure removal policy by amending § 414.1350 by adding the proposed cost removal criteria in paragraph (e). Specifically, we are proposing at § 414.1350(e) that CMS may remove a cost measure from MIPS based on one or more of the following factors, provided however CMS may retain a cost measure that meets one or more of the following factors if CMS determines the benefit of retaining the measure outweighs the benefit of removing it.

- It is not feasible to implement the measure specifications.
- A measure steward is no longer able to maintain the cost measure.
- The implementation costs or negative unintended consequences associated with a cost measure outweigh the benefit of its continued use in the MIPS cost performance category.
- The measure specifications do not reflect current clinical practice or guidelines.
- The availability of a more applicable measure, including a measure that applies across settings, applies across populations, or is more proximal in time to desired patient outcomes for the particular topic.

We invite comments on this proposal.

(3) Improvement Activities Performance Category

(a) Background

For previous discussions on the general background of the improvement activities performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77177 and 77178), the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53661), the CY 2019 Physician Fee Schedule (PFS) final rule (83 FR 59776 and 59777), the CY 2020 PFS final rule (84 FR 62980 through 62990), CY 2021 PFS final rule (85 FR 84881 through 84886), the CY 2022 PFS final rule (86 FR 65462 through 65466), the CY 2023 PFS final rule (87 FR 70057 through 70061), and the CY 2024 PFS final rule (88 FR 79350 and 88 FR 79351). We also refer readers to 42 CFR 414.1305 for the definitions of improvement activities

and attestation, § 414.1320 for standards establishing the performance period, § 414.1325 for the data submission requirements, § 414.1355 for standards related to the improvement activity performance category generally, § 414.1360 for data submission criteria for the improvement activity performance category, and § 414.1380(b)(3) for improvement activities performance category scoring.

We are proposing two changes to the traditional Merit-based Incentive Payment System (MIPS) and the MIPS Value Pathways (MVPs) improvement activities policies for the CY 2025 performance period/2027 MIPS payment year. We are also proposing at § 414.1355 to codify the seven improvement activity removal factors, which were adopted in the CY 2020 PFS final rule (FR 84 62988 through 62990) to establish criteria used to identify activities for potential removal or modification. In addition, we are proposing changes to the improvement activities Inventory for the CY 2025 performance period/2027 MIPS payment year and future years as follows: adding two new improvement activities; modifying two existing improvement activities; and removing eight previously adopted improvement activities.

(b) Improvement Activities Inventory

(i) Annual Call for Activities Background

In the CY 2017 Quality Payment Program final rule (81 FR 77190), for the transition year of MIPS, we implemented the initial improvement activities Inventory consisting of approximately 95 activities (81 FR 77817 through 77831). We took several steps to ensure the Inventory was inclusive of activities in line with statutory and program requirements, including conducting interviews with highly performing organizations of all sizes, conducting an environmental scan to identify existing models, activities, or measures that met all or part of the improvement activities performance category criteria, and reviewing comments received in the CY 2016 PFS final rule with comment period (80 FR 71259) and in response to the MIPS and Advanced Payment Models (APMs) Requests for Information (RFIs) in relation to the improvement activities performance category.

For the CY 2018 performance period/2020 MIPS payment year, we provided an informal process for submitting new improvement activities or modifications for potential inclusion in the comprehensive improvement activities Inventory for the CY 2018 performance period/2020 MIPS payment year and future years through guidance.[755] In the CY 2018 Quality Payment Program final rule (82 FR 53656 through 53659), for the CY 2019 performance period/2021 MIPS payment year and for future years, we finalized a formal Annual Call for Activities process for the addition of possible new activities and possible modifications to current activities in the improvement activities Inventory. An interested party must submit a nomination form regarding a new activity or a modification to an existing improvement activity (OMB control # 0938–1314) available at *www.qpp.cms.gov* during the Annual Call for Activities.

(ii) Codification of Improvement Activity Removal Factors

In the CY 2018 Quality Payment Program proposed rule (82 FR 30056), we solicited comments on the criteria that may be used to identify improvement activities for removal from the improvement activities Inventory, citing that, over time, certain improvement activities should be considered for removal to ensure the Inventory is robust and relevant. In the CY 2020 PFS final rule (84 FR 62568 through 63563), we established seven removal factors to identify activities for potential removal or modification from the Inventory. In this proposed rule, we are proposing to codify at § 414.1355 the following existing seven improvement activity removal factors:

- *Factor 1:* Activity is duplicative of another activity.
- *Factor 2:* There is an alternative activity with a stronger relationship to quality care or improvements in clinical practice.
- *Factor 3:* Activity does not align with current clinical guidelines or practice.
- *Factor 4:* Activity does not align with at least one meaningful measure area.
- *Factor 5:* Activity does not align with the quality, cost, or Promoting Interoperability performance categories.
- *Factor 6:* There have been no attestations of the activity for 3 consecutive years.
- *Factor 7:* Activity is obsolete.

We note that these factors are criteria that are used as guidance in determining removal of an activity, but its use is at CMS discretion. For example, there may be instances when an activity meets one or multiple activity removal factors but may be retained in the improvement activities performance category Inventory, because the benefit of retaining outweighs the benefit of removing. We believe that codifying these removal factors would provide transparency and alignment with removals of improvement activities from the Inventory. We solicit comment on this proposal.

(iii) Changes to the Improvement Activities Inventory

In the CY 2018 Quality Payment Program final rule (82 FR 53660), we finalized that we would establish improvement activities through notice-and-comment rulemaking. We refer readers to Table H in the Appendix to the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199), Tables F and G in the Appendix to the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229), Tables A and B in the Appendix 2 to the CY 2019 PFS final rule (83 FR 60286 through 60303), Tables A, B, and C in the Appendix 2 to the CY 2020 PFS final rule (84 FR 63514 through 63538), Tables A, B, and C in the Appendix 2 to the CY 2021 PFS final rule (85 FR 85370 through 85377), Tables A, B, and C in the Appendix 2 to the CY 2022 PFS final rule (86 FR 65969 through 65997), Tables A, B, and C in the Appendix 2 to the CY 2023 PFS final rule (70633 through 70650), and Tables A, B, and C in the Appendix 2 to the CY 2024 PFS final rule (88 FR 79965 through 79977) for our previously finalized improvement activities Inventories. We also refer readers to the Quality Payment Program website under Explore Measures and Activities at *https://qpp.cms.gov/mips/explore-measures?tab=improvementActivities&py=2024#measures* for a complete list of the current improvement activities. In the CY 2017 Quality Payment Program final rule (81 FR 77539), we codified the definition of improvement activities at § 414.1305 to mean an activity that relevant MIPS eligible clinicians, organizations, and other relevant interested parties identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes.

We are proposing to add two new improvement activities, modify two existing improvement activities, and remove eight previously adopted improvement activities for the CY 2025 performance period/2027 MIPS payment year and future years. We refer readers to Appendix 2 of this proposed rule for more details.

[755] CMS, Annual Call for Measures and Activities: Fact Sheet, *https://www.cms.gov/Medicare/Quality-IniCtiatives-Patient-Assessment-Instruments/MMS/Downloads/Annual-Call-for-Measures-and-Activities-for-MIPS_Overview-Factsheet.pdf.*

In response to stakeholder feedback, we are making efforts to streamline the Inventory over the coming rulemaking cycles to include only the most robust and clinically meaningful improvement activities. The removal and modification of 10 total activities is an initial step toward our goal of reducing the size of the Inventory and helping to ensure that it includes only the most meaningful activities that have a clear path to clinical practice improvement, while the two proposed new activities would help fill gaps we have identified in the Inventory.

Currently, there are 106 finalized activities in the improvement activities Inventory, all of which are assigned either a high or medium weight. When each of the activities was added, their requirements reflected clinical practice standards of the time, addressed areas of opportunity for fostering clinical practice improvements, and aligned with national public health priorities and CMS programs. The last seven performance periods have provided sufficient time for analysis and review of submissions data to learn how MIPS eligible clinicians are choosing activities to report each year. Over the last several performance years, we have observed that some activities have not remained aligned with the latest updates to clinical practice standards, have not incorporated the latest national priorities, and/or have activity requirements that are no longer substantive enough to promote a sufficient level of clinical practice improvement in today's health care environment. Some activities are continuing to be highly utilized even though the goals of the improvement activity have largely been achieved, with the completion of these improvement activities contributing toward a final score without a corresponding result of ongoing improvement. Therefore, we are proposing to remove several of these improvement activities and to modify activities to better promote more meaningful clinical practice improvement opportunities. In proposing activities for removal or modification, we are considering the seven adopted improvement activity removal factors, discussed in the CY 2020 PFS final rule (84 FR 62568 through 63563) and in section IV.A.4.e.(3)(b)(ii) of this proposed rule.

We refer readers to Table C of Appendix 2 of this proposed rule for details on the proposal of these eight activity removals.

We are proposing two new improvement activities in the Population Management subcategory. One new activity, IA_PM_XX, titled ''Implementation of Protocols and Provision of Resources to Increase Lung Cancer Screening Uptake'' would allow MIPS eligible clinicians to receive credit for establishing a process or procedure to increase rates of lung cancer screening. While lung cancer is a leading cause of cancer-related deaths in the U.S., lung cancer screening is under-utilized. This activity aims to increase this screening and improve associated outcomes. Another activity, IA_PM_XX, titled ''Save a Million Hearts: Standardization of Approach to Screening and Treatment for Cardiovascular Disease Risk'' would allow MIPS eligible clinicians to receive credit for implementing a standardized, evidence-based cardiovascular disease risk assessment and care management plan in their practices. This activity proposal is informed by the results of the CMS Innovation Center Million Hearts Model, which included initial atherosclerotic cardiovascular disease (ASCVD) assessment as well as cardiovascular care management, which were shown to contribute to improved identification and treatment of patients at risk for ASCVD and would expand on the work of this Model by (1) increasing flexibility in requirements, allowing more clinician specialties to participate, along with increased flexibility in risk assessment to fit the needs of attesting clinicians and their patient populations; and (2) requiring the use of structured documentation of risk factors and associated treatment plans with the aim of addressing all risk factors directly.

We are proposing two modifications to improvement activities focused on strengthening the activities to better promote more meaningful clinical practice improvement. We are proposing to modify IA_PM_XX (formerly IA–ERP_6), titled ''Vaccine Achievement for Practice Staff—COVID–19, Influenza, and Hepatitis B,'' and its validation criteria to revise its target goals, and to expand its focus and promote the vaccination of staff for COVID–19 as well as Influenza and Hepatitis B. Adjusting the target goals for this activity would align with the latest Centers for Disease Control and Prevention (CDC) recommendations, and feedback received indicates that this could increase its utilization. Additionally, we are proposing to expand the focus of this activity to include influenza and hepatitis B to highlight the importance of staff vaccination for vaccine-preventable diseases prevalent today. We are also proposing to change the activity's subcategory, from Emergency Response & Preparedness to Population Management, to emphasize that staff vaccination is a long-term strategy in reducing morbidity and mortality rates for these diseases.

We are proposing to modify IA_BE_4, currently titled ''Engagement of patients through implementation of improvements in patient portal,'' and its validation criteria to limit the activity to new implementations of a patient/caregiver portal and encourage the measure's adoption by clinicians who do not currently utilize this health information exchange technology. We are proposing to modify this activity's name, description, and its validation criteria to better align with current practices. This activity was originally created during a time of transition to EHRs to encourage electronic information exchange. It has become standard practice to use patient portals; therefore, the activity is no longer driving improvement among clinicians who have already implemented patient portals.

We are separately proposing to remove eight existing activities, presented in Table 61.

TABLE 61: Improvement Activities Inventory: Proposed Removals

Proposed Removals Titles	*Removal Criteria (Factor)*
EPA_1 Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record	Factor 7, activity is obsolete
PM_12 Population empanelment	Factor 7, activity is obsolete
TABLE 61: Improvement Activities Inventory: Proposed Removals	**TABLE 61: Improvement Activities Inventory: Proposed Removals**
CC_2 Implementation of improvements that contribute to more timely communication of test results	Factor 7, activity is obsolete
ERP_4 Implementation of a Personal Protective Equipment (PPE) Plan	Factor 7, activity is obsolete
ERP_5 Implementation of a Laboratory Preparedness Plan	Factor 7, activity is obsolete
BMH_8 Electronic Health Record Enhancements for BH data capture	Factor 2, there is an alternative activity with a stronger relationship to quality care or improvements in clinical practice
PSPA_27 Invasive Procedure or Surgery Anticoagulation Medication Management	Factor 1, activity is duplicative

We refer readers to Appendix 2 of this proposed rule for details on the proposed revisions to the improvement activities Inventory.

(iv) Improvement Activity Scoring and Reporting Policies

We are proposing two scoring and reporting policy changes for the improvement activities performance category effective for the CY 2025 performance period/2027 MIPS payment year and subsequent years. First, we are proposing to eliminate the weighting of improvement activities. This would simplify scoring of the category, as well as complement our ongoing efforts to refine and improve the Inventory. In the CY 2017 Quality Payment Program final rule (81 FR 77177 and 77178), we codified at 42 CFR 414.1380(b)(3) the scoring policies for the improvement activities performance category. We established there that clinicians (except for non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic health professional shortage areas (HPSAs)) receive 10 points for each medium-weighted improvement activity and 20 points for each high-weighted improvement activity. Non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs receive 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity. We established a differentially weighted model for the improvement activities performance category with two categories, medium and high, to provide flexible scoring and because there are no nationally recognized standards or definitions for these activities (81 FR 28210). Weights were assigned based on the level of effort and resources needed to complete each activity, as well as alignment with current national public health priorities and programs such as the Quality Innovation Network-Quality Improvement Organization (QIN/QIO).

We have subsequently determined that the benefit to categorizing activities as high or medium weighted has greatly diminished. Over the last several years of the Quality Payment Program, we have made refinements and enhancements to the improvement activities Inventory by adding new activities to incorporate newly identified opportunities for clinical improvement and by modifying existing activities to support changes in practice standards, while also eliminating activities that are duplicative or that no longer promote a sufficient level of clinical improvement. In this and subsequent rulemaking cycles, we are focusing our efforts on streamlining the Inventory to retain the highest priority activities that offer the strongest promotion of clinical practice improvement. As the Inventory is streamlined, each retained activity highlights a unique and vital aspect of clinical practice improvement, and therefore every activity would be considered high priority.

Second, and related to the proposal in this section of this proposed rule, we are proposing to further simplify improvement activity reporting requirements by reducing the number of activities to which clinicians are required to attest to achieve a full score in the improvement activities performance category. Currently, MIPS eligible clinicians are required to report two high-weighted activities, four medium-weighted activities, or one high-weighted and two medium-weighted activities while MVP participants are currently required to report one high-weighted activity or two medium-weighted activities. We are proposing that MIPS eligible clinicians who participate in traditional MIPS would be required to report two activities. In addition, we are proposing that MIPS eligible clinicians who are categorized as small practice, rural, in a provider-shortage area, or non-patient facing would now be required to report one activity. We are proposing that these policies would be effective for the CY 2025 performance period/2027 MIPS payment year and subsequent years.

We are also proposing that MVP participants would be required to report one activity. In the CY 2022 PFS final rule (86 FR 65412 through 65413), we established that MVP Participants submitting MVPs report fewer improvement activities than eligible clinicians reporting traditional MIPS to incentivize and support MVP adoption. We continue to believe that reduced reporting requirements are necessary to support the adoption of and reduce the burden for implementation of MVPs.

We are proposing to lower the number of activities that MIPS eligible clinicians are required to complete in order to obtain a full score to adjust for the ongoing reduction of activities in the Inventory as well as to support eligible clinicians with simplified reporting as they engage in fewer but more demanding activities. If the number of activities in the Inventory is reduced after this and subsequent rulemaking, there would be fewer activities from which to choose. However, the retained activities in the Inventory from which to choose would be the highest priority activities that offer the strongest promotion of clinical practice improvement. This proposal is also responsive to commenters who, in the past, have requested that the number of required activities be reduced and that more activities be highly weighted (81 FR 77182). The activity removals and modifications being proposed would result in an Inventory of activities that are meaningful, timely, and rigorous. While decreasing the number of required activities would simplify reporting, MIPS eligible clinicians would still be required to participate in meaningful activities that yield significant practice improvement.

We are requesting comments on our proposals to remove weighting and to reduce the number of activities to which clinicians are required to attest to achieve a full score in the improvement activities performance category.

Specifically, we are requesting comments on our proposal to revise § 414.1380(b)(3) to read that, beginning with the CY 2025 performance period/2027 MIPS payment year, MIPS eligible clinicians (except for non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs) receive 20 points for each improvement activity, while non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs receive 40 points for each improvement activity. Therefore, to receive a score of 40 points, or full credit, MIPS eligible clinicians (except for non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs) must report two improvement activities, while non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs must report one improvement activity.

We are also requesting comment on our proposal to revise § 414.1365(c)(3) to state that, beginning with the CY 2025 performance period/2027 MIPS payment year, MVP participants receive 40 points for each improvement activity. Therefore, to receive a score of 40 points, or full credit, MVP participants would be required to report one improvement activity.

(4) Promoting Interoperability Performance Category

(a) Background

Section 1848(q)(2)(A) of the Act includes the meaningful use of certified electronic health record (EHR) technology (CEHRT) as a performance category under MIPS. We refer to this performance category as the Promoting

Interoperability performance category (and in past rulemaking, we referred to it as the advancing care information performance category).

For our previously established policies regarding the Promoting Interoperability performance category, we refer readers to our regulation at 42 CFR 414.1375, the CY 2017 Quality Payment Program final rule (81 FR 77199 through 77245), CY 2018 Quality Payment Program final rule (82 FR 53663 through 53688), CY 2019 PFS final rule (83 FR 59785 through 59820), CY 2020 PFS final rule (84 FR 62991 through 63006), CY 2021 PFS final rule (85 FR 84886 through 84895), CY 2022 PFS final rule (86 FR 65466 through 65490), CY 2023 PFS final rule (87 FR 70060 through 70087), and CY 2024 PFS final rule (88 FR 79308 through 79312 and 88 FR 79351 through 79365).

(b) Current Definition of CEHRT for the Quality Payment Program

In the CY 2024 Medicare Physician Fee Schedule (PFS) final rule (88 FR 79307 through 79312), we finalized revisions to the definition of CEHRT for the Quality Payment Program at 42 CFR 414.1305. In the CY 2024 PFS final rule (88 FR 79309 and 79310), we amended the definition of CEHRT to be more flexible in response to changes proposed by the Office of the National Coordinator for Health IT (ONC) in the ''Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing'' (HTI–1) proposed rule (88 FR 23746 through 23917). Specifically, we amended our definition of CEHRT at § 414.1305 to ensure references to ONC's definition of Base EHR at 45 CFR 170.102 and its health IT certification criteria at 45 CFR 170.315 were responsive to any changes ONC makes to its definition and criteria at any time. Instead of requiring that CEHRT meet only the ''2015 Edition Base EHR definition,'' we added that it also may meet the ''subsequent Base EHR definition'' as defined at 45 CFR 170.102. We also amended our definition of CEHRT to provide that the CEHRT must be certified to the ONC health IT certification criteria ''as adopted and updated'' in 45 CFR 170.315. This approach is consistent with the policies subsequently finalized in the HTI–1 final rule (89 FR 1205 through 1210). For additional background and information on this update, we refer readers to the discussion in the CY 2024 PFS final rule on this topic (88 FR 79307 through 79312).

In consideration of the updates finalized in the CY 2024 PFS final rule and the HTI–1 final rule, we refer to ''ONC health IT certification criteria'' throughout this proposed rule where we previously would have referred to ''2015 Edition health IT certification criteria.'' These revisions to the definition of CEHRT in 42 CFR 414.1305 ensure that updates to the definition of Base EHR in 45 CFR 170.102, and updates to applicable ONC health IT certification criteria in 45 CFR 170.315, are incorporated into the CEHRT definition without additional regulatory action by CMS. For ease of reference, Table 65 sets forth the ONC health IT certification criteria required to meet the Promoting Interoperability performance category objectives and measures.

In the CY 2024 PFS final rule (88 FR 79408 through 79414), we also finalized changes to the CEHRT definition at 42 CFR 414.1305 for Advanced APMs requiring use of EHR technology certified under the ONC Health IT Certification Program that meets the ONC Base EHR definition at 45 CFR 170.102 and any such ONC health IT certification criteria adopted or updated in 45 CFR 170.315 that are determined applicable for the APM, for the year, considering factors such as clinical practice area, promotion of interoperability, relevance to reporting on applicable quality measures, clinical care delivery objectives of the APM, or any other factor relevant to documenting and communicating clinical care to patients or their health care providers in the APM. This CEHRT definition affords Advanced APMs the ability to tailor additional CEHRT use requirements to those features or capabilities that are clinically relevant to the APM and its participants, rather than referring to the same criteria associated with measures in the Promoting Interoperability performance category of MIPS (88 FR 79413).

We highlight certain updates to ONC health IT certification criteria finalized in the ONC HTI–1 final rule that impact certification criteria referenced under the CEHRT definition. ONC adopted the certification criterion ''Decision Support Interventions (DSI)'' in 45 CFR 170.315(b)(11) to ultimately replace the ''clinical decision support (CDS)'' certification criterion in 45 CFR 170.315(a)(9) included in the Base EHR definition (89 FR 1236). The finalized ''DSI'' criterion ensures that Health IT Modules certified to 45 CFR 170.315(b)(11) must, among other functions, enable a limited set of identified users to select (that is, activate) certain evidence-based decision support interventions and Predictive DSI (as the latter term is defined in 45 CFR 170.102) (89 FR 1241) and support user access to specified ''source attributes''—categories of technical performance and quality information—for both evidence-based and Predictive DSI (89 FR 1236). ONC further finalized that a Health IT Module may meet the Base EHR definition by either being certified to the existing CDS certification criterion in 45 CFR 170.315(a)(9) or being certified to the revised DSI criterion in 45 CFR 170.315(b)(11), for the period up to, and including, December 31, 2024. On and after January 1, 2025, ONC finalized that a Health IT Module must be certified to the DSI certification criterion in 45 CFR 170.315(b)(11) in order to meet the Base EHR definition, and the adoption of the CDS certification criterion in 45 CFR 170.315(a)(9) will expire on January 1, 2025 (89 FR 1281).

In the HTI–1 final rule, ONC also finalized other updates related to ONC health IT certification criteria referenced in the CEHRT definition. ONC finalized January 1, 2026, as the date when updates discussed below would take effect; accordingly, health IT developers must update and provide certified Health IT Modules to their customers consistent with the Maintenance of Certification requirements in 45 CFR 170.402(b)(3) by this date, including the following updates:

- ONC updated the ''Transmission to public health agencies—electronic case reporting'' criterion in 45 CFR 170.315(f)(5) to specify the use of consensus-based, industry-developed electronic standards and implementation guides (IGs) to replace functional, descriptive requirements in the existing criterion on and after January 1, 2026 (89 FR 1228).
- ONC adopted the United States Core Data for Interoperability (USCDI) version 3 in 45 CFR 170.213(b) and finalized that USCDI version 1 in 45 CFR 170.213(a) will expire on January 1, 2026 (89 FR 1211 and 1223). This change impacts ONC health IT certification criteria that reference the USCDI, including the ''transitions of care'' certification criteria in 45 CFR 170.315(b)(1)(iii)(A)(*1*) and (*2*), ''clinical information reconciliation and incorporation—Reconciliation'' (45 CFR 170.315(b)(2)(iii)(D)(*1*) through (*3*)); and ''view, download, and transmit to 3rd party'' (45 CFR 170.315(e)(1)(i)(A)(*1*)) (89 FR 1214).
- ONC updated the ''demographics'' certification criterion (45 CFR 170.315(a)(5)), including renaming the criterion to ''patient demographics and observations'' (89 FR 1295 and 1296).
- ONC updated the ''standardized API for patient and population services'' certification criterion in 45 CFR

170.315(g)(10) including finalizing references to newer versions of standards referenced in the criterion, such as the US Core IG 6.1.0 (89 FR 1285) and the SMART App Launch Implementation Guide Release 2.0.0 (89 FR 1292).

For complete information about the updates to ONC health IT certification criteria finalized in the HTI–1 final rule, we refer readers to the text of the final rule (89 FR 1192) as well as resources available on ONC's website.[756]

(c) Potential Future Update of the SAFER Guides Measure

(i) Background

ONC developed the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) in 2014, and later updated in 2016. ONC provided the SAFER Guides, including the High Priority Practices SAFER Guide, as a tool to help organizations at all levels conduct self-assessments to optimize the safety and use of EHRs.[757] In the CY 2022 PFS final rule (86 FR 65475 through 65477), we adopted the SAFER Guides measure under the Protect Patient Health Information objective beginning with the CY 2022 performance period/2024 MIPS payment year. For the CY 2022 performance period/2024 MIPS payment year and the CY 2023 performance period/2025 MIPS payment year, MIPS eligible clinicians were required to attest to whether they have conducted an annual self-assessment using the High Priority Practices SAFER Guide[758] at any point during the calendar year in which the performance period occurs, with one ''yes/no'' attestation statement. MIPS eligible clinicians were not scored based on their answer to the attestation, or their level of implementation of each of the practices. However, failure to attest to this measure would result in earning a score of zero for the Promoting Interoperability performance category for failing to meet the minimum reporting requirements.

In the CY 2024 PFS final rule (88 FR 79354 through 79356), we modified the SAFER Guides measure. Beginning with the CY 2024 performance period/2026 MIPS payment year, this modified measure requires MIPS eligible clinicians to conduct, and attest ''yes'' to having completed, an annual self-assessment of their CEHRT, using the High Priority Practices SAFER Guide. We remind readers that the SAFER Guides measure only requires completion of a self-assessment and does not require MIPS eligible clinicians to implement fully each of the practices identified in their self-assessment.

(ii) Status of Updates to SAFER Guides

As summarized in the CY 2024 PFS final rule (88 FR 79354 through 79356), we received comments in response to our proposal to modify the SAFER Guides measure, including many comments recommending that we collaborate with ONC to update the SAFER Guides, noting that the SAFER Guides were last updated in 2016 (88 FR 59264). In response to these comments, we noted that, while the current SAFER Guides reflect relevant and valuable guidelines for safe practices with respect to current EHR systems, we would consider exploring updates in collaboration with ONC. We reminded readers to visit the CMS resource library website at *https://www.cms.gov/regulations-guidance/promoting-interoperability/resource-library* and the ONC website at *https://www.healthit.gov/topic/safety/safer-guides* for resources on the content and appropriate use of the SAFER Guides (88 FR 59262). We also noted that future updates to the SAFER Guides would be provided with accompanying educational and promotional materials to notify participants, in collaboration with ONC, when available (88 FR 59265).

In this proposed rule, we are seeking to make readers aware that efforts to update the SAFER Guides are currently underway. We anticipate that updated versions of the SAFER Guides may become available as early as CY 2025. We would consider proposing a change to the SAFER Guides measure, as soon as feasible, potentially beginning in the CY 2026 performance period/2028 MIPS payment year to permit use of an updated versions of the SAFER Guides at that time. We encourage MIPS eligible clinicians to become familiar with the updated versions of the SAFER Guides when they become available and consider them as they implement appropriate EHR safety practices.

(d) Modification of the Definition of Meaningful EHR User for Healthcare Providers That Have Committed Information Blocking

The Department of Health and Human Services (HHS) final rule ''21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking'' (hereafter referred to as the Disincentives final rule), was displayed for public inspection by the Office of the Federal Register on June 26, 2024, and appeared in the **Federal Register** on July 1, 2024.[759] The final rule implements the provision of the 21st Century Cures Act specifying that a healthcare provider, determined by the HHS Office of the Inspector General (OIG) to have committed information blocking, shall be referred to the appropriate agency to be subject to appropriate disincentives set forth through notice and comment rulemaking. In the Disincentives final rule, we finalized that a MIPS eligible clinician (other than a qualified audiologist) will not be considered a meaningful EHR user in a performance period if the OIG refers, during the calendar year of the performance period, a determination that the MIPS eligible clinician committed information blocking as defined at 45 CFR 171.103. Information blocking, in the case of a health care provider as defined in 45 CFR 171.102, is a practice that is likely to interfere with the access, exchange, or use of electronic health information, except as required by law or specified in an information blocking exception in 45 CFR part 171, subpart B, C, or D, and that the health care provider knows is unreasonable and is likely to interfere with access, exchange, or use of electronic health information. Furthermore, we finalized to revise the definition of ''meaningful EHR User for MIPS'' at § 414.1305 to state that a MIPS eligible clinician (other than a qualified audiologist) is not a meaningful EHR user for a performance period if the OIG refers a determination that the MIPS eligible clinician committed information blocking, as defined at 45 CFR 171.103, during the calendar year of the performance period. We also finalized amending the requirements at § 414.1375(b) to specify that a MIPS eligible clinician must be a meaningful EHR user for MIPS (as defined at § 414.1305) to earn a score for MIPS Promoting Interoperability performance category. Under the final policies, a MIPS eligible clinician that OIG determines has committed information blocking would not be a meaningful EHR user, and therefore would be unable to earn a score (instead earning a score of zero) for the Promoting Interoperability performance category.

Additional regulatory provisions were finalized at 45 CFR part 171, subpart J,

[756] For more information, see *https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program.*

[757] *https://www.healthit.gov/topic/safety/safer-guides.*

[758] *https://www.healthit.gov/sites/default/files/safer/guides/safer_high_priority_practices.pdf.*

[759] 88 FR 54662. Available at *https://www.govinfo.gov/content/pkg/FR-2024-07-01/pdf/2024-13793.pdf. See also https://www.healthit.gov/topic/information-blocking#Disincentives.*

related to the application of disincentives.

We note that, as finalized, the revised definition of ''meaningful EHR user for MIPS'' at § 414.1305 and the revisions to § 414.1375(b) would become effective when the final rule takes effect on July 31, 2024. For additional background and information, we refer readers to the discussion in the ''21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking'' proposed rule (88 FR 74957 through 74962), as well as the Disincentives final rule.

(e) Future Goals of the Promoting Interoperability Performance Category

(i) Future Goals With Respect to Fast Healthcare Interoperability Resources® (FHIR) APIs for Patient Access

In partnership with ONC, we envision a future where patients have timely, secure, and easy access to their health information through the health application of their choice. We are working with ONC to enable this type of access to health information by requiring the use of APIs that utilize the Health Level Seven International® (HL7) FHIR standard. We work with ONC and other Federal partners to improve timely and accurate data exchange, partner with industry to enhance digital capabilities, advance adoption of FHIR, support enterprise transformation efforts that increase our technological capabilities, and promote interoperability.

In the CY 2021 PFS proposed rule (85 FR 50303), we described our future vision for the Promoting Interoperability performance category and stated that we will continue to consider changes that support a variety of HHS goals, including supporting alignment with the 21st Century Cures Act, advancing interoperability and the exchange of health information, and promoting innovative uses of health IT. We also described plans to continue to align the Promoting Interoperability performance category with policies finalized in the ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' final rule (85 FR 25642), including finalization of a new certification criterion for a standards-based API using FHIR, among other health IT topics.

ONC finalized the HTI–1 final rule (89 FR 1192), effective March 11, 2024, to further implement the 21st Century Cures Act, among other policy goals. ONC finalized revisions to the ''standardized API for patient and population services'' certification criterion at § 170.315(g)(10). It also adopted the HL7 FHIR US Core Implementation Guide (IG) Standard for Trial Use version 6.1.0 at § 170.215(b)(1)(ii), which provides the latest consensus-based capabilities aligned with the USCDI version 3 [760] data elements for FHIR APIs. The HTI–1 final rule also created the Insights Condition and Maintenance of Certification requirements (Insights Condition) within the ONC Health IT Certification Program to provide transparent reporting on certified health IT (89 FR 1199). This Insights Condition will require developers of certified health IT subject to the requirements to report on measures that provide information about the use of specific certified health IT functionalities by end users. One such measure calculates the number of unique individuals who access their electronic health information overall and by different methods such as through a standardized API for patient and population services (89 FR 1313 and 1314).

By adopting these new and updated standards, implementation specifications, certification criteria, and conditions of certification, provisions in the HTI–1 final rule advance interoperability, improve transparency, and support the access, exchange, and use of electronic health information. We aim to further advance the use of FHIR APIs through policies in the Promoting Interoperability performance category to advance interoperability, encourage the exchange of health information, and promote innovative uses of health IT. We also hope to gain insights into the adoption and use of FHIR APIs by MIPS eligible clinicians due to the ONC Health IT Certification Program's Insights Condition. We believe maintaining our focus on promoting interoperability, alignment, and simplification would reduce healthcare provider burden while allowing flexibility to pursue innovative applications that improve care delivery. For additional background and information, we refer readers to the discussion in the ONC HTI–1 final rule on this topic (89 FR 1192).

(ii) Improving Cybersecurity Practices

The Promoting Interoperability performance category encourages the advancement of EHR safety by promoting appropriate cybersecurity practices through the Security Risk Analysis and SAFER Guides measures. On February 14, 2023, the National Institute of Standards and Technology (NIST) published updated guidance for health care entities implementing requirements of the Health Insurance Portability and Accountability of 1996 (HIPAA) Security Rule (45 CFR part 160 and subparts A and C of 45 CFR part 164). The guidance, NIST SP 800–66r2, provides information and resources to HIPAA-covered entities to improve their cybersecurity risk practices.[761] We also wish to alert readers of additional HHS resources and activities regarding cybersecurity best practices as recently summarized in an HHS strategy document that provides an overview of HHS recommendations to help the health care sector address cyber threats.[762] HHS has also recently published a website detailing recommended cybersecurity performance goals.[763] We intend to consider how the Promoting Interoperability performance can promote cybersecurity best practices for MIPS eligible clinicians in the future.

(iii) Improving Prior Authorization Processes

We recently released the CMS Interoperability and Prior Authorization final rule, which appeared in the **Federal Register** on February 8, 2024 (89 FR 8758). The final rule aims to enhance health information exchange and access to health records for patients, healthcare providers, and payers, and improve prior authorization processes. In the final rule, we finalized the addition of a new measure, the ''Electronic Prior Authorization'' measure, under the HIE objective for the MIPS Promoting Interoperability performance category beginning with the CY 2027 performance period/2029 MIPS payment year (89 FR 8909 through 8927).

(f) Requirements for the Promoting Interoperability Performance Category for the CY 2025 Performance Period/ 2027 MIPS Payment Year

(i) Objectives and Measures for the CY 2025 Performance Period/2027 MIPS Payment Year

For ease of reference, Table 62 lists the objectives and measures for the Promoting Interoperability performance category required for the CY 2025 performance period/2027 MIPS payment year as revised to reflect the

[760] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#uscdi-v3.*

[761] *https://csrc.nist.gov/pubs/sp/800/66/r2/final.*

[762] *https://aspr.hhs.gov/cyber/Documents/Health-Care-Sector-Cybersecurity-Dec2023-508.pdf.*

[763] *https://hphcyber.hhs.gov/performance-goals.html.*

policies we will finalize in the final rule.

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TABLE 62: Objectives and Measures for the Promoting Interoperability Performance Category for the CY 2025 Performance Period/2027 MIPS Payment Year

Objective	Measure	Numerator	Denominator	Exclusion
Electronic Prescribing: Generate and transmit permissible prescriptions electronically	e-Prescribing: At least one permissible prescription written by the MIPS eligible clinician is transmitted electronically using CEHRT.	Number of prescriptions in the denominator generated and transmitted electronically using CEHRT.	Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription in order to be dispensed during the performance period.	Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.
Electronic Prescribing	Query of PDMP: For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history.	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	Any MIPS eligible clinician who: 1. is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period; or 2. Any MIPS eligible clinician who does not electronically prescribe any Schedule II opioids or Schedule III or IV drugs during the performance period.
Health Information Exchange: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the	Support Electronic Referral Loops by Sending Health Information: For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or healthcare provider (1) creates a summary of	Number of transitions of care and referrals in the denominator where the summary of care record was created using CEHRT and exchanged electronically	Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transferring or referring clinician	Any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times during the performance period.

Objective	Measure	Numerator	Denominator	Exclusion
first patient encounter with a new patient, and reconciles summary of care information from other healthcare providers into their EHR using the functions of CEHRT	care using CEHRT; and (2) electronically exchanges the summary of care record.			
Health Information Exchange	Support Electronic Referral Loops by Receiving and Reconciling Health Information: For at least one electronic summary of care record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, mediation allergy, and current problem list.	Number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy – Review of the patient's known medication allergies; and (3) Current Problem List – Review of the patient's current and active diagnoses.	Number of electronic summary of care records received using CEHRT for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, and for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient.	Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period.
Health Information Exchange	HIE Bi-Directional Exchange: Statement 1: I participate in an HIE to enable secure, bi-directional exchange to occur for every patient encounter, transition or referral and record stored or maintained in the EHR during the performance period in accordance with applicable law and policy. Statement 2: The HIE that I participate in is capable of exchanging information across a	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	N/A

Objective	Measure	Numerator	Denominator	Exclusion
	broad network of unaffiliated exchange partners including those using disparate EHRs, and not engaging in exclusionary behavior when determining exchange partners. Statement 3: I use the functions of CEHRT to support bi-directional exchange with an HIE.			
Health Information Exchange	Enabling Exchange Under TEFCA MIPS eligible clinicians would attest to the following: • Participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ONC's website) in good standing (i.e. not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period, in accordance with applicable law and policy. • Using the functions of CEHRT to support bi-directional exchange of patient information, in production, under this Framework Agreement.	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	N/A
Provider to Patient Exchange: The MIPS eligible clinician provides patients (or patient-authorized	Provide Patients Electronic Access to Their Health Information: For at least one unique	Number of patients in the denominator (or patient authorized representative) who	Number of unique patients seen by the MIPS eligible clinician during the performance period.	N/A

Objective	Measure	Numerator	Denominator	Exclusion
representative) with timely electronic access to their health information.	patient seen by the MIPS eligible clinician: 1. The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and 2. The MIPS eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the MIPS eligible clinician's CEHRT.	are provided timely access to health information to view online, download, and transmit to a third party and to access using an application of their choice that is configured meet the technical specifications of the API in the MIPS eligible clinician's CEHRT.		
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Immunization Registry Reporting: The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	The MIPS eligible clinician: 1.does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the performance period; OR 2.operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the performance period.
Public Health and Clinical Data	Electronic Case Reporting: The MIPS	N/A (measure is Yes/No and requires	N/A (measure is Yes/No and requires	The MIPS eligible clinician: 1.Does not treat or diagnose

Objective	Measure	Numerator	Denominator	Exclusion
Exchange	eligible clinician is in active engagement with a public health agency to electronically submit case reporting of reportable conditions.	an affirmative attestation to fulfill)	an affirmative attestation to fulfill)	any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the performance period; OR 2.operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the performance period:
Public Health and Clinical Data Exchange	Public Health Registry Reporting: (bonus) The MIPS eligible clinician is in active engagement with a public health agency to submit data to public health registries.	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	none
Public Health and Clinical Data Exchange	Clinical Data Registry Reporting: (bonus) The MIPS eligible clinician is in active engagement to submit data to a clinical data registry.	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	none
Public Health and Clinical Data Exchange	Syndromic Surveillance Reporting: (bonus) The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	none
Protect Patient Health Information: Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and	Security Risk Assessment: Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	none

Objective	Measure	Numerator	Denominator	Exclusion
physical safeguards.	data created or maintained by certified electronic health record technology (CEHRT) in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3). implement security updates as necessary, and correct identified security deficiencies as part of the MIPS eligible clinician's risk management process.			
Protect Patient Health Information	SAFER Guides High Priority Practices Guide: Conduct an annual assessment of the High Priority Practices Guide SAFER Guides	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	none

(ii) Scoring Methodology for the CY 2025 Performance Period/2027 MIPS Payment Year

Table 63 reflects the scoring methodology for the Promoting Interoperability performance category for the CY 2025 performance period/2027 MIPS payment year.

TABLE 63: Scoring Methodology for the CY 2025 Performance Period/2027 MIPS Payment Year

Objective	Measure	Maximum Points	Required/Optional
Electronic Prescribing	e-Prescribing	10 points	Required
	Query of PDMP	10 points	Required
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points	Required (MIPS eligible clinician's choice of one of the three reporting options)
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points	
	-OR-		
	Health Information Exchange Bi-Directional Exchange	30 points	
	-OR-		
	Enabling Exchange under TEFCA	30 points	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points	Required
Public Health and Clinical Data Exchange	Report the following two measures: • Immunization Registry Reporting • Electronic Case Reporting	25 points	Required
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting • Syndromic Surveillance Reporting	5 points (*bonus*)	Optional

Notes: The Security Risk Analysis measure and the SAFER Guides measure are required but will not be assigned points. Failure to submit an affirmative ("yes") attestation will result in a zero score for the Promoting Interoperability performance category.
In addition, MIPS eligible clinicians must submit an affirmative ("yes") attestation regarding ONC direct review, and an affirmative ("yes") attestation that they did not knowingly and willfully take action to limit or restrict the compatibility or interoperability of CEHRT, as required by § 414.1375(b)(3).

(iii) Exclusion Redistribution

Many required measures have exclusions associated with them as shown in Table 62. If a MIPS eligible clinician believes that an exclusion for a particular measure applies to them, they may claim it when they submit their data. The maximum points available in Table 63 do not include the points that will be redistributed if a MIPS eligible clinician claims an exclusion for a specific measure. For ease of reference, Table 64 shows how points will be redistributed among the objectives and measures specified for the Promoting Interoperability performance category for the CY 2025 performance period/2027 MIPS payment year in the event a MIPS eligible clinician claims an exclusion for a given measure.

TABLE 64: Exclusion Redistribution for CY 2025 Performance Period/2027 MIPS Payment Year

Objective	Measure	Redistribution if exclusion is claimed
Electronic Prescribing	e-Prescribing	10 points to HIE objective
	Query of PDMP	10 points to e-Prescribing measure
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points to Provide Patients Electronic Access to Their Health Information measure
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points to the Support Electronic Referral Loops by Sending Health Information measure
	-OR-	
	Health Information Exchange Bi-Directional Exchange	No exclusion
	-OR-	
	Enabling Exchange under TEFCA	No exclusion
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	No exclusion
Public Health and Clinical Data Exchange	Report the following two measures: • Electronic Case Reporting • Immunization Registry Reporting	If an exclusion is claimed for both measures, 25 points are redistributed to the Provide Patients Electronic Access to their Health Information measure

Notes: The Security Risk Analysis measure and the SAFER Guides measure are required but will not be assigned points. Failure to submit an affirmative ("yes") attestation will result in a zero score for the Promoting Interoperability performance category.
In addition, MIPS eligible clinicians must submit an affirmative ("yes") attestation regarding ONC direct review, and an affirmative ("yes") attestation that they did not knowingly and willfully take action to limit or restrict the compatibility or interoperability of CEHRT, as required by § 414.1375(b)(3).

(iv) ONC Health IT Certification Criteria

For ease of reference, Table 65 lists the objectives and measures for the Promoting Interoperability performance category for the CY 2025 performance period/2027 MIPS payment year and the associated ONC health IT certification criteria set forth at 45 CFR 170.315, as is currently applicable. We refer readers to the CY 2024 PFS final rule (88 FR 79307 through 79312) for our discussion of and amendments to the definition of CEHRT at § 414.1305.

TABLE 65: Promoting Interoperability Performance Category Objectives and Measures and ONC Health IT Certification Criteria

Objective	Measure	Certification Criteria (CY 2025 Performance Period/2027 MIPS Payment Year) in Title 45 of the CFR
Electronic Prescribing	e-Prescribing	§ 170.315(b)(3) Electronic prescribing
	Query of PDMP	§ 170.315(b)(3) Electronic prescribing
Health Information Exchange	Support electronic referral loops by sending health information	§ 170.315(b)(1) Transitions of care
	Support electronic referral loops by receiving and reconciling health information	§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
Health Information Exchange (alternative)	Health Information Exchange (HIE Bi-Directional Exchange	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:
		§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Health Information Exchange (alternative)	Enabling Exchange under TEFCA	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:
		§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Provider to Patient Exchange	Provide patients electronic access to their health information	§ 170.315(e)(1) View, download, and transmit to 3rd party
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Public Health and Clinical Data Exchange	Immunization registry reporting	§ 170.315(f)(1) Transmission to immunization registries
	Syndromic surveillance reporting	§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance
	Electronic case reporting	§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting
	Public health registry reporting	§ 170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting
		§ 170.315(f)(7) Transmission to public health agencies — health care surveys
	Clinical data registry reporting	No 2015 health IT certification criteria at this time.
Protect Patient Health Information	Security Risk Assessment	The requirements are a part of CEHRT specific to each certification criterion.
	Safety Assurance Factors for EHR Resilience Guides (SAFER Guides)	No 2015 health IT certification criteria at this time.

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(g) Request for Information (RFI) Regarding Public Health Reporting and Data Exchange

Please note, this is an RFI only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

Respondents are encouraged to provide complete but concise responses. This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. Not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. Please note that CMS will not respond to questions about the policy issues raised in this RFI. CMS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to this notice are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. CMS may publicly post the comments received, or a summary thereof.

(i) Background

The COVID–19 public health emergency (PHE) highlighted the interdependencies of public health and healthcare, and the importance of timely, integrated, and interoperable data exchange across the health ecosystem to protect the health and safety of patients, populations, and the broader public. It also called attention to the distance between where we are as a nation, and where we want to be, with the interoperability of data between healthcare providers and Public Health Agencies (PHAs), especially in the event of a fast-evolving pandemic or other type of PHE. While many jurisdictions were able to demonstrate the advantages of capabilities such as electronic laboratory reporting for reportable conditions, surveillance systems to support case investigations, immunization registries to track COVID–19 immunizations, and syndromic surveillance data for situational awareness, exchange across jurisdictions remains inconsistent and, in some cases, burdensome.

The Promoting Interoperability performance category plays an important role in advancing the exchange of health information between PHAs and MIPS eligible clinicians, using certified Health IT Modules that meet criteria and standards established under the ONC Health IT Certification Program. Measures under the Public Health and Clinical Data Exchange objective focus on a key set of exchange capabilities for healthcare providers that have evolved over time to incorporate new priorities and technical approaches. In recent years, we have also focused on expanding and strengthening the Public Health and Clinical Data Exchange objective to further support the exchange of data that ultimately supports better patient and public health outcomes.

Efforts across HHS to advance the public health information infrastructure offer opportunities to further evolve the Promoting Interoperability performance category. In 2020, Centers for Disease Control and Prevention (CDC) launched the Data Modernization Initiative (DMI),[764] a multi-year, billion-plus dollar public health ecosystem initiative aimed at moving the public health community from a siloed and brittle public health data system to connected, resilient, adaptable, and sustainable ''response-ready'' systems capable of meeting present and future health challenges. CDC's vision for public health data expands on modernization efforts and focuses on critical components to advance data for public health action to equitably protect health, safety and security.[765] To establish clear, near-term priorities and milestones that complement that longer term vision and improve alignment of data modernization efforts at all levels of public health and across partners, CDC released its first Public Health Data Strategy (Ph.D.S) in 2023 and recently updated it.[766] The Ph.D.S outlines the data, technology, policy, and administrative actions essential to exchange critical core data efficiently and securely across healthcare and public health and sets ambitious goals against which CDC will measure progress over the next two years.

In tandem with these efforts to chart a new strategic direction for improvements to the nation's public health infrastructure, evolving technical approaches are offering opportunities to automate and expand information exchange between healthcare providers and PHAs. ONC is exploring updates to existing health IT certification criteria that support current measures in the Promoting Interoperability performance category's Public Health and Clinical Data Exchange objective, new criteria that incorporate modern approaches to exchange, support additional types of information needed by PHAs, and criteria that focus on entities receiving public health data. In the HTI–1 final rule, ONC finalized updates to the health IT certification criterion for electronic case reporting in 45 CFR 170.315(f)(5) incorporating standards-based approaches to existing functional requirements in accordance with the HL7 FHIR Electronic Case Report (eCR) Implementation Guide (IG) or HL7 Clinical Document Architecture (CDA) Electronic Initial Case Report (eICR) IG (89 FR 1226). ONC is also considering recent recommendations from Federal advisory committees that have focused on issues related to public health interoperability. These include the Public Health Data Systems Task Force, which was charged by the Health Information Technology Advisory Committee (HITAC) to inform ONC's continued collaborative work with CDC

[764] *https://www.cdc.gov/surveillance/data-modernization/index.html.*

[765] *https://www.cdc.gov/ophdst/about/advancing-data-for-public-health-action.html.*

[766] *https://www.cdc.gov/ophdst/public-health-data-strategy/index.html.*

on improving public health data systems, and in support of CDC's greater DMI efforts. In November 2022, the Public Health Data Systems Task Force issued recommendations to the HITAC,[767] which included a focus on new criteria for Health IT modules that support public health use cases that aim to standardize technology that receives information from healthcare providers. In addition, the CDC Advisory Committee to the Director (ACD) Data and Surveillance Workgroup adopted a report on November 3, 2022, which addressed standards for public health data systems and implementing a certification program for public health IT as well as other issues.[768]

We are working in partnership with the CDC and ONC to explore how the Promoting Interoperability performance category could advance public health infrastructure through more advanced use of health IT and data exchange standards. This RFI describes a series of goals and principles for the Promoting Interoperability performance category's Public Health and Clinical Data Exchange objective, provides information about recommended updates to health IT certification criteria under consideration that may impact MIPS eligible clinicians, and seeks public comment on potential updates that could help achieve these goals.

(ii) Goals for Public Health Reporting

As we look toward the future of the Public Health and Clinical Data Exchange objective of the Promoting Interoperability performance category, we believe decision-making and prioritization about policy change should adhere to four goals:

(1) The meaningful use of CEHRT enables continuous improvement in the quality, timeliness, and completeness of public health data being reported;

(2) The meaningful use of CEHRT allows for flexibility to respond to new public health threats and meet new data needs without requiring new and substantial regulatory and technical development;

(3) The meaningful use of CEHRT supports mutual data sharing between public health and healthcare providers; and

(4) Reporting burden on MIPS eligible clinicians is significantly reduced.

These goals inform the questions provided at the end of this RFI. We invite public comment on these four goals.

(iii) Public Health in the ONC Health IT Certification Program

We continue to collaborate closely with ONC on policy changes in the ONC Health IT Certification Program that either impact existing functionality reflected in the Promoting Interoperability performance category's measures or represent new capabilities for MIPS eligible clinicians that could offer opportunities to achieve our goals for the Public Health and Clinical Data Exchange objective in the Promoting Interoperability performance category. In this section, we describe specific topics we are discussing through this collaboration with ONC.

(1) Making available new capabilities for exchanging data with PHAs using the FHIR standard.

Current public health certification related criteria at 45 CFR 170.315(f)(1) through (7) generally reference HL7 version 2 and CDA standards that support single-patient, event-based submission of data from healthcare providers to PHAs, such as electronic transmission of laboratory results (HL7® Version 2.5.1 Implementation Guide for Electronic Laboratory Reporting to Public Health, Release 1 with Errata and Clarifications) or electronic initial case reports (HL7 CDA® R2 Implementation Guide: Public Health Case Report—the Electronic Initial Case Report (eICR) Release 2). However, these standards may not adequately support more complex data exchange use cases, such as bulk exchange of data for patients who received a specific vaccine. Approaches using FHIR could more effectively support a wide-scale public health response and reduce burden of implementation and maintenance for data exchange between and among healthcare providers and PHAs.

Increased availability of FHIR-based APIs across systems used by PHAs and healthcare providers could help to create an ecosystem where PHAs could use health IT to securely query data directly from the source, in real time, based on an initial push of relevant data when needed. Availability of a FHIR API in a healthcare provider's certified health IT could enable a PHA to query a MIPS eligible clinician's CEHRT for data on any patient with a specific condition when needed, avoiding the need for a MIPS eligible clinician to take action to submit additional information.

As noted, ONC has already finalized an update to the electronic case reporting criterion in 45 CFR 170.315(f)(5), which provides an option to implement the HL7 FHIR eCR IG as part of a Health IT Module certified to the criterion (89 FR 1226). The Public Health Data Systems Task Force report stated that ''FHIR-based query may offer public health additional avenues to meet the needs of case investigation to supplement electronic case reporting and emerging public health threats'' and that ''FHIR may support a more focused and relevant response by providers to meet public health queries.'' [769]

While FHIR specifications are not available for all the use cases currently supported in the public health criteria at § 170.315(f)(1) through (7), ONC continues to evaluate standards development activities around the use of FHIR for public health data exchange that could be incorporated into existing or new certification criteria, such as replacing HL7 version 2 and CDA exchange specifications with a FHIR approach over time.

(2) Expanding the scope of public health exchange supported by certified health IT capabilities.

Existing health IT certification criteria are linked to measures under the Promoting Interoperability performance category, covering use cases from transmission to immunization registries and syndromic surveillance, and electronic case reporting.

The Public Health Data Systems Task Force report recommended the addition of several additional certification criteria reflecting exchange of information such as birth and death data, the results of newborn screening services, and situational awareness. ONC is monitoring these and other areas of importance to public health that are not reflected in the current certification criteria.

(3) Introducing health IT certification criteria for systems that receive public health data.

To date, ONC health IT certification criteria have been designed with systems that send data to PHAs in mind, particularly health IT systems used by healthcare providers, that exchange data with PHAs. Misalignment between certified health IT products and technology and systems used by PHAs has created challenges for both healthcare providers and PHAs, including reliance on complex

[767] See ''Final Report of the Health Information Technology Advisory Committee on Public Health Data Systems'' *https://www.healthit.gov/sites/default/files/page/2022-11/2022-11-10_PHDS_TF_Recommendations_Report_Transmittal_Letter_508.pdf.*

[768] See ''Data and Surveillance Workgroup Report,'' CDC Advisory Committee to the Director (ACD) Data and Surveillance Workgroup (DSW). *www.cdc.gov/about/pdf/advisory/DSW-Recommendations-Report.pdf.*

[769] See ''Final Report of the Health Information Technology Advisory Committee on Public Health Data Systems,'' *https://www.healthit.gov/sites/default/files/page/2022-11/2022-11-10_PHDS_TF_Recommendations_Report_Transmittal_Letter_508.pdf.*

workflows to accommodate non-harmonized and variable data elements and exchange standards. Inefficiencies associated with workarounds and custom processes can lead to further reductions in data quality, completeness, consistency, and interoperability.

The HITAC Public Health Data Systems Task Force's report includes a recommendation that ONC establish certification criteria for public health technologies used by Public Health Authorities in support of their responsibilities in exchanging data for public health purposes including those defined in the existing (f) criteria.[770]

By establishing minimum functional capabilities and exchange standards to both send and receive public health data, health IT certification criteria could enhance interoperability across healthcare providers and PHAs and provide a long-term mechanism for alignment as data exchange matures over time. An expansion of the ONC Health IT Certification Program to focus on the receiving side could also bolster CDC's public health infrastructure modernization efforts, described above, by helping PHAs to align with healthcare provider data sources using the same certification criteria and standards, enabling these entities to move together on a common timeline for updating technology requirements.

(iv) RFI Questions

Section 1848(q)(2)(B)(iv) of the Act requires that we must apply the requirements under section 1848(o)(2) of the Act for our assessment of whether a MIPS eligible clinician is a meaningful EHR user under the Promoting Interoperability performance category. Section 1848(o)(2)(A) of the Act sets forth three criteria for determining whether a MIPS eligible clinician is a meaningful EHR user. One of these criteria at section 1848(o)(2)(A)(ii) of the Act requires that the MIPS eligible clinician demonstrate to the satisfaction of the Secretary that during the performance period their CEHRT is connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination. We request that commenters consider this criterion in responding to our questions for this RFI.

(1) Questions for Goal #1: Quality, Timeliness, and Completeness of Public Health Reporting

The Promoting Interoperability performance category's requirement that MIPS eligible clinicians report the level of ''active engagement'' between the MIPS eligible clinician, and a PHA, as well as the recently established one-year limitation in how long a MIPS eligible clinician may spend in Pre-Production and Validation for measures under the Public Health and Clinical Data Exchange objective, has provided a basis to broadly incentivize the exchange of EHR data (87 FR 49339 through 49340). It has helped to identify barriers that prevent MIPS eligible clinicians from moving from Pre-Production and Validation (Option 1) to Validated Data Production (Option 2), and it has helped the development of solutions to overcome identified barriers. However, because active engagement reporting only requires an attestation of whether a MIPS eligible clinician is reporting production data or still in the process of validation, this approach does not allow us to assess MIPS eligible clinicians on the comprehensiveness, quality, or timeliness of the data they provide to PHAs.

We are considering whether alternatives to the ''active engagement'' approach for the measures under the Public Health and Clinical Data Exchange objective could better allow us to assess MIPS eligible clinician's performance, meet the data needs of PHAs, and ultimately allow us to incentivize increased performance in these areas. We are interested in how we could recommend alternatives to the ''active engagement'' approach in the context of the evolving technical infrastructure described above. We are also interested in the increasing focus on leveraging FHIR-based data exchange for public health reporting. Finally, we are interested in ensuring that any changes to the active engagement approach are implemented in a way that takes advantage of opportunities to further automate reporting and minimize administrative burden for MIPS eligible clinicians.

- To date, all the measures in the Public Health and Clinical Data Exchange objective assess whether there is active engagement between a MIPS eligible clinician, but they do not measure the level of performance the MIPS eligible clinician has achieved in sending information. Specifically, we are seeking public comment on the following questions:

++ Should CMS shift to numerator/denominator reporting requirements for current and future measures in the Public Health and Clinical Data Exchange objective? If so, should CMS prioritize only certain measures for numerator/denominator reporting?

++ New technical approaches such as the use of FHIR APIs to support information exchange with PHAs could enable PHAs to query healthcare provider systems directly, after an initial trigger, rather than relying on a healthcare provider to take action to share information. Healthcare providers having to take action to share information adds burden to the healthcare providers and increases the time it takes for the PHA to receive the information. How could performance be measured under approaches such as the use of FHIR APIs to support information exchange with PHAs? Would numerator/denominator reporting be appropriate under such approaches?

- Continued expansion of the measures under the Public Health and Clinical Data Exchange objective to address different reporting use cases can incentivize MIPS eligible clinicians to make more comprehensive information available to PHAs. We are seeking public comment on the following questions:

++ Should CMS continue add measures under the Public Health and Clinical Data Exchange objective to include additional system-specific requirements (for example, vital records)? If so, which ones and why?

++ Should CMS create a new measure for each new type of data or use case added to the Public Health and Clinical Data Exchange objective? What are the risks of including too many measures under the objective?

++ Alternatively, should CMS explore ways to group data types and use cases under a more limited set of Public Health and Clinical Data Exchange objective measure? If so, are there specific scenarios where doing so would make sense? Anecdotal reports suggest that some healthcare providers are attesting to active engagement with public health for the eCR measure if they report cases for at least one notifiable condition (for example, COVID–19).

++ How can CMS incentivize more complete electronic case reporting to PHAs? For example, should CMS update the measure to require healthcare providers to meet a certain threshold for conditions reported?

++ What potential benefit versus burden trade-offs CMS should consider? How should CMS account for varying levels of public health readiness and capacity for expanding conditions

[770] Public Health Data Systems Task Force, Recommendation 23, p. 11 *https://www.healthit.gov/sites/default/files/page/2022-11/2022-11-10_PHDS_TF_Recommendations_Report_Transmittal_Letter_508.pdf.*

reported electronically, such as in rural areas?

++ What additional levers besides the Promoting Interoperability performance category should CMS explore to improve the completeness of reporting to public health? How should CMS work with other partners to incentivize or require reporting?

(2) Questions for Goal #2: Flexibility and Adaptability of the Public Health Reporting Enterprise

During the COVID–19 and Mpox PHEs, healthcare providers and PHAs often had to quickly update their systems to report case, laboratory, and vaccination data related to these novel pathogens and interventions devised in response to them. In this section, we are seeking information about how the Promoting Interoperability performance category could improve the ability for public health infrastructure [771] to quickly adapt to new threats. Specifically, we are seeking public comment on the following questions:

- How can the Promoting Interoperability performance category support or incentivize response ready reporting capabilities for healthcare providers? What, if any, challenges exist around sharing data with PHAs?
- How can CMS and ONC work with EHR vendors to ensure that provider systems are being continually updated to meet new data needs, such as those in rural areas?

(3) Questions for Goal #3: Increasing Bi-Directional Exchange With Public Health Agencies

The transition to, and use of more modern, flexible approaches and networks that support data exchange between and across public health and healthcare is a key goal of HHS efforts to modernize the public health information infrastructure. We are interested in ways that the Promoting Interoperability performance category can support this transition. Specifically, we are seeking public comment on the following questions:

- Both CDC's ACD and ONC's HITAC have recommended that CDC and ONC work together to establish certification criteria for public health technologies used by PHAs and implement a coordinated, phased approach to incentivize and eventually require their adoption.[772] How, if at all, could the Promoting Interoperability performance category support or incentivize PHA adoption of certified systems and technologies?
- How can CMS use the Public Health and Clinical Data Exchange objective to incentivize early adoption of FHIR-based APIs for public health data exchange?
- CMS previously finalized the Enabling Exchange under TEFCA measure under the HIE objective for MIPS eligible clinicians to attest to engaging in health information exchange. Should CMS introduce an additional measure to allow MIPS eligible clinicians to receive credit for the HIE objective by exchanging public health data through participation in TEFCA?

(4) Questions for Goal #4: Significantly Reduce Reporting Burden for Healthcare Providers

We are committed to continuing to reduce reporting burden for healthcare providers, such as in rural areas, as part of any updates to the Promoting Interoperability performance category undertaken to support the priorities described above. Specifically, we are seeking public comment on the following questions:

- Under the current Public Health and Clinical Data Exchange objective, which measures, or other requirements result in the most administrative burden for MIPS eligible clinicians?
- How can the Promoting Interoperability performance category balance robust Public Health and Clinical Data Exchange objective requirements with our desire to reduce burden on MIPS eligible clinicians?
- How can new technical approaches to data exchange with PHAs, such as the use of FHIR APIs, reduce burden for MIPS eligible clinicians? What are potential barriers to achieving burden reduction as these new approaches are implemented?

f. MIPS Final Score Methodology

(1) Performance Category Scores

(a) Background

Sections 1848(q)(1)(A)(i) and (ii) and (5)(A) of the Act provide, in relevant part, that the Secretary shall develop a methodology for assessing the total performance of each MIPS eligible clinician according to certain specified performance standards and, using such methodology, provide for a final score for each MIPS eligible clinician. Section 1848(q)(6)(A) of the Act specifies that, to then determine a MIPS payment adjustment factor for each MIPS eligible clinician for an applicable MIPS payment year, we must compare the MIPS eligible clinician's final score for the given year to the performance threshold we established for that same year in accordance with section 1848(q)(6)(D) of the Act. We refer readers to section IV.A.4.g.(2) of this proposed rule for further discussion of the performance threshold, and our calculation of MIPS payment adjustment factors, and our proposals with respect thereto.

Section 1848(q)(2)(A) of the Act provides that the Secretary must assess each MIPS eligible clinician with respect to four performance categories in determining each MIPS eligible clinician's final score: quality, resource use (referred to as ''cost''), clinical practice improvement activities (referred to as ''improvement activities''), and meaningful use of certified EHR technology (referred to as ''Promoting Interoperability''). Section 1848(q)(2)(B) of the Act describes the measures and activities that must be specified under each performance category, including the quality performance category and cost performance category. Section 1848(q)(3) of the Act provides that we must establish performance standards with respect to the measures and activities specified under the four performance categories for a performance period, considering historical performance standards, improvement, and the opportunity for continued improvement. To calculate a final score for each MIPS eligible clinician for the performance period of an applicable MIPS payment year, section 1848(q)(5)(A) of the Act provides that we must develop a methodology for assessing the total performance of each MIPS eligible clinician according to the performance standards we have established with respect to applicable measures and activities specified for each performance category, using a scoring scale of 0 to 100.

In calculating the final score, we must apply different weights for the four performance categories, subject to certain exceptions, as set forth in section 1848(q)(5) of the Act and at § 414.1380. Unless we assign a different scoring weight pursuant to these exceptions, for the CY 2025 performance period/2027 MIPS payment year, the scoring weights for each performance category are as follows: 30 percent for the quality performance category; 30 percent for the cost performance category; 15 percent for the improvement activities performance category; and 25 percent for the Promoting Interoperability performance category.

[771] *https://www.cdc.gov/infrastructure/pdfs/PHIC-Overview.pdf.*

[772] *https://www.healthit.gov/sites/default/files/page/2023-03/2023-02 08_HITAC_Annual_Report_for_FY22_508_1.pdf.*

For the CY 2025 performance period/2027 MIPS payment year, we propose to update our scoring methodologies to respond to statutory requirements and impacts observed in performance data. In this proposed rule, we are proposing to update our scoring policies consistent with these goals. Specifically, we propose to—

- Establish defined topped out benchmarks for certain topped out measures for clinicians impacted by limited measure choice;
- Establish Complex Organization Adjustment for eCQMs reported by Virtual Groups and APM Entities.
- Score Medicare CQMs using flat benchmarks for their first two performance periods in the program.
- Modify the benchmarking methodology for scoring measures in the cost performance category;
- Adopt a new cost measure exclusion policy;
- Eliminate the weighting of activities in the improvement activities performance category; and
- Reduce the number of activities to which clinicians are required to attest.

We do not propose any changes to scoring policies for the Promoting Interoperability performance category.

We refer readers to section IV.A.4.e.(3)(b)(iv) for discussion of scoring proposals in the Improvement Activities performance category.

We refer readers to section IV.A.4.f.(1)(d) for discussion of proposals for scoring the cost performance category.

(b) Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures

We refer readers to the CY 2017, CY 2018, and CY 2019 Quality Payment Program final rules, the CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules, and § 414.1380(b)(1) for our current policies regarding, among other things, quality measure benchmarks, calculating total measure achievement points, calculating the quality performance category score, including achievement and improvement points, and the small practice bonus (81 FR 77276 through 77308, 82 FR 53716 through 53748, 83 FR 59841 through 59855, 84 FR 63011 through 63018, 85 FR 84898 through 84913, 86 FR65490 through 65509, and 87 FR 70088 through 70091). In the CY 2024 PFS final rule, we finalized updates to our scoring flexibilities policy at § 414.1380(b)(1)(vii)(A) (88 FR 79368 through 79369).

(i) Scoring for Topped Out Measures in Specialty Measure Sets With Limited Measure Choice

We refer readers to the CY 2017, CY 2018, and CY 2019 Quality Payment Program final rules, the CY 2023 PFS final rule (81 FR 77282 through 77287, 82 FR 53721 through 53727, 83 FR 59761 through 59765, and 88 FR 70090 through 70091), and § 414.1380(b)(1)(iv) for our established topped out measure scoring policies.

Topped out measures are measures for which measure performance is considered so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (81 FR 77136). We define topped out measures in § 414.1305 differently for process measures and non-process measures. A topped out process measure means a measure with a median performance rate of 95 percent or higher. A topped out non-process measure means a measure where the Truncated Coefficient of Variation is less than 0.01 and the 75th and 90th percentile are with 2 standard errors. For MIPS eligible clinicians electing to report on measures where they expect to perform well, we anticipated many measures would have performance distributions clustered near the top. (81 FR 77282). Section 1848(q)(3)(B) of the Act requires that in establishing performance standards with respect to measures and activities, we consider, among other things, the opportunity for continued improvement. Topped out measures do not provide an opportunity for continued improvement nor, more broadly, do payment adjustments based on topped out measures incentivize clinicians to improve their care. As a result, we finalized policies to identify and cap the scoring potential of such measures. Additionally, we established practices for the removal of such measures, such as establishing the topped out measure lifecycle, to continue to drive quality improvement in areas where such improvement is possible and necessary.

The topped out measure lifecycle is described in the CY 2018 PFS final rule (82 FR 53721 and 53727). We established at § 414.1380(b)(1)(iv)(B) that we would cap scoring for topped out measures at 7 points in the second consecutive year that it is identified as topped out. If a measure has been identified as topped out for 3 consecutive years after being originally identified through the benchmarks, such measure may then be proposed for removal through notice-and-comment rulemaking (83 FR 59761). This timeline, however, is not fixed. We noted our concern where removal of topped out measures would leave clinicians with fewer than 6 applicable measures to report and that such removal in those instances would impact some specialties more than others (82 FR 53721). We stated that consideration for ensuring available applicable measures would be made when considering measure removals (83 FR 59763).

The topped out scoring cap and the topped out measure lifecycle were established with the intention to drive continued quality improvement by providing clinicians with the ability to plan for optimal quality measurement and reporting and by providing measure developers time to develop and submit alternative measures for use in the program (82 FR 53727). However, the pace of measure development has not matched the rate at which topped out measures would ideally be removed under the established topped out lifecycle policy. Since the CY 2017 performance period/2019 MIPS payment year, the MIPS final list of quality measures has decreased from 271 to 198 including the removal of 34 topped out measures that had reached the end of the topped out measure lifecycle.

We have received feedback from interested parties and independently verified that clinicians reporting specialty sets in which there is high presence of topped out measures receiving the 7-point cap are often facing both limited measure choice and limited scoring opportunities. Analysis of data from the CY 2022 performance period/2024 MIPS payment year showed that only 7 percent of quality measure submissions were for topped out measures. However, of those submissions, clinicians representing five specialties accounted for 54 percent of the submissions of topped out measures that contributed to the final score. When we analyzed the data from the CY2022 performance period/2024 MIPS payment year, we found that clinicians in these specialties were facing limited measure choice, with an overrepresentation of topped out measures among their measure selection. Some such topped out measures have been retained in the program to ensure specialists will have applicable measures in the absence of more robust measure development.

We acknowledge that certain clinician specialists have limited measure choice and that their opportunities to maximize their MIPS performance score may be

particularly affected by the current topped out measure scoring policy. We appreciate that, as the performance threshold increases, it may become more difficult for these clinician specialists to maximize their MIPS performance score and secure positive payment adjustments for reasons entirely outside of their control, primarily the topped-out measure scoring cap. In order to determine a MIPS payment adjustment factor for each MIPS eligible clinician for a year, we must compare the MIPS eligible clinician's final score for the given year to the performance threshold we established for that same year in accordance with section 1848(q)(6)(D) of the Act. Section 1848(q)(6)(D)(i) of the Act requires that we compute the performance threshold such that it is the mean or median (as selected by the Secretary) of the final scores for all MIPS eligible clinicians with respect to a ''prior period'' specified by the Secretary. In the CY 2024 PFS final rule, we finalized the performance threshold at a score of 75 points for the CY 2024 performance period/2026 MIPS payment year at § 414.1405(b)(9)(iii) (88 FR 79319). We are proposing in section IV.A.4.g.(2)(c) to maintain the performance threshold at 75 points for the CY 2025 performance year/2027 MIPS payment year. As the number of topped out measures a clinician reports increases, a clinician who must report topped out measures will see their maximum potential quality performance category score decrease and the clinician must score as close to perfect as possible on the topped out measures to mitigate the effect of the 7-point cap on the clinician's final score. Affected clinicians face additional difficulty should they be subject to additional scoring policies, including reweighting of performance categories and reporting quality measures that lack benchmarks. Reweighting of the Promoting Interoperability, cost, or both performance categories increases the weighting of the quality performance category in the final score from 30 percent to 55 or 85 percent.

We want to address scoring scenarios in which limited measure choice compels clinicians to report topped out measures with scoring caps consistent with our desire to facilitate fairer scoring of all specialties. For this reason, we are proposing that beginning with the CY 2025 performance period/2027 MIPS payment year CMS could remove the 7-point cap for certain topped out measures that we would select based on evaluating the factors discussed below. This would allow clinicians who practice in specialties impacted by limited measure choice to be scored according to defined topped out measure benchmarks that do not cap scores at 7 measure achievement points. Table 66 is an illustrative example of the defined topped out measure benchmark.

TABLE 66: Example Defined Topped Out Measure Benchmark

Measure Achievement Points	Performance Rate
1-1.9	84-85.9%
2- 2.9	86-87.9%
3-3.9	88-89.9%
4-4.9	90-91.9%
5-5.9	92-93.9%
6-6.9	94-95.9%
7-7.9	96-97.9%
8-8.9	98-99.9%
10	100%

As discussed above, given that clinicians reporting specialty measure sets with limited measure choice are disproportionately hindered by the 7-point topped out measure scoring cap, we would, in accordance with the methodology discussed below, focus on identifying the topped out measures within specialty measure sets which clinicians with limited measure choice report. We propose to identify the measures for which we would apply the defined topped out measure benchmark on a yearly basis. Measures receiving the defined topped out measure benchmarks would be proposed and adopted through notice-and-comment rulemaking concurrent with our adoption of the MIPS final list of quality measures.

This proposed performance standard would aim, for clinicians with limited measure availability, to continue to require high performance, but would not cap scoring potential for exceptional performers and would offer better scoring opportunities for those performing below the median in the distribution than under our current policy. Under the proposed topped out measure benchmarking methodology, those achieving high performance rates would be rewarded for high performance. Scores between 9–9.9 were intentionally left out. We considered inclusion of scores in the 9th decile, but ultimately excluded them to necessitate exceptional clinical quality performance to achieve maximum scores. This approach would ameliorate the challenge of reporting on measures with a scoring cap while maintaining a high performance standard for topped out measures.

In addition to addressing the scoring limit of the cap, we are also proposing to address the scoring limits caused by the heavily skewed distribution of topped out measures. Previously, because median clinician performance was heavily skewed towards the top of distribution for many topped out measures the second highest achievable decile after the 7th decile may be the 3rd or 4th decile. We therefore propose to specify a topped out measure benchmark that would set an even performance standard. Such a benchmark policy would facilitate clinician efforts to improve clinical quality among clinicians for whom improvement is still possible. The proposed distribution would allow those performing at or above the 97th percentile to achieve a score of 7.5 measure achievement points or greater to reward high performance and encourage clinical quality improvement for those who perform below the median.

We propose to conduct an analysis annually to determine which specialty

measure sets are impacted by limited measure choice and which measures should be subject to the scoring cap exemption. Our analysis would evaluate all specialty measure sets by collection type to assess the impact of limited measure choice taking into account the influence of several scoring considerations including the number of capped topped out measures, the number of measures in the specialty set without historical benchmarks, and the scoring potential to meet or exceed the performance threshold. We would then consider each capped topped out measure in the corresponding specialty measure sets on a case-by-case basis for application of the defined topped out measure benchmark. Additionally, annual consideration of which measures would have the defined topped out measure benchmark applied would take into account any changes to the availability of applicable measures and changes in the topped out status of measures that previously had the defined topped out measure applied. A measure would not have a defined topped out measure benchmark applied until it was identified as topped out for 2 consecutive performance periods, the point at which point the 7-point cap would be applied. If suppression of a measure or removal of a benchmark impacts a measure scored according to the defined topped out measure benchmark, it would not be proposed again for the application of the defined topped out measure benchmark and the performance standard would return to the standard scoring policy at § 414.1380(b)(1)(i).

Measures that are identified as topped out for 3 consecutive performance periods may still be proposed for removal through notice-and-comment rulemaking and extremely topped out measures, those with an average mean performance within the 98th to 100th percentile range, can also still be proposed for removal in the next rulemaking cycle, regardless of whether or not they are in the midst of the topped out measure lifecycle (83 FR 59763). If a measure that is scored according to a defined topped out measure benchmark later shows extremely topped out status, it will be subject to this policy. Any such measure removal would continue to occur through notice-and-comment rulemaking. While we aim to be responsive to those facing limited measure choice, we do not believe that measures with topped out performance have the same value in the program as measures that are not topped out, and they should be scored accordingly in instances where doing so does not unfairly limit a clinician's scoring opportunity. We believe these parameters identify those most impacted by limited measure choice while continuing to encourage high clinical quality measure performance.

This proposal would remain consistent with our current topped out measure lifecycle, program goals, and historical approaches to scoring scenarios with limited measure choice. In the CY 2017 Quality Payment Program final rule, we exempted measures reported via the CMS Web Interface from the 7-point measure cap. The CMS Web Interface requires that MIPS eligible clinicians submitting via the CMS Web Interface must submit all measures included in the CMS Web Interface (81 FR 77116). Their lack of ability to select alternative measures made the application of the 7-point measure cap inappropriate. Instead, we finalized a proposal at § 414.1380(b)(1)(ii)(A) to use benchmarks from the corresponding year of the Shared Saving Program as the Shared Savings Program incorporates a methodology for measures with high performance into the benchmark (82 FR 53721). The defined topped out measure benchmark similarly aims to score clinicians facing limited measure choice on topped out measures using a methodology that adjusts for high performance.

We considered several policy options to address topped out measure scoring for clinicians facing limited measure choice. These included removing all topped out measures at the end of the topped out measure lifecycle, exempting all topped out measures in specialty measure sets from application of the 7-point cap, applying a denominator reduction for those scoring 7 out of 10 measure achievement points on topped out measures in specialty measure sets, and adopting a new reweighting policy for the quality performance category for clinicians impacted by limited measure choice that score below the performance threshold. These approaches would not appropriately address the barriers to fair scoring posed by limited measure choice, nor would they incentivize and reward improvement in clinical quality measure performance. Additionally, these alternatives would introduce additional scoring complexity and in one case, require clinicians' additional submission of a reweighting application to access potential benefits. The proposed approach of applying defined topped out measure benchmarks for certain topped out measures selected in accordance with the methodology set forth above avoids the additional complexity of the other approaches by building on historical and current quality measure scoring policies to topped out measures that does not require additional steps to access and is applicable as we transition to MVPs.

For the reasons stated above, we are proposing to add § 414.1380(b)(1)(iv)(C) to state that beginning with the CY 2025 performance period/2027 MIPS payment year, measures impacted by limited measure choice as specified in paragraph (b)(1)(ii)(E) are not subject to the 7 measure achievement point cap specified in paragraph (b)(1)(iv)(B). We propose a conforming change to § 414.1380(b)(1)(iv)(B).

We also propose to add § 414.1380(b)(1)(ii)(E) to state that, beginning with the CY 2025 performance period/2027 MIPS payment year, CMS will publish a list in the **Federal Register** of topped out measures determined to be impacted by limited measure choice. Measures included in the list are scored from 1 to 10 measure achievement points according to defined topped out measure benchmarks calculated from performance data in the baseline period in which a performance rate in the 97th percentile corresponds to 7.5 measure achievement points. Accordingly, we also propose to update § 414.1380(b)(1)(ii) to state that except as provided in paragraphs (b)(1)(ii)(B) through (F), benchmarks will be based on performance by collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period. We are also proposing to make conforming changes to this section to include a previous inadvertent omission of paragraph (b)(1)(ii)(D) in addition the proposed new exceptions in paragraphs (b)(1)(ii)(E) and (F) corresponding to policies discussed in sections IV.A.4.f.(1)(b)(i) and IV.A.4.f.(1)(c)(i) respectively.

(ii) Proposed Approach for Determining Topped Out Measures Impacted by Limited Measure Choice and Subject to the Proposed Defined Topped Out Measure Benchmark and the Proposed List of Measures That Would Be Subject to the Defined Topped Out Measure Benchmark for the CY 2025 Performance Period/2027 MIPS Payment Year

Under this proposal, we would annually determine and publish a list of topped out measures that would have the 7-point cap removed and be subject to the proposed defined topped out measure benchmark. To identify which topped out measures would be added to

the list, we would review each specialty measure set by collection type and identify if the prevalence of topped out measures within such a set hinders a clinician's ability to successfully participate in the MIPS quality performance category. To make such a determination, we would analyze the ability of clinicians reporting the specialty measure sets under review to reasonably achieve 75 percent of available quality achievement points based upon the measures available to them and program requirements. As stated, the analysis would be conducted for each specialty measure set and would be further broken down by collection type. At the collection type level, each measure would be assigned points based upon the current benchmarking data: new measures receive 7 or 5 points based on year in the program, measures with benchmarks are given points based upon the highest decile achievable with a less than perfect score (less than 100 percent or greater than 0 percent for inverse measures), and measures with no available historic benchmark are given 0 points. All measure set points would be added together to get an output of scoring potential; the Medicare Part B claims collection type measure sets have an additional 6 points added to the output to account for the small practice bonus. The sum of quality achievement points for each measure set would be compared to the analysis threshold, which is 75 percent of available quality achievement points, based upon number of available measures. Any measure sets that are not able to meet or exceed the threshold would be flagged as 'at-risk.' Additional factors that we would take into consideration would include whether or not:

- A measure within the specialty measure set is considered a cross cutting measure;
- A measure within the specialty measure set is a broadly applicable measure, which we would consider to be a measure included in three or more specialty sets; and
- There are more than ten measures, by collection type, available in the specialty set. We request comment on our proposal to score topped out measures impacted by limited measure choice using specialty defined topped out measures including the proposed defined topped out measure benchmark.

Table 67 contains the list of measures that meet the criteria specified above and for which we are proposing to apply the defined topped out measure benchmark for the CY 2025 performance period/2027 MIPS payment year. Specialty sets impacted by limited measure choice include Pathology, Anesthesiology, Diagnostic Radiology, and Radiation Oncology.

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TABLE 67: Proposed topped out measures impacted by limited measure choice and subject to defined topped out measure benchmark for the CY 2025 performance period/2027 MIPS Payment Year by Specialty Set

Measure ID	Collection Type	Measure Title
143	eCQM, MIPS CQM	Oncology: Medical and Radiation – Pain Intensity Quantified
249	Medicare Part B Claims, MIPS CQM	Barret's Esophagus
250	Medicare Part B, MIPS CQM	Radical Prostatectomy Pathology Reporting
360	MIPS CQM	Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medical Studies
364	MIPS CQM	Optimized Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines
395	Medicare Part B, MIPS CQM	Lung Cancer Reporting (Biopsy/Cytology Specimens)
396	MIPS CQM	Lung Cancer Reporting (Resection Specimens
397	Medicare Part B, MIPS CQM	Melanoma Reporting
405	MIPS CQM	Appropriate Follow-up Imaging for Incidental Abdominal Lesions
406	MIPS CQM	Appropriate Follow-up Imaging for Incidental Thyroid Nodules in Patients
424	MIPS CQM	Perioperative Temperature Management
430	MIPS CQM	Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy
436	MIPS CQM	Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques
440	MIPS CQM	Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician
463	MIPS CQM	Prevention of Post-Operative (POV) – Combination Therapy (Pediatrics)
477	MIPS CQM	Multimodal Pain Management

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We request comment on the proposed approach that we would use each year to identify the list of measures subject to the defined topped out measure benchmark, as well as the proposed list of topped out measures impacted by limited measure choice and subject to defined topped out measure benchmark for CY 2025 performance period/2027 MIPS Payment Year.

(iii) Complex Organization Adjustment for Virtual Groups and APM Entities

Section 1848(q)(5)(B)(ii)(I) of the Act requires the Secretary to encourage MIPS eligible clinicians to report on applicable quality measures through the use of Certified Electronic Health Record Technology (CEHRT) and qualified clinical data registries. Section 1848(q)(5)(B)(ii)(II) of the Act provides that the Secretary shall treat such clinicians as satisfying the clinical quality measures reporting requirement described in section 1848(o)(2)(A)(iii) of the Act if they report such measures through the use of such EHR technology for a given performance period.[773] In the CY 2017 Quality Payment Program final rule (81 FR 77297), we established the measure bonus point and bonus cap for

[773] Section 1848(o)(2)(A)(iii) of the Act requires a meaningful EHR user to demonstrate to the satisfaction of the Secretary that the eligible professional, among other things, has not knowingly and willfully taken action to limit or restrict the compatibility or interoperability of the certified EHR technology.

using CEHRT for end-to-end electronic reporting. We refer readers to § 414.1380(b)(1)(v)(B) for our previously finalized policies regarding measure bonus points for end-to-end electronic reporting.

In the CY 2022 PFS final rule, we finalized our proposal to end measure bonus points for end-to-end electronic reporting. We noted that as we move to MVPs we are simplifying scoring by removing many of the transition policies that we established in the early years of the program in order to develop a stronger MVP program and promote alignment between MIPS and MVPs. As stated in previous rulemaking, we are working to develop ways to encourage the use of CEHRT for electronic reporting without offering measure bonus points. We stated that we believed that we could fulfill the statutory requirement at section 1848(q)(5)(B)(ii)(I) of the Act to encourage the usage of CEHRT, through other means. Accordingly, over the past few years, we have reduced the availability and limited who can submit data for the Medicare Part B claims collection type to only small practices noting that the Medicare Part B claims collection type is not an electronic means of submission.

In the current state, satisfying quality reporting requirements is not equally attainable for each MIPS eligible clinician or entity in the Quality Payment Program (QPP). As the QPP and its components (MIPS and Advanced APMs) has matured, reliance on and subsequent requirements necessitating the use of CEHRT have increased (88 FR 79331). The adoption of CEHRT has been slower than anticipated, indicating additional support for quality reporting may further support attainment of program goals while also addressing the observed and reported challenges faced by complex entities and organizations working to meet new requirements.

Virtual Groups and APM Entities may experience technological barriers to electronic report, including challenges aggregating patient data across multiple TINs, data deduplication, and interoperability between different health IT/EHR systems. In the CY 2018 Quality Payment Program final rule, commenters indicated that data aggregation across multiple TINs for Virtual Groups would be burdensome for rural and small practices and that this burden could be prohibitive for Virtual Groups' successful participation in MIPS (82 FR 53610). Commenters stated that the requirement for Virtual Groups to aggregate data across the Virtual Group could be a potential barrier for Virtual Group participation and would not likely occur without error (82 FR 53610). Commenters noted that the potential penalty for failure to overcome technical challenges in data aggregation was, at that time, a severe 5 percent decrease to the payment adjustment for TINs that are already operating on small margins (82 FR 53610). Commenters noted that the aggregation of data across various TINs and health IT systems may be logistically difficult and complex, as groups and health IT systems have different ways of collecting and storing data and stated that data aggregation across various systems for measures and activities under each performance category may not be possible if qualified registries do not have the option to assist Virtual Groups (82 FR 53610). Additionally, commenters stated that practices already have an issue of not being able to deduplicate patient data across different health IT systems/multiple EHRs and indicated that Virtual Groups need clear guidelines regarding how to achieve accurate reporting (82 FR 53613).

Furthermore, commenters expressed concerns that registries supporting Virtual Group reporting would be opening themselves to potential penalties as a result of technical challenges in data aggregation across multiple EHR systems (82 FR 53610). The commenters indicated that registries may not be able to support Virtual Group reporting due to legal and operational complexity. Certain registries have internal data governance standards, including patient safety organization requirements, that they must follow when contracting with single TIN participants that may complicate their ability to support Virtual Group reporting due to necessary legal agreements between solo practitioners and small groups within a Virtual Group (82 FR 53611). Commenters requested that CMS provide guidance to registries regarding how to handle data sharing among Virtual Groups with respect to patient safety organization requirements and provide guidance regarding the expectations for registries supporting virtual group reporting (82 FR 53611).

APM Entities are organizations that participate in CMS's various APMs, including the Medicare Shared Savings Program and CMS Innovation Center models. APM Entities face similar organizational challenges reporting eCQMs because of their complex structures, new and innovative partnerships under their respective APMs, and utilization of multiple EHR technologies (88 FR 79097). For ACOs in the Shared Savings Program, and ACOs and other large organizations in CMS Innovation Center models, these issues are further exacerbated by scale and patient volume, as discussed in more detail further in this section. In the CY 2023 PFS proposed rule, commenters noted issues for ACOs participating in the Shared Savings Program reporting all payer/all patient eCQMs/MIPS CQMs related to meeting all-payer data requirements, data completeness requirements, and data aggregation (87 FR 69837). ACOs also noted the financial burden of aggregating, deduplicating, and exporting eCQM data across multiple TINs and EHRs (88 FR 79097). As summarized in the CY 2024 PFS final rule, commenters noted that the current state of data standards and interoperability will not yet fully enable Shared Saving Programs ACOs to meet the eCQM reporting requirements successfully and encouraged CMS to continue working with providers to facilitate the transition to all-payer/all-patient measures even as/if the provider or ACO chooses to report Medicare CQMs (88 FR 79107). In the CY 2024 PFS final rule (88 FR 79098), we stated that our long-term goal continues to be to support Shared Savings Program ACOs in the adoption of all payer/all patient measures and transition to digital quality measurement reporting. These challenges also can be faced by other large APM Entities participating in CMS Innovation Center models.

Additionally, APM Entities in CMS Innovation Center models, regardless of size, are participating in innovative payment and delivery designs through which they may forging new partnerships among different providers and provider types to provide care to attributed beneficiaries to meet the APM's care delivery requirements. For example, the Making Care Primary (MCP) Model includes several payment innovations to support participants in delivering advanced primary care and aims to strengthen coordination between patients' primary care clinicians, specialists, social service providers, and behavioral health clinicians, ultimately leading to chronic disease prevention, fewer emergency room visits, and better health outcomes. The model will operate through three progressive tracks, with the first track being designed for organizations with no prior value-based care experience. Additionally, the model includes State partnerships and multi-payer alignment objectives. Participation in this model will involve forming new relationships to provide whole-person care to

beneficiaries, which is likely to necessitate bridging data across multiple technologies and involve new and complex administrative burdens in the provision of this advanced primary care.

Based on our assessment and understanding over the past 2 years, we have learned that there are complexities and challenges for Virtual Groups and APM Entities in adopting all-payer/all-patient collection types, and as a result, the widespread adoption of the all-payer/all patient collection types requires further time and support. We have come to understand that further support is needed for complex organizations. As an example, Shared Saving Program ACOs provide a high volume of services, particularly those related to preventative screening measures. An internal analysis of performance year 2022 submission data indicates that Shared Savings Program ACOs reported on 33 times more denominator eligible patients for eCQM 001—Diabetes: HbA1c Poor Control (>9%), 53 times more denominator eligible patients for eCQM 134—Preventative Care and Screening: Screening for Depression and Follow-Up Plan, and 25 times more denominator eligible patients for eCQM 236—Controlling High Blood Pressure than other MIPS reporters. In performance year 2022, one ACO reported on over 700,000 denominator eligible beneficiaries for a single eCQM.

The requirement to aggregate patient data collected across multiple health records into a single data stream before sending to CMS poses administrative challenges and the need for additional resources for Virtual Groups and APM Entities, including Shared Savings Program ACOs. Additionally, data deduplication is resource intensive and requires the development of new workflows to ensure accuracy. Stakeholders have also noted that patient files exist in multiple, disparate EHRs since each EHR system collects and stores data differently. This is important as moving to reporting eCQMs requires building new processes to fill data gaps and ensure data accuracy and causes participants often to customize workflows for data processing, such as using Quality Reporting Document Architecture (QRDA) I (individual patient) and QRDA III (measured entity's aggregate) data submission approaches for quality reporting. EHR vendors have also expressed concerns regarding the need for more time to develop new features that can facilitate eCQM reporting processes. Some interested parties have also voiced concerns that clinician specialty or patient population could yield lower quality scores when reporting eCQMs and create resistance to switching to this collection type.

We noted in the CY 2024 PFS final rule that a few commenters agreed that Medicare CQMs would address most of ACOs' concerns regarding all payer/all patient reporting in the Shared Saving Program, such as difficulties reporting for those ACOs with a higher proportion of specialty practices or groups with multiple EHRs, beneficiaries with no primary care relationship, and shouldering a greater burden when matching and deduplicating patient records (88 FR 79101). Other commenters noted Medicare CQMs reduce concerns about specialists reporting on primary care focused measures. Commenters shared that Medicare CQMs were responsive to several key concerns raised by Shared Savings Program ACOs regarding feasibility of implementing eCQMs/MIPS CQMs, including equity concerns (88 FR 79101). However, we maintain that consistent with section 1848(q)(5)(B)(ii)(I) we support and encourage providers as they perform any necessary bridging of data across multiple technologies, which can involve new and complex administrative burdens.

To account for the organizational complexities faced by Virtual Groups and APM Entities, including ACOs in the Shared Savings Program, we are proposing to establish a Complex Organization Adjustment beginning in the CY 2025 performance period/2027 MIPS Payment Year. Virtual Group and APM Entities would receive one measure achievement point for each submitted eCQM that meets the data completeness at § 414.1380(b)(1)(iii) and case minimum requirements at § 414.1340. Each reported eCQM may not receive more than 10 measure achievement points and the total achievement points (numerator) may not exceed the total available measure achievement points (denominator) for the quality performance category. The Complex Organization Adjustment for a Virtual Group or APM Entity may not exceed 10 percent of the total available measure achievement points in the quality performance category. The adjustment would be added for each measure submitted at the individual measure level.

Adding one point for each eCQM would help complex organizations to overcome barriers to reporting eCQMs while not masking overall quality performance. By limiting the Complex Organization Adjustment to Virtual Groups and APM Entities, we can limit scoring inflation and target this intervention to those facing challenges to eCQM implementation. Moreover, while acknowledging the Complex Organization Adjustment is a recognition of current challenges to eCQM reporting we believe that adoption of the Fast Healthcare Interoperability Resources (FHIR) Application Programing Interface (API) would reduce or eliminate the barriers posed by organizational complexities to eCQM reporting and will revisit and end this Adjustment as uptake of FHIR API increases, requirements surrounding the use of FHIR API are established, or other barriers posed by organizational complexity are otherwise reduced. This Adjustment differs from the previous end-to-end electronic reporting bonus in that it does not merely award measure achievement points for reporting but provides an adjustment for clinicians facing complex organizational barriers for adopting the eCQM collection type.

We propose to add § 414.1380(b)(1)(vii)(C) to provide that, beginning in the CY 2025 performance period/2027 payment year, a Virtual Group and an APM Entity receives one measure achievement point for each eCQM submitted that meets the case minimum requirement at paragraph (b)(1)(iii) and the data completeness requirement at § 414.1340. Each measure may not to exceed 10 measure achievement points. The total adjustment to the Virtual Group or APM Entity's quality performance category score under this paragraph may not exceed 10 percent of the total available measure achievement points. Accordingly, we proposed to update § 414.1380(b)(1)(vii) to state a MIPS eligible clinician's quality performance category score is the sum of all the measure achievement points assigned for the measures required for the quality performance category criteria plus the measure bonus points in paragraph (b)(1)(v) and Complex Organization Adjustment in paragraph (b)(1)(vii)(C). The sum is divided by the sum of total available measure achievement points. The improvement percent score in paragraph (b)(1)(vi) is added to that result. The quality performance category score cannot exceed 100 percentage points.

We request comment on our proposal to implement a Complex Organization Adjustment for Virtual Groups and APM Entities, including ACOs in the Shared Savings Program.

(c) Scoring the Quality Performance Category Through MIPS for ACOs in the Shared Saving Program.

(i) Proposal To Score for Shared Savings Program ACOs Reporting Medicare CQMs Using Flat Benchmarks

In section III.G.4.c.2.c of this proposed rule we are proposing to score Shared Savings Program ACOs reporting Medicare CQMs in the APP Plus quality measure set using flat benchmarks for their first two performance periods in MIPS. Consistent with this discussion, we are proposing to add § 414.1380(b)(1)(ii)(F) to state that beginning in the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQM collection type would be scored using flat benchmarks for their first two performance periods in MIPS. We request comment on our proposal to score Medicare CQMs using flat benchmarks for their first two performance periods in MIPS.

(d) Cost Performance Category Score

(i) Scoring the Cost Performance Category Background

As discussed previously, to calculate a final score for each MIPS eligible clinician for the performance period of an applicable MIPS payment year, section 1848(q)(5)(A) of the Act requires that we must develop a methodology for assessment of the total performance of each MIPS eligible clinician, according to the performance standards we have established in accordance with section 1848(q)(3) of the Act, with respect to applicable measures and activities specified for each performance category. For the final score, we must use a scoring scale of 0 to 100.

We refer readers to § 414.1380(b)(2) for our policies regarding scoring for the cost performance category and to previous rules where these policies were finalized, including the CY 2017 Quality Payment Program final rule (81 FR 77308 through 77311), the CY 2018 Quality Payment Program final rule (82 FR 53748 through 53752), the CY 2019 PFS final rule (83 FR 59856), the CY 2021 PFS final rule (85 FR 84877 through 84880), the CY 2022 PFS final rule (86 FR 65507 through 65509), the CY 2023 PFS final rule (87 FR 70091 through 70093), and the CY 2024 PFS final rule (88 FR 79369 through 79373).

We are proposing to: (1) modify the benchmark methodology for scoring measures specified for the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year; and (2) adopt a new cost measure exclusion policy beginning with the CY 2025 performance period/2027 MIPS payment year.

(ii) Benchmark Methodology for Scoring the Cost Performance Category

(A) Background on Methodology for Scoring the Cost Performance Category

Under § 414.1350(a), we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category. Under § 414.1380(b)(2), we score each MIPS eligible clinician [774] on each cost measure attributed to them in accordance with § 414.1350(b) so long as the MIPS eligible clinician meets the minimum case volume specified under § 414.1350(c) to be scored on that cost measure. Cost performance category measures are attributed to MIPS eligible clinicians through, and scored based on, claims data; we do not require MIPS eligible clinicians to submit any additional data on cost measures to CMS (§ 414.1325(a)). We have codified our cost performance category scoring policies at § 414.1380(b)(2).

Specifically, we finalized at § 414.1380(b)(2) that we will score each cost measure attributed to a MIPS eligible clinician (meeting or exceeding the minimum case volume) by assigning achievement points between one and ten based on the MIPS eligible clinician's performance on the cost measure during the performance period compared to the measure's benchmark. We award the achievement points (including partial points) based on which benchmark decile range the MIPS eligible clinician's performance on the measure is between. The MIPS eligible clinician's cost performance category score (to be added to the final score) is the sum (not to exceed 100 percent) of: (1) the total number of achievement points earned by the MIPS eligible clinician divided by the total number of available achievement points; and (2) the cost improvement score, as determined under § 414.1380(b)(2)(iv) (§ 414.1380(b)(2)(iii)). We will not calculate a cost performance category score if the MIPS eligible clinician is not attributed any cost measures for the performance period because the MIPS eligible clinician has not met the minimum case volume as specified under § 414.1350(c) for any of the cost measures or a benchmark has not been created for any of the cost measures that would otherwise be attributed to the MIPS eligible clinician (§ 414.1380(b)(2)(v)).

As set forth in § 414.1380(b)(2)(i), we determine cost measure benchmark ranges based on all MIPS eligible clinicians' performance on each attributed cost measure during the performance period. We determine a benchmark for a cost measure only if at least 20 MIPS eligible clinicians are attributed and meet the minimum case volume for that measure, as specified under § 414.1350(c). If we cannot determine a benchmark for a cost measure because an insufficient number of MIPS eligible clinicians were attributed the measure (that is, less than 20 MIPS eligible clinicians meet the minimum case volume), then we will not assign any score for the measure for any MIPS eligible clinician (§ 414.1380(b)(2)(i) and (v)). We refer readers to our prior rulemakings, including the CY 2017 Quality Payment Program final rule (81 FR 77308 through 77311), for detailed discussion of our previously finalized policies for determining a benchmark for each cost measure and then assignment of achievement points based on comparison of a MIPS eligible clinician's performance to that established benchmark.

Specifically, under our current scoring policy at § 414.1380(b)(2) and benchmark methodology, MIPS eligible clinicians with the lowest average cost per episode or per beneficiary would be in the top decile (Decile 10) and receive the highest number of available achievement points (10). On the other end of the spectrum, MIPS eligible clinicians with the highest average cost per episode or per beneficiary would be in the bottom decile (Decile 1) and receive the lowest number of achievement points (1). More information about how average cost per beneficiary or per episode are calculated and translated to MIPS achievement points is available in the 2023 MIPS Cost User Guide.[775]

Table 68 provides an example of using benchmark deciles along with partial achievement points to assign achievement points for a sample cost measure under our current methodology. The following formula is used to determine the number of partial points awarded to the MIPS eligible clinician:

Benchmark Decile # + [(measure score, expressed as a dollar amount − bottom

[774] As noted previously, the term MIPS eligible clinician is defined in § 414.1305 as including a group of at least one MIPS eligible clinician billing under a single tax identification number. A cost measure therefore may be attributed to a group that includes at least one MIPS eligible clinician and the group may therefore be scored on the cost performance category as a whole. We refer readers to our policies governing group reporting and scoring under MIPS as set forth in § 414.1310(e).

[775] *https://qpp.cms.gov/resources/document/fac61617-20ef-4d31-9f0f-4a0e76620ca3.*

of benchmark decile range)/(top of benchmark decile range − bottom of benchmark decile range)] = Cost Measure Achievement Points.[776]

TABLE 68: Example of Using Benchmark Deciles and Partial Points to Assign Achievement Points for Performance on the Screening/Surveillance Colonoscopy Cost Measure

Benchmark Decile	Cost per Episode	Percentile	Possible Points
Benchmark Decile 1	$1330.65-$1126.35	99th	1.0–1.9
Benchmark Decile 2	$1126.34-$1062.93	90th	2.0-2.9
Benchmark Decile 3	$1062.92-$1025.75	80th	3.0-3.9
Benchmark Decile 4	$1025.74-$997.78	70th	4.0-4.9
Benchmark Decile 5	$997.77-$969.73	60th	5.0-5.9
Benchmark Decile 6	$969.72-$940.03	50th	6.0-6.9
Benchmark Decile 7	$940.02-$904.83	40th	7.0-7.9
Benchmark Decile 8	$904.82-$860.44	30th	8.0-8.9
Benchmark Decile 9	$860.43-$779.69	20th	9.0-9.9
Benchmark Decile 10	$779.68 and lower	10th	10

In the CY 2021 PFS final rule (85 FR 84877 through 84880), we finalized at § 414.1350(d)(4) the weight of the cost performance category to be 20 percent of the MIPS final score for the 2023 MIPS payment year and at § 414.1350(d)(5) the weight of the cost performance category to be 30 percent of the MIPS final score for the 2024 MIPS payment year and each subsequent MIPS payment year. We noted that such an approach would allow us to reach the statutorily required weight of 30 percent by the 2024 MIPS payment year (see section 1848(q)(5)(E)(i)(II) of the Act) while reducing the impact of experiencing an increase in the weight of the cost performance category too much in any one year and providing clinicians with an eased gradual and incremental transition starting with the 2023 MIPS payment year.

Since, MIPS eligible clinicians have raised concerns about cost performance category scoring having a negative impact on their final MIPS score. Multiple factors have likely contributed to clinician concerns.

First, there has been an increase in weight for the cost performance category over time. Particularly, due to the COVID–19 Public Health Emergency (PHE) which ended on May 11, 2023, we reweighted the cost performance category's score to zero percent of the final score for many MIPS eligible clinicians. Specifically, we announced on April 6, 2020 that, due to the COVID–19 PHE, we would apply our extreme and uncontrollable circumstances reweighting policies described under § 414.1380(c)(2)(i) to MIPS eligible clinicians nationwide and extend the deadline to submit an application for reweighting the quality, cost, improvement activities or Promoting Interoperability reporting categories for the CY 2019 performance period/2021 MIPS payment year (85 FR 19277 and 19278). Also, for the CY 2020 performance period/2022 MIPS payment year and the CY 2021 performance period/2023 MIPS payment year, we extensively applied our reweighting policies, described under § 414.1380(c)(2)(i), to MIPS eligible clinicians nationwide due to the COVID–19 PHE.[777] [778] As a result, the CY 2022 performance period/2024 MIPS payment year was the first MIPS payment year that the cost performance category score generally constituted 30 percent of MIPS eligible clinicians' final scores (section 1848(q)(5)(E)(i)(II) of the Act). Second, the number of cost measures has increased over time, and therefore, more MIPS eligible clinicians are being measured on the cost performance category and on new measures.

Additionally, based on our calculation of cost performance category scores for the CY 2022 performance period/2024 MIPS payment year, we observed lower scores for the cost performance category than for the quality performance category, even though they each generally constitute 30 percent of the final score. Recent analyses of CY 2022 performance period/2024 MIPS payment year data have identified the unweighted mean cost performance category score was 59 out of 100, while the unweighted mean score for the quality performance category was 74 out of 100. We also note that the unweighted mean scores were 95 out of 100 for the improvement activities performance category and 94 out of 100 for the Promoting Interoperability performance category.

There are several factors that may have contributed to a significantly lower score in the cost performance category, compared to the other categories. First, measures in the cost performance category are scored against a benchmark determined based on average performance of all MIPS eligible clinicians during that same performance period (§ 414.1380(b)(2) introductory text and (b)(2)(i)) rather than a benchmark determined based on historical data, which is used, wherever possible, for non-administrative claims-based quality measures in the quality performance category. Benchmarks determined based on historical data for the quality performance category provide MIPS eligible clinicians with helpful performance targets in advance of or during the performance period. Meanwhile, the performance period benchmarks for the cost performance category do not provide MIPS eligible clinicians with information about performance targets before or during the performance period. We believe that using benchmarks based in the performance period is a better approach for the cost performance category than using benchmarks based on historical data because different payment policies

[776] *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2378/2023%20MIPS%20Cost%20User%20Guide.pdf.*

[777] *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/816/2020%20Cost%20Quick%20Start%20Guide.pdf.*

[778] *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1298/2021%20MIPS%20Cost%20Quick%20Start%20Guide.pdf.*

may apply during the historical period than during the performance period, which may affect the cost of care for patients treated by MIPS eligible clinicians.

Second, in traditional MIPS (compared to MVP reporting), MIPS eligible clinicians are scored on each cost measure for which they meet the established case minimum and a benchmark can be calculated. In the quality performance category, if a clinician reports more than the required number of quality measures, we use the highest scored outcome measure and then the next highest scored measures to reach a total of 6 sored quality measures to calculate the clinician's MIPS quality performance category score. The current cost benchmark methodology uses a decile range based on linear percentile distributions and assigns 5.0 to 6.9 achievement points to clinicians with cost measure scores within the 50th to 60th percentiles (Table 68).

For the example cost measure presented in Table 68, the cost measure median, the 50th percentile, is $969.72. If a MIPS eligible clinician's average cost per episode for the measure is $1,104 (about $135 above the median), the MIPS eligible clinician's cost falls within Benchmark Decile 2, for which the MIPS eligible clinician may receive between 2.0 and 2.9 achievement points. We then use the following formula to determine the number of partial points awarded to the MIPS eligible clinician:

Benchmark Decile # + [(measure score, expressed as a dollar amount − bottom of benchmark decile range)/(top of benchmark decile range − bottom of benchmark decile range)] = Cost Measure Achievement Points.[779]

Based on this partial points calculation formula, the clinician would receive 0.3 partial points, resulting in a cost measure score of 2.3 out of 10 achievement points for the Screening/Surveillance Colonoscopy cost measure under this example.

This score may have the effect of lowering the MIPS eligible clinician's final score, as discussed previously. If the MIPS eligible clinician is only attributed and scored on this single cost measure and does not receive a cost improvement score, then their score for the cost performance category would be based on the cost measure's score of 2.3 out of 10 achievement points. Their score for the cost performance category would be 0.23 (2.3/10 = 0.23), equal to the total number of achievement points earned by the MIPS eligible clinician divided by the total number of available achievement points under § 414.1380(b)(2)(iii)(A). Based on the final score calculation under § 414.1380(c), the contribution of the cost performance category score to the final score for this MIPS eligible clinician would be equal to the cost performance category score multiplied by the cost performance category weight (30 percent if the MIPS eligible clinician has not received any reweighting) and would be 6.9 out of 30 ($0.23 \times 30 = 6.9$), which would be 23 out of 100 points for the cost performance category's contribution to the final score.

To illustrate how this cost performance category score could lower the final score, if this MIPS eligible clinician received perfect scores in each of the other three performance categories, based on the final score calculation under § 414.1380(c) and the respective performance category weights when all four performance categories are scored without reweighting, we would use the formula as described below. For this example, we have not included the complex patient bonus.

MIPS Final score = [(60/60 × 30 for quality) + (2.3/10 × 30 for cost) + (40/40 × 15 for improvement activities) + (100/100 × 25 for Promoting Interoperability)] × 100 = 76.9.

In this example, MIPS final score of 76.9 for the MIPS eligible clinician is just above the 2024 MIPS payment year performance threshold of 75. Therefore, under the current cost scoring methodology, a MIPS eligible clinician scoring near the median on a cost measure would need to score perfectly (or nearly perfectly) within the other three performance categories to receive a final score slightly above the performance threshold and to avoid a negative payment adjustment. The unweighted cost performance category score of 23 out of 100 noticeably lowers the MIPS eligible clinician's MIPS final score.

(B) Proposed Modification to Scoring Methodology for the Cost Performance Category Beginning With CY 2024 Performance Period/2026 MIPS Payment Year

In light of the concerns identified with our current cost scoring policies, we are proposing to modify the methodology for scoring the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year. The proposed cost scoring methodology would be based on standard deviation, median, and an achievement point value that is derived from the performance threshold. Specifically, for a MIPS eligible clinician whose average costs attributed under a cost measure would be equal to the median cost for all MIPS eligible clinicians attributed that measure, we would assign an achievement point value equal to 10 percent of the performance threshold. For example, for the CY 2024 performance period/2026 MIPS payment year, the median would have an achievement point value of 7.5, based on a performance threshold of 75 as finalized at § 414.1405(b)(9)(iii). For each cost measure, the cut-offs for benchmark ranges would be calculated based on standard deviations, expressed in dollars, from the median.

The benchmark ranges, the median, and the performance threshold-derived achievement point values aligned with the median would be dynamic and responsive to changes in average costs per episode or per beneficiary assessed by cost measures and performance thresholds for each CY performance period/MIPS payment year. The performance threshold-derived point values could change based on the performance threshold established for each performance period/MIPS payment year. The standard deviations from the median used to determine cutoffs for benchmark ranges for each year would be reviewed for any necessary updates annually based on performance across MIPS eligible clinicians within the cost performance category and the performance threshold established for the performance period/MIPS payment year. We would perform analyses when the performance threshold changes to set the benchmark ranges. To determine the benchmark ranges, we would adhere to the following principles: (1) center the majority of average costs per episode or per beneficiary around the performance threshold-derived point value; (2) determine benchmark ranges according to the statistical distribution curve of the average cost per episode or per beneficiary; and (3) distribution of achievement points for cost measures should be reflective of overall program performance. We refer readers to Table 69 for an example of how the proposed cost scoring methodology could be implemented for a specific cost measure when the performance threshold is set to 75.

[779] *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2378/2023%20MIPS%20Cost%20User%20Guide.pdf.*

TABLE 69: Example of Implementation of the Proposed Cost Scoring Methodology for Assignment of Achievement Points for Performance on the Screening/Surveillance Colonoscopy cost measure

Benchmark Range	Points	Proposed Methodology for Bottom of Benchmark Range ($)	Example Benchmark Ranges
Benchmark Range 1	1 - 1.9	Median cost + (2.75 x standard deviation)	$1341.93 - $1308.10
Benchmark Range 2	2 - 2.9	Median cost + (2.5 x standard deviation)	$1308.09 - $1.274.26
Benchmark Range 3	3 - 3.9	Median cost + (2.25 x standard deviation)	$1274.25 - $1240.43
Benchmark Range 4	4 - 4.9	Median cost + (2 x standard deviation)	$1240.42 - $1172.75
Benchmark Range 5	5 - 5.9	Median cost + (1.5 x standard deviation)	$1172.74 - $1105.08
Benchmark Range 6	6 – 6.9	Median cost + (1 standard deviation)	$1105.07 - $1037.40
Benchmark Range 7	7 - 7.9	Median cost + (0.5 x standard deviation)	$1037.39 - $902.05
Benchmark Range 8	8 - 8.9	Median cost - (0.5 x standard deviation)	$902.04 - $834.38
Benchmark Range 9	9 - 9.9	Median cost - (1 x standard deviation)	$834.37 - $766.70
Benchmark Range 10	10	Median cost - (1.5 x standard deviation)	$766.69 and below

Continuing with the example of the Screening/Surveillance Colonoscopy cost measure, now presented in Table 69 as an example of implementation of the proposed cost scoring methodology, the median (50th percentile) cost would remain $969.72. Under the proposed cost scoring methodology, for the CY 2024 performance period/2026 MIPS payment year, a MIPS eligible clinician with a cost per episode equal to the median cost of all cases attributed to all MIPS eligible clinicians would receive 7.5 achievement points out of 10 possible achievement points.

Using the same example as previously presented in section IV.A.4.f.(1)(d)(ii)(A) of this proposed rule, we would apply the proposed cost scoring benchmark methodology as shown in Table 69 to a MIPS eligible clinician with an average cost per episode for this measure that is $1,104 (about $135 above the median). Based on the analysis of data in this example, the standard deviation for the Screening/Surveillance Colonoscopy cost measure would be $135.35. This value for the standard deviation would then be used to calculate the benchmark ranges in Table 69 by plugging in this value for the standard deviation for each benchmark range. For example, ''Median cost + (1 × $135.35)'' would be calculated for ''Median cost + (1 standard deviation)'' for the bottom of Benchmark range 6. As shown with the example in Table 69, under our proposed cost scoring methodology, the MIPS eligible clinician's average cost per episode of $1,104 would fall within Benchmark Range 6 for the Screening/Surveillance Colonoscopy cost measure, for which the MIPS eligible clinician may receive between 6.0 and 6.9 achievement points.

Under our proposal to modify the cost performance category's scoring methodology for individual cost measures, we would continue to use our established formula to assign partial achievement points:

Benchmark Range # + [(measure score, expressed as a dollar amount − bottom of benchmark range)/(top of benchmark range − bottom of benchmark range)] = Cost Measure Achievement Points.

As a result, using the example shown in Table 69, under our proposed cost scoring methodology, the MIPS clinician would receive 6.02 cost measure achievement points (6 + [($1,104 − $1,105.07)/ ($1,037.40 − $1,105.07)] = 6.02). The assignment of 6.02 achievement points under the proposed cost scoring methodology would be closer to the performance threshold equivalent of 7.5 than the assignment of 2.3 achievement points under the current cost scoring methodology, as discussed in our previous example in section IV.A.4.f.(1)(d)(ii)(A) of this proposed rule.

In this example, the MIPS eligible clinician's score for the cost performance category would be 0.602 (6.02/10 = 0.602), equal to the total number of achievement points earned by the MIPS eligible clinician divided by the total number of available achievement points under § 414.1380(b)(2)(iii)(A). Based on the final score calculation under § 414.1380(c), the contribution of the cost performance category score to the final score for this MIPS eligible clinician would be equal to the cost performance category score multiplied by the cost performance category weight (30 percent if the MIPS eligible clinician has not received any reweighting) and would be 18.06 out of 30 (0.602 × 30 = 18.06) or 60.2 out of 100.

If this MIPS eligible clinician received perfect scores in each of the other three performance categories, based on the final score calculation under § 414.1380(c) and the respective performance category weights when all four performance categories are scored without reweighting, we would use the formula as described below. For this example, we have not included the complex patient bonus.

MIPS Final score = [(60/60 × 30 for quality) + (6.02/10 × 30 for cost) + (40/40 × 15 for improvement activities) + (100/100 × 25 for Promoting Interoperability)] × 100 = 88.06.

This MIPS final score of 88.06 for the MIPS eligible clinician would be well above the 2024 MIPS payment year performance threshold of 75. The cost performance category score of 60.2 out of 100 would not noticeably lower the MIPS eligible clinician's MIPS final score.

This proposed modification in our scoring methodology for cost measures would align the assignment of achievement points for cost measures so that clinicians with costs near the measure's 50th percentile (median) would not receive a disproportionately low score. Based on our analyses utilizing data from the CY 2022 performance period/2024 MIPS payment year, this proposed methodology would increase the mean cost performance category score (unweighted) for clinicians with a cost performance category score from 59 out of 100 to 71 out of 100 (an increase of 11.9 points). Further, this proposed cost scoring methodology would increase the means for each cost measure score by amounts ranging from 0.04 to 2.52

points. Our analysis showed that, under our proposed methodology, the mean final score for MIPS eligible clinicians assessed on at least one cost measure and receiving a cost performance category score would increase by 3.89 points. Under our analysis, our proposed scoring methodology would not negatively impact MIPS eligible clinicians whose average costs for a specific cost measure are around the median.

Specifically, our analysis supports our intended goal for the proposed modification to the scoring methodology: MIPS eligible clinicians who deliver care at an average cost near the median costs for all MIPS eligible clinicians attributed the measure would receive scores at, or very close to, the performance threshold-derived score. Additionally, this proposed modification would address MIPS eligible clinicians' concerns that cost measure scoring negatively impacts their final scores more than other performance categories, including disparate negative effects for MIPS eligible clinicians who are scored on the cost performance category compared to clinicians not scored on the cost performance category.

To codify this proposed policy, we propose to modify § 414.1380(b)(2) to specify that achievement points are awarded based on which benchmark range the MIPS eligible clinician's performance on the measure is in. We also propose to specify that CMS assigns partial points based on where the MIPS eligible clinician's performance falls between the top and the bottom of the benchmark ranges. The terms ''decile'' and ''percentile distribution'' are currently used in § 414.1380(b)(2) to describe the scoring methodology used to award achievement points and assign partial points. However, under the proposed methodology, the term ''decile'' no longer accurately describes how the benchmark ranges would be constructed. We believe the more general term ''benchmark range'' accurately describes both the current and the proposed cost scoring methodology, and therefore propose to modify § 414.1380(b)(2) to use ''benchmark range'' in lieu of ''decile'' and ''percentile distribution.'' We are not proposing any modifications to the remainder of the language currently at § 414.1380(b)(2), which provides that, for each cost measure attributed to a MIPS eligible clinician, the clinician receives one to ten achievement points based on the clinician's performance on the measure during the performance period compared to the measure's benchmark.

We are also not proposing any modifications to the language currently at § 414.1380(b)(2)(i), generally governing if and how CMS determines a cost measure's benchmark. However, we are proposing to codify our current cost scoring policy, previously finalized in the CY 2017 QPP final rule (81 FR 77308 through 77311), with modification by adding language at § 414.1380(b)(2)(i)(A). We propose to specify at § 414.1380(b)(2)(i)(A) that, for the 2019 through 2025 MIPS payment years, CMS determines cost measure benchmark ranges based on linear percentile distributions.

We are also proposing to codify our proposed benchmarking methodology at § 414.1380(b)(2)(i)(B). We propose to specify at § 414.1380(b)(2)(i)(B) that, beginning with the 2026 MIPS payment year, for each cost measure, CMS determines 10 benchmark ranges based on the median cost of all MIPS eligible clinicians attributed the measure, plus or minus standard deviations and that CMS awards achievement points based on which benchmark range a MIPS eligible clinician's average cost for a cost measure corresponds. We also propose to codify at § 414.1380(b)(2)(i)(B) that, beginning with the 2026 MIPS payment year, CMS awards achievement points equivalent to 10 percent of the performance threshold for a MIPS eligible clinician whose average cost attributed under a cost measure is equal to the median cost for all MIPS eligible clinicians attributed the measure.

We request public comments on this proposal to modify our scoring methodology for measures specified under the cost performance category.

(iii) Proposed Adoption of Additional Cost Measure Exclusion Policy

(A) Background on Cost Measure Exclusion Policy

We refer readers to § 414.1380(b)(2)(v)(A) and the CY 2022 PFS final rule (86 FR 65507 through 65509) for our previously established policy for excluding a single cost measure from a MIPS eligible clinician's score for the cost performance category. As described at § 414.1380(b)(2)(v)(A), we established that, beginning with the 2024 MIPS payment year, if data used to calculate a score for a cost measure are impacted by significant changes during the performance period, such that calculating the cost measure score would lead to misleading or inaccurate results, then the affected cost measure is excluded from the MIPS eligible clinician's or group's cost performance category score. We also established at § 414.1380(b)(2)(v)(A) that ''significant changes'' are changes external to the care provided, and that CMS determines may lead to misleading or inaccurate results. We specified at § 414.1380(b)(2)(v)(A) that significant changes include, but are not limited to, rapid or unprecedented changes to service utilization, and will be empirically assessed by CMS to determine the extent to which the changes impact the calculation of a cost measure score that reflects clinician performance.

As described in the CY 2022 PFS final rule (86 FR 65507 through 65509), we finalized the policy at § 414.1380(b)(2)(v)(A) to provide scoring flexibility in instances where changes during a performance period impede the effective measurement of cost. We identified that there is a need for additional flexibility in calculating the scores for cost measures to account for the impact of changing conditions that are beyond the control of individual MIPS eligible clinicians and groups. We noted that this flexibility would allow us to ensure that clinicians are not impacted negatively when performance is affected not due to the care provided, but due to external factors. We noted that we would determine whether such external changes impede the effective measurement of cost by considering factors including: The extent and duration of the changes, and the conceptual and empirically tested relationship between the changes and each measure's ability to accurately capture clinician cost performance (86 FR 65508). Empirical testing could include assessing whether there are rapid or unprecedented changes to patient case volume or case mix, and the extent to which this could lead to misleading or inaccurate results (86 FR 65508).

(B) Proposal To Permit Exclusion of a Cost Measure When Impacted by Errors and When Significant Changes Occur Outside of the Performance Period

In the CY 2022 PFS final rule, for the quality performance category, we modified the quality measure exclusion policy at § 414.1380(b)(1)(vii)(A) to change ''significant changes'' to ''significant changes or errors'' (86 FR 65492) and to include the omission of codes or inclusion of inactive or inaccurate codes to provide that for each measure submitted, if applicable, and impacted by significant changes or errors prior to the applicable data submission deadline at § 414.1325(e), performance is based on data for 9 consecutive months of the applicable CY performance period. Currently, for

the cost performance category, we do not include ''errors'' in addition to ''significant changes'' within our cost measure exclusion policy at § 414.1380(b)(2)(v)(A). To provide CMS with greater flexibilities to be responsive to any errors or significant changes outside of the control of MIPS eligible clinicians that negatively impact the ability of specific cost measure(s) to assess clinician performance, we are proposing to add a new cost measure exclusion policy at § 414.1380(b)(2)(v)(B) similar to the quality measure exclusion policy. Additionally, to further align our measure exclusion policies among the performance categories, we propose to include ''errors'' for the cost performance category. Specifically, we are proposing that, beginning with the 2027 MIPS payment year, if data used to calculate a score for a cost measure are impacted by significant changes or errors affecting the performance period, such that calculating the cost measure score would lead to misleading or inaccurate results, then the affected cost measure is excluded from the MIPS eligible clinician's or group's cost performance category score.

For purposes of this cost measure exclusion policy at § 414.1380(b)(2)(v)(B), we are proposing to define ''significant changes or errors'' as changes or errors external to the care provided, and that CMS determines may lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance. While we are proposing to include ''errors'' within this policy for the cost performance category, as the quality performance category already does, the list of what ''significant changes or errors'' includes would differ by performance category to capture differences in how cost measures and quality measures are calculated and measured. For instance, unlike quality measures for which MIPS eligible clinicians generally must submit data to CMS to be assessed, cost measures are calculated by CMS solely based on the review of administrative claims data and should not be impacted by reporting errors. However, cost measures could be impacted by CMS calculation errors. Further, under our proposed cost measure exclusion policy, errors would be external to the care provided, and such that CMS determines may lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance. Under our proposed exclusion policy for cost measures, significant changes or errors would include, but would not be limited to, rapid or unprecedented changes to service utilization, the inadvertent omission of codes or inclusion of codes, or changes to clinical guidelines or measure specifications. Additionally, these would not automatically result in cost measure exclusion. Instead, we would determine whether there is a negative impact from the significant change or error when deciding if a cost measure will be excluded.

Specifically, before applying this cost measure exclusion policy, we are proposing that CMS would empirically assess the affected cost measure to determine the extent to which the changes or errors impact the calculation of a cost measure score such that calculating the cost measure score would lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance. We believe that it is important to clarify that a change or error would not automatically result in measure exclusion, but instead, that we would need to determine whether there is a negative impact from the change or error that would affect cost measure scoring.

Because significant changes or errors can have an ongoing impact on a measure beyond a single performance period, we are proposing that the new cost measure exclusion policy at § 414.1380(b)(2)(v)(B) allow us to exclude cost measures when such changes and errors occur outside of the performance period, but otherwise affect the performance period. For example, if a cost measure is impacted by a coding change or guidance that requires substantive changes to a measure, we may not be able to modify the measure within one performance period. In such circumstances, we would want to exclude the cost measure for the affected performance periods due to the ongoing impact on the measure. We would ensure that if data used to calculate a score for a cost measure are impacted by significant changes or errors affecting one or more performance periods delivering misleading or inaccurate results, then the affected cost measure could be excluded from the MIPS eligible clinician's or group's cost performance category score. We believe that the cost measure should be able to be excluded regardless of when we become aware of the issue, when the significant change came into effect, or when the error first occurred. Therefore, we are proposing language at § 414.1380(b)(2)(v)(B) to address data used to calculate a score for a cost measure being impacted by significant changes and errors affecting a performance period, even if they do not occur during the performance period.

We are proposing that this cost measure exclusion policy would be effective beginning with the CY 2025 performance period/2027 MIPS payment year so this policy would be in place as soon as feasible after the opportunity for notice-and-comment rulemaking.

This proposal would add language at § 414.1380(b)(2)(v)(B) to specify that, beginning with the 2027 MIPS payment year, if data used to calculate a score for a cost measure are impacted by significant changes or errors affecting the performance period, such that calculating the cost measure score would lead to misleading or inaccurate results, then the affected cost measure would be excluded from the MIPS eligible clinician's or group's cost performance category score. We propose to specify that ''significant changes or errors'' are changes or errors external to the care provided, and that CMS determines may lead to misleading or inaccurate results that negatively impact the measure's ability to reliable assess performance. We also propose to specify that significant changes or errors would include, but are not limited to, rapid or unprecedented changes to service utilization, the inadvertent omission of codes or inclusion of codes, or changes to clinical guidelines or measure specifications. We propose that CMS would empirically assess the affected cost measure to determine the extent to which the changes or errors impact the calculation of a cost measure score such that calculating the cost measure score would lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance.

We request public comments on this proposal.

g. MIPS Payment Adjustments

(1) Background

Section 1848(q)(6)(A) of the Act requires that we specify a MIPS payment adjustment factor for each MIPS eligible clinician for a year. This MIPS payment adjustment factor is a percentage determined by comparing the MIPS eligible clinician's final score for the given year to the performance threshold we established for that same year in accordance with section 1848(q)(6)(D) of the Act. The MIPS payment adjustment factors specified for a year must result in differential payments such that MIPS eligible clinicians with final scores above the performance threshold receive a

positive MIPS payment adjustment factor, those with final scores at the performance threshold receive a neutral MIPS payment adjustment factor, and those with final scores below the performance threshold receive a negative MIPS payment adjustment factor.

For previously established policies regarding our determination and application of MIPS payment adjustment factors to each MIPS eligible clinician, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77329 through 77343), CY 2018 Quality Payment Program final rule (82 FR 53785 through 53799), CY 2019 PFS final rule (83 FR 59878 through 59894), CY 2020 PFS final rule (84 FR 63031 through 63045), CY 2021 PFS final rule (85 FR 84917 through 84926), CY 2022 PFS final rule (86 FR 65527 through 65537), CY 2023 PFS final rule (87 FR 70096 through 70102), and CY 2024 PFS final rule (88 FR 79373 through 79380).

(2) Establishing the Performance Threshold

(a) Statutory Authority and Background

As discussed above, to determine a MIPS payment adjustment factor for each MIPS eligible clinician for a year, we must compare the MIPS eligible clinician's final score for the given year to the performance threshold we established for that same year in accordance with section 1848(q)(6)(D) of the Act. Section 1848(q)(6)(D)(i) of the Act requires that we compute the performance threshold such that it is the mean or median (as selected by the Secretary) of the final scores for all MIPS eligible clinicians with respect to a prior period specified by the Secretary. Section 1848(q)(6)(D)(i) of the Act also provides that the Secretary may reassess the selection of the mean or median every 3 years.

Sections 1848(q)(6)(D)(ii) through (iv) of the Act provided special rules, applicable only for certain initial years of MIPS, for our computation and application of the performance threshold for our determination of MIPS payment adjustment factors. These special rules are no longer applicable for establishing the performance threshold for the CY 2025 performance period/2027 MIPS payment year. We refer readers to the CY 2024 PFS proposed rule (88 FR 52596) for further information on these previously applicable requirements as they explain our prior computations of the performance threshold.

In the CY 2022 PFS final rule (86 FR 65527 through 65532), we selected the mean as the methodology for determining the performance threshold for the CY 2022 performance period/2024 MIPS payment year through CY 2024 performance period/2026 MIPS payment year. We also established in our regulation at § 414.1405(g) that, for each of the 2024, 2025, and 2026 MIPS payment years, the performance threshold would be the mean of the final scores for all MIPS eligible clinicians from a prior period. As discussed under section IV.A.4.g.(2)(b) of this proposed rule, we are proposing to continue using the mean as the methodology for determining the performance threshold for the 2027, 2028, and 2029 MIPS payment years.

In the CY 2024 PFS final rule (88 FR 79373 through 79380), we established the performance threshold for the CY 2024 performance period/2026 MIPS payment year by calculating the mean of the final scores for all MIPS eligible clinicians using CY 2017 performance period/2019 MIPS payment year data. As further discussed under section IV.A.4.g.(2)(c), we are proposing to continue using the mean of the final scores for all MIPS eligible clinicians from the CY 2017 performance period/2019 MIPS payment year to establish the performance threshold as 75 points for the CY 2025 performance period/2027 MIPS payment year.

For further information on our current performance threshold policies, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77333 through 77338), CY 2018 Quality Payment Program final rule (82 FR 53787 through 53792), CY 2019 PFS final rule (83 FR 59879 through 59883), CY 2020 PFS final rule (84 FR 63031 through 63037), CY 2021 PFS final rule (85 FR 84919 through 84923), CY 2022 PFS final rule (86 FR 65527 through 65532), CY 2023 PFS final rule (87 FR 70096 through 70100), and CY 2024 PFS final rule (88 FR 79373 through 79380).

We codified the performance thresholds for each of the first 8 years of MIPS at § 414.1405(b)(4) through (9). These performance thresholds are shown in Table 71.

TABLE 71: Performance Thresholds for the CY 2017 Performance Period/2019 MIPS Payment Year through the CY 2024 Performance Period/ 2026 MIPS Payment Years

MIPS Performance Period	2017 MIPS Performance Period	2018 MIPS Performance Period	2019 MIPS Performance Period	2020 MIPS Performance Period	2021 MIPS Performance Period	2022 MIPS Performance Period	2023 MIPS Performance Period	2024 MIPS Performance Period
Year of MIPS	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**	**Year 8**
Performance Threshold	3 points	15 points	30 points	45 points	60 points	75 points	75 Points	75 Points
Change from prior year	N/A	12 points	15 points	15 points	15 points	15 points	0 points	0 points

(b) Establishing the Performance Threshold Methodology for the 2027, 2028, and 2029 MIPS Payment Years

Section 1848(q)(6)(D)(i) of the Act requires that we compute the performance threshold such that it is the mean or median (as selected by the Secretary) of the final scores for all MIPS eligible clinicians with respect to a prior period specified by the Secretary. That section also provides that the Secretary may reassess the selection of the mean or median every three years. In accordance with section 1848(q)(6)(D)(i) of the Act, we are

proposing to continue using the mean of the final scores for all MIPS eligible clinicians to compute the performance threshold for the 2027, 2028, and 2029 MIPS payment years.

In the CY 2022 PFS final rule (86 FR 65527 through 65532), we selected the mean (rather than the median) as the methodology for determining the performance threshold for the 2024, 2025, and 2026 MIPS payment years. For the CY 2019 performance period/CY 2021 MIPS payment year through CY 2021 performance period/2023 MIPS payment year, section 1848(q)(6)(D)(iv) of the Act required that we methodically increase the performance threshold each year to ''ensure a gradual and incremental transition'' to the performance threshold we estimated would be applicable in the CY 2022 performance period/2024 MIPS payment year. Although sections 1848(q)(6)(D)(ii) through (iv) of the Act were no longer applicable for establishing the performance threshold for the CY 2024 performance period/2026 MIPS payment year, these previously applicable statutory requirements explained prior computations of the performance threshold that impacted our policy considerations for establishing the performance threshold for MIPS going forward. Based on our review of possible values for the CY 2022 performance period/2024 MIPS payment year, we believed that using the mean as our methodology for setting the performance threshold for the CY 2022 performance period/2024 MIPS payment year through the CY 2024 performance period/2026 MIPS payment year would continue the ''gradual and incremental transition'' that was previously required under section 1848(q)(6)(D)(iv) of the Act, as well as to provide consistency to our stakeholders. Therefore, we finalized the proposal to use the mean as our methodology for setting the performance threshold for that 3-year period. We also codified this methodology in our regulation at § 414.1405(g), providing that, for each of the 2024, 2025, and 2026 MIPS payment years, the performance threshold would be the mean of the final scores for all MIPS eligible clinicians from a prior period as specified.

At the time of this proposed rule, we have data available on MIPS eligible clinicians' final scores from the CY 2017 performance period/2019 MIPS payment year through CY 2022 performance period/2024 MIPS payment year, as shown in Table 72. These values represent all available computations of mean and median final scores for those performance periods/MIPS payment years. As discussed previously, we may use either the mean or median of the final scores from a prior period for computing the performance threshold for the next three years, beginning with the CY 2025 performance period/2027 MIPS payment year. At the time of this proposed rule, we do not have available MIPS eligible clinicians' final scores from performance periods after the CY 2022 performance period/2024 MIPS payment year, which may inform the performance thresholds for the CY 2026 performance period/2028 MIPS payment year and CY 2027 performance period/2029 MIPS payment year. As provided in section 1848(q)(6)(D)(i) of the Act, we must select whether we will use the mean or median of MIPS eligible clinicians' final scores from a prior period, which we may reassess after three years. We assess these selection options based on the data we currently have available.

TABLE 72: Possible Values for the 2027 MIPS Payment Year Performance Threshold

MIPS Payment Years	2019 MIPS Payment Year	2020 MIPS Payment Year	2021 MIPS Payment Year	2022 MIPS Payment Year	2023 MIPS Payment Year	2024 MIPS Payment Year
Mean	74.65	87.00	85.65	89.47	89.22	82.71
Median	89.71	99.63	92.32	96.82	97.22	85.17

As shown in Table 72, using the median final score gives a possible range of performance thresholds from 85.17 points to 99.63 points (rounded to 85 points and 100 points, respectively). Given our performance threshold of 75 points for the CY 2024 performance period/2026 MIPS payment year, these values would result in an increase of 10 points to 25 points for the CY 2025 performance period/2027 MIPS payment year, and potentially the CY 2026 performance period/2028 MIPS payment year and CY 2027 performance period/2029 MIPS payment year. Selecting the median of final scores as our methodology would, at a minimum, result in a 13 percent increase in the performance threshold of 75 points, which we had established for the CY 2022 performance period/2024 MIPS payment year through the CY 2024 performance period/2026 MIPS payment year. Further, as shown in Table 71, 75 points is the highest performance threshold we have established for any MIPS payment year to date.

As shown in Table 72, using the mean final score as the methodology would yield a possible range of performance thresholds from 74.65 points to 89.47 points (rounded to 75 points and 89 points, respectively). Given our performance threshold of 75 points in the CY 2024 performance period/2026 MIPS payment year, these values would result in an increase of zero to 14 points for the CY 2025 performance period/2027 MIPS payment year, and potentially the CY 2026 performance period/2028 MIPS payment year and CY 2027 performance period/2029 MIPS payment year. Selecting the mean of final scores as our methodology would, at a maximum, result in a 19 percent increase in the performance threshold of 75 points, which we had established for the CY 2022 performance period/2024 MIPS payment year through the CY 2024 performance period/2026 MIPS payment year.

We believe that it is appropriate to incentivize performance improvement while also ensuring that it is reflective of true clinician performance. Moreover, we believe that where possible, it is important to offer stability and consistency for clinicians. After evaluating the possible values for mean and median shown in Table 72 and our prior policies for consistently selecting a performance threshold value of 75 points for the CY 2022 performance period/2024 MIPS payment year through the CY 2024 performance period/2026 MIPS payment year, we believe that using the mean as our methodology for the 2027 through 2029 MIPS payment years would offer the most consistent and predictable approach for MIPS eligible clinicians.

On this basis, we are proposing to continue using the mean of the final scores for all MIPS eligible clinicians from a prior period as specified to compute the performance threshold for each of the 2027 through 2029 MIPS payment years.

We also are proposing to codify this proposal by amending our regulation text at § 414.1405. We propose to amend § 414.1405 by: (1) revising paragraph (g) to read only ''Performance Threshold Methodology''; (2) redesignating, with minor technical modification, the substantive provision at paragraph (g) as a new paragraph (g)(1) to reflect the performance threshold methodology we established and used to specify the performance threshold for the 2024, 2025 and 2026 MIPS payment years under § 414.1405(b)(9); and (3) adding paragraph (g)(2) to provide that, for each of the 2027, 2028, and 2029 MIPS payment years, the performance threshold is the mean of the final scores for all MIPS eligible clinicians from a prior period as specified under § 414.1405(b)(10).

We request public comments on this proposal.

(c) Establishing the Performance Threshold for the CY 2025 Performance Period/2027 MIPS Payment Year

We believe using the mean of 75 points from the CY 2017 performance period/2019 MIPS payment year continues to be the most appropriate option for establishing the performance threshold for the CY 2025 performance period/2027 MIPS payment year for various reasons described in this section, including: providing consistency for MIPS eligible clinicians while allowing additional time for more recent data to become available, continuing to provide opportunities for MIPS eligible clinicians to gain experience with cost measure scoring (particularly if the methodology proposed in section IV.A.4.f.(1)(d)(ii)(B) of this proposed rule is finalized), and ensuring that we do not inadvertently disadvantage certain clinician types, such as small practices and solo practitioners, as we increase the performance threshold.

As shown in Table 72, we calculated the mean values for the CY 2017 performance period/2019 MIPS payment year through the CY 2022 performance period/2024 MIPS payment year, and we believe that the mean of 75 points from the CY 2017 performance period/CY 2019 MIPS payment year continues to be the most appropriate option that would provide stability for MIPS eligible clinicians while still encouraging high quality of care. The final scores for the CY 2023 performance period/2025 MIPS payment year were not finalized in time for this proposed rule and, therefore, the mean final score for the CY 2023 performance period/2025 MIPS payment year was not included for consideration as a potential performance threshold value for the CY 2025 performance period/2027 MIPS payment year.

Though we did consider the mean of 87 points from the CY 2018 performance period/2020 MIPS payment year, we believe a substantial increase of 12 points could unfairly impact clinicians as they continue to recover from the COVID–19 public health emergency (PHE), which ended on May 11, 2023. We also considered using the means of the final scores from the CY 2019 performance period/2021 MIPS payment year through the CY 2022 performance period/2024 MIPS payment year for establishing the CY 2025 performance period/2027 MIPS payment year performance threshold. However, we decided they would not be appropriate for measuring future clinician performance given the impact of the COVID–19 PHE on data for MIPS, as described below.

Given issues with underlying data in prior periods due to the COVID–19 pandemic, we believe that we should wait for more recent data that better reflects clinicians' performance and continue to rely on data from the CY 2017 performance period/2019 MIPS payment year, which predated the COVID–19 PHE. Due to the timing of the COVID–19 PHE and our announcement on March 22, 2020, extending the deadline for MIPS data submission,[780] we are still evaluating the usability of data from the CY 2019 performance period/2021 MIPS payment year. While data collection occurred during the CY 2019 performance period prior to the start of the COVID–19 PHE, data submission for the CY 2019 performance period (occurring during the first quarter of CY 2020) was impacted. Specifically, in addition to extending the deadline for submitting MIPS data, we announced on April 6, 2020, that, due to the COVID–19 PHE, we would apply our extreme and uncontrollable circumstances reweighting policies described under § 414.1380(c)(2)(i) to MIPS eligible clinicians nationwide and extend the deadline to submit an application for reweighting the quality, cost, improvement activities or Promoting Interoperability reporting categories for the CY 2019 performance period/2021 MIPS payment year (85 FR 19277 and 19278). These flexibilities for the submission of MIPS data occurring in the first quarter of CY 2020 were intended to alleviate reporting burden on clinicians that were responding to the onset of the COVID–19 pandemic. We believe the geographic differences of COVID–19 incidence rates along with different impacts resulting from Federal, state, and local laws and policy changes implemented in response to COVID–19 may have affected which MIPS eligible clinicians were able to submit data for the CY 2019 performance period. This may have led to final scores that were not wholly representative of performance for all MIPS eligible clinicians. Also, for the CY 2020 performance period/2022 MIPS payment year and the CY 2021 performance period/2023 MIPS payment year, we extensively applied our reweighting policies, described under § 414.1380(c)(2)(i), to MIPS eligible clinicians nationwide due to the COVID–19 PHE. We believe these actions, particularly reweighting the performance categories, skewed the final scores from those years such that they are not an appropriate indicator for future performance of MIPS eligible clinicians. Specifically, we are concerned that the final scores during the COVID–19 PHE reflect the performance of only MIPS eligible clinicians that may have been less impacted by the pandemic, and do not accurately represent MIPS eligible clinician performance overall during this period.

As discussed further in section IV.A.4.f.(1)(d)(ii) of this proposed rule, MIPS eligible clinicians have expressed concern that the cost performance category scoring has a negative impact on their MIPS final score. The CY 2022 performance period/2024 MIPS payment year was the first MIPS payment year that the cost performance category score generally constituted 30 percent of MIPS eligible clinicians' final scores (section 1848(q)(5)(E)(i)(II) of the Act). We have observed lower category scores for the cost performance category as compared to the quality performance category. In light of these concerns, which are supported by our analysis of cost performance category scores as discussed in section IV.A.4.f.(1)(d)(ii) of this proposed rule, we believe that maintaining a performance threshold of 75 points for the CY 2025 performance period/2027 MIPS payment year would provide stability for MIPS eligible

[780] *https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting.*

clinicians as they become acquainted with the cost performance category (particularly if the scoring methodology proposed in section IV.A.4.f.(1)(d)(ii)(B) of this proposed rule is finalized) without unfairly and negatively impacting their final scores and MIPS payment adjustments. We also believe maintaining the performance threshold at 75 points for the 2027 MIPS payment year would provide us time to incorporate the impacts of this proposed cost performance category scoring methodology (if finalized) as we establish future performance thresholds.

As discussed in section IV.A.4.f.(1)(d)(ii) of this proposed rule, we believe multiple factors have likely contributed to MIPS eligible clinicians' concerns, including increases in the weight for the cost performance category over time (see section 1848(q)(5)(E)(i)(II) of the Act), the number of cost measures, and the number of MIPS eligible clinicians that are being attributed new cost measures and receiving a score for the cost performance category. This increase in weight for the cost performance category over time has been particularly notable because, as discussed previously, due to the application of our reweighting policies described under § 414.1380(c)(2)(i) for the COVID–19 PHE, many MIPS eligible clinicians were not scored on the cost performance category for the CY 2019 performance period/2021 MIPS payment year through the CY 2021 performance period/2023 MIPS payment year (85 FR 19277 through 19278).[781] [782] We believe that our proposal to maintain a performance threshold of 75 points for the CY 2025 performance period/2027 MIPS payment year may help alleviate some of MIPS eligible clinicians' concerns related to the cost performance category and its impact on their MIPS final score.

We are also concerned that any increase in the performance threshold may inadvertently and unfairly disadvantage certain clinician types, specifically small practices and solo practitioners. As we stated in the CY 2024 PFS final rule, we want to consider the impacts of the performance threshold and its related policies on small practices (88 FR 79377). We have received feedback that many small practices and solo practitioners face challenges in their ability to participate in MIPS, including the costs to implement and maintain certified electronic health record (EHR) technology (CEHRT), staff and training costs, and limited staff capacity to manage the complexity of the program. We have also heard that increases in the performance threshold add administrative and financial burden for small practices that discourage their participation in MIPS. Though we have several policies within MIPS that continue to support small and solo practices, including scoring and reweighting policies, we are interested in understanding how to best support small practices and enhance their ability to successfully participate in MIPS as MIPS continues to evolve. As such, we have performed qualitative analysis through engagement with small practices, third party intermediaries, and other interested parties to gather information about the experience of small practices participating in the program. We are also planning to reach out to small practices and solo practitioners in CY 2024 to gather additional information about barriers for actively engaging with MIPS. On this basis, we believe establishing a performance threshold of 75 points for the CY 2025 performance period/2027 MIPS payment year would allow us time to gather additional data on the impacts of new policies on small and rural practices, and to develop strategies to reduce barriers for small practices and solo practitioners participating in MIPS.

We refer readers to the Regulatory Impact Analysis in section VII.E.17.d.(4) of this proposed rule for an estimate of the percent of MIPS eligible clinicians that would receive a negative payment adjustment for the CY 2025 performance period/2027 MIPS payment year if the policies proposed in this proposed rule are finalized and the performance threshold is established at 75 points.

As discussed in this section IV.A.4.g.(2)(c), we believe that maintaining a performance threshold of 75 points allows additional time for more data to become available, continues to provide opportunities for clinicians to become familiar with the cost measure scoring, and ensures that we do not inadvertently disadvantage certain clinician types, such as small practices and solo practitioners. Therefore, we are proposing to establish a performance threshold of 75 points for the CY 2025 performance period/2027 MIPS payment year based on the mean of MIPS eligible clinicians' final scores from the CY 2017 performance period/2019 MIPS payment year, and to codify this performance threshold in our regulation by adding paragraphs at § 414.1405(b)(10) introductory text and (b)(10)(i).

We request public comments on this proposal.

(3) Example of Adjustment Factors

Figure 4 provides an illustrative example of how various final scores would be converted to a MIPS payment adjustment factor using the statutory formula and based on our proposed policies for the CY 2025 performance period/2027 MIPS payment year. In Figure 4, the performance threshold is set at 75 points, as we have proposed in section IV.A.4.g.(2)(c) of this proposed rule.

For purposes of determining the maximum and minimum range of potential MIPS payment adjustment factors, section 1848(q)(6)(B) of the Act defines the applicable percentage as 9 percent for the CY 2025 performance period/2027 MIPS payment year. The MIPS payment adjustment factor is determined on a linear sliding scale from zero to 100, with zero being the lowest possible score which receives the negative applicable percentage and resulting in the lowest payment adjustment, and 100 being the highest possible score which receives the highest positive applicable percentage and resulting in the highest payment adjustment.

However, there are two modifications to this linear sliding scale. First, as specified in section 1848(q)(6)(A)(iv)(II) of the Act, there is an exception for a final score between zero and one-fourth of the performance threshold (zero and 18.75 points based on the proposed performance threshold of 75 points for the CY 2025 performance period/2027 MIPS payment year). All MIPS eligible clinicians with a final score in this range will receive a negative MIPS payment adjustment factor equal to 9 percent (the applicable percentage). Second, the linear sliding scale for the positive MIPS payment adjustment factor is adjusted by the scaling factor, which cannot be higher than 3.0, as required by section 1848(q)(6)(F)(i) of the Act.

If the scaling factor is greater than zero and less than or equal to 1.0, then the MIPS payment adjustment factor for a final score of 100 will be less than or equal to 9 percent (the applicable percentage). If the scaling factor is above 1.0 but is less than or equal to 3.0, then the MIPS payment adjustment factor for a final score of 100 will be greater than 9 percent. Only those MIPS eligible clinicians with a final score equal to 75 points (the performance threshold

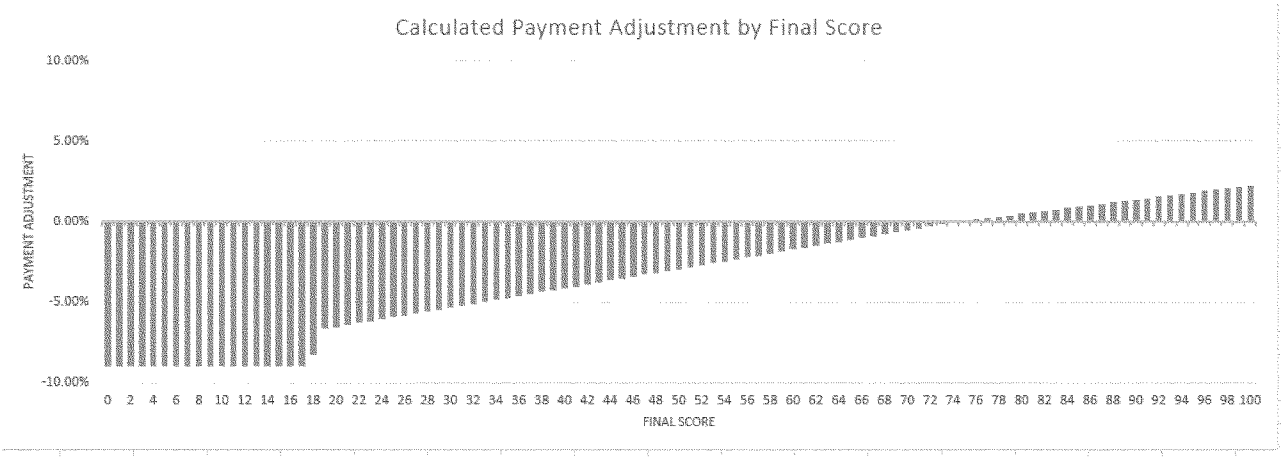
[781] *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1198/2020%20MIPS%20Automatic%20EUC%20Fact%20Sheet.pdf.*

[782] *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1437/2021%20MIPS%20Automatic%20EUC%20Fact%20Sheet.pdf.*

proposed for the CY 2025 performance period/2027 MIPS payment year) will receive a neutral MIPS payment adjustment.

Beginning with the CY 2023 performance period/2025 MIPS payment year, the additional MIPS payment adjustment for exceptional performance described in section 1848(q)(6)(C) of the Act is no longer available. For this reason, Figure 4 does not illustrate an additional adjustment factor for MIPS eligible clinicians with final scores at or above the additional performance threshold described in section 1848(q)(6)(D)(ii) of the Act.

FIGURE 4: Illustrative Example of MIPS Payment Adjustment Factors Based on Final Scores and Performance Threshold for the CY 2025 performance period/2027 MIPS Payment Year



Note: The adjustment factor for final score values above the performance threshold is illustrative. For MIPS eligible clinicians with a final score of 100, the adjustment factor will be 9 percent times a scaling factor greater than zero and less than or equal to 3.0. The scaling factor is intended to ensure budget neutrality (BN) but cannot be higher than 3.0. This example is illustrative as the actual payment adjustments may vary based on the distribution of final scores for MIPS eligible clinicians.

Table 73 illustrates the changes in payment adjustment based on the final policies from the CY 2024 PFS final rule (88 FR 52599 through 56001) for the CY 2024 performance period/2026 MIPS payment year and the proposed policies for the CY 2025 performance period/2027 MIPS payment year, as well as the applicable percent required by section 1848(q)(6)(B) of the Act.

TABLE 73: Illustration of Point System and Associated Adjustments Comparison between the CY 2024 Performance Period/2026 MIPS Payment Year and the CY 2025 Performance Period/2027 MIPS Payment Year

2024 Performance Period Final Score Points	MIPS Adjustment for 2024 Performance Period	2025 Performance Period Final Score Points	MIPS Adjustment for 2025 Performance Period
0.0-18.75	Negative 9%	0.0-18.75	Negative 9%
18.76-74.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale	18.76-74.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale
75.00	0% adjustment	75.00	0% adjustment
75.01-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from greater than 0% to 9% for scores from 75.01 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.	75.01-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from greater than 0% to 9% for scores from 75.01 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.

h. Review and Correction of MIPS Final Score—Feedback and Information To Improve Performance

Under section 1848(q)(12)(A)(i) of the Act, we are required to provide MIPS eligible clinicians with timely (such as quarterly) confidential feedback on their performance under the quality and cost performance categories beginning July 1, 2017, and we have discretion to provide such feedback regarding the improvement activities and Promoting Interoperability performance categories. In the CY 2018 Quality Payment Program final rule (82 FR 53799 through 53801), we finalized that on an annual basis, beginning July 1, 2018, performance feedback will be provided to MIPS eligible clinicians and groups for the quality and cost performance categories, and if technically feasible, for the improvement activities and advancing care information (now called the Promoting Interoperability) performance categories.

We made performance feedback available for the CY 2019 performance period/2021 MIPS payment year on August 5, 2020; for the CY 2020 performance period/2022 MIPS payment year on August 2 and September 27, 2021; for the CY 2021 performance period/2023 MIPS payment year on August 22, 2022; and for the CY 2022 performance period/2024 MIPS payment year on August 10, 2023. Although we aim to provide feedback for the CY 2023 performance period/2025 MIPS payment year on or around July 1, 2024, it is possible the release date could be later depending on circumstances. We direct readers to *qpp.cms.gov* for more information.

i. Calculating the Final Score

For a description of the statutory basis and our previously finalized policies for calculating the final score for each MIPS eligible clinician, including performance category weights and reweighting the performance categories, we refer readers to § 414.1380(c) and the discussion in the CY 2017 and CY 2018 Quality Payment Program final rules, and the CY 2019, CY 2020, CY 2021, CY 2022 and CY 2023 PFS final rules (81 FR 77319 through 77329, 82 FR 53769 through 53785, 83 FR 59868 through 59878, 84 FR 63020 through 63031, 85 FR 84908 through 84917, 86 FR 65509 through 65527, and 87 FR 70093 through 70096, respectively).

As described in more detail in the following sections, we propose to supplement our current policies for reweighting one or more performance categories (that is, quality, improvement activities, and Promoting Interoperability) to permit reweighting in circumstances where we determine that data for a MIPS eligible clinician are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because the MIPS eligible clinician delegated submission of the data to their third party intermediary, evidenced by a written agreement between the MIPS eligible clinician and third party intermediary, and the third party intermediary did not submit the data for the performance category(ies) on behalf of the MIPS eligible clinician in accordance with applicable deadlines.

We note that we are only proposing that this reweighting policy be available for the quality, improvement activities, and Promoting Interoperability performance categories because a MIPS eligible clinician may delegate data submission to a third party intermediary only with respect to these three performance categories, and not the cost performance category. MIPS eligible clinicians do not submit data separately for measures for the cost performance category; we score cost measures based solely on Medicare claims data.

(1) Background

Section 1848(q)(5)(A) of the Act requires the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician according to the performance standards for the applicable measures and activities for each performance category applicable to such clinician for a performance period and, using the methodology, provide for a final score (using a scoring scale of 0 to 100) for each MIPS eligible clinician for the performance period.

Additionally, section 1848(q)(5)(E) of the Act specifies how we must weigh the scores for each performance category in our calculation of the MIPS eligible clinician's final score. We have codified these weights at § 414.1380(c)(1). Meanwhile, section 1848(q)(5)(F) of the Act provides that, if there are not sufficient measures and activities applicable and available to each type of

MIPS eligible clinician involved, the Secretary shall assign different scoring weights (including a weight of 0). We previously finalized at § 414.1380(c) that if a MIPS eligible clinician is scored on fewer than two performance categories, they will receive a final score equal to the performance threshold (81 FR 77326 through 77328 and 82 FR 53778 through 53779).

We also have finalized at § 414.1380(c)(2) several policies addressing on what basis we may reweight one or more performance categories, and how those weights will be redistributed to the remaining performance categories. For example, in the CY 2020 PFS final rule (84 FR 63023 through 63026), we finalized a reweighting policy at § 414.1380(c)(2)(i)(A)(*9*) and (c)(2)(i)(C)(*10*) for the four MIPS performance categories. Under this policy, we may reweight one or more of the performance categories for a MIPS eligible clinician if we determine, based on information known to us prior to the beginning of the relevant MIPS payment year, that data for a MIPS eligible clinician for the applicable performance category(ies) are inaccurate, unusable, or otherwise compromised due to circumstances outside of the control of the clinician and its agents. Under this policy, we are able to address circumstances where submitted data are inaccurate, unusable, or otherwise compromised.

However, we have found this policy, and our other reweighting policies at § 414.1380(c)(2), do not address circumstances where data are inaccessible or unable to be submitted due to circumstances outside of the control of the MIPS eligible clinician, particularly where the clinician has delegated submission of the data to a third party intermediary and that third party intermediary does not submit the data in accordance with applicable deadlines. In accordance with our regulations governing third party intermediaries at § 414.1400(a)(3)(iv) and (e)(1), we may take remedial action in the event a third party intermediary fails to meet the criteria necessary for their approval as a third party intermediary, fails to comply with other requirements applicable to third party intermediaries, has submitted a false certification, or discontinues their services and do not assist MIPS eligible clinicians in connecting with a different third party intermediary. However, our regulations do not address the impact of a third party intermediary's action or inaction resulting in failure to submit the MIPS eligible clinician's data as required, over which the MIPS eligible clinician has little to no control, on a MIPS eligible clinician's final score.

Currently, if we determine that data for a MIPS eligible clinician were not submitted during the MIPS data submission period for reasons outside the clinician's control, we assign the clinician a score of zero for the performance category or categories for which data were not submitted.[783] Because an excusable failure to submit data is not currently a basis for reweighting, the lack of data may reduce the MIPS eligible clinician's final score and therefore may reduce the clinician's MIPS payment adjustment. However, we believe that reweighting of the applicable performance categories may be appropriate in these rare cases as described in this section IV.A.4.i. of this proposed rule.

Specifically, we believe that a MIPS eligible clinician should not be penalized in cases where the MIPS eligible clinician enters into an agreement with a third party intermediary to submit data on their behalf, and the data are not submitted due to reasons outside of the control of the MIPS eligible clinician. While we encourage the impacted MIPS eligible clinician to take steps to ensure data submission for subsequent years, by, for example, selecting an alternate third party intermediary, there may be cases where there is insufficient time for the MIPS eligible clinician to submit the data through an alternative mechanism in time for the data to be considered for the relevant performance period. For instance, the MIPS eligible clinician may become aware that their third party intermediary did not submit data on their behalf after the data submission period closes. In these cases, we believe it is appropriate to provide relief to the MIPS eligible clinician so that they are not unfairly penalized for their third party intermediary's inaction.

(2) Proposal To Adopt Reweighting Performance Category(ies) Policy When a Third Party Intermediary Did Not Submit Data Due to Reasons Outside the MIPS Eligible Clinician's Control

We are proposing to adopt a new reweighting policy at § 414.1380(c)(2)(i)(A)(*10*) and (c)(2)(i)(C)(*12*) to address this circumstance. Specifically, beginning with the CY 2024 performance period/2026 MIPS payment year, we are proposing that we may reweight one or more of the quality, improvement activities, and Promoting Interoperability performance categories where we determine, based on documentation submitted to us through a reweighting request on or before November 1st of the year preceding the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because the MIPS eligible clinician delegated submission of their data to a third party intermediary, evidenced by a written agreement between the MIPS eligible clinician and the third party intermediary, and the third party intermediary did not submit the data for the performance category(ies) on behalf of the MIPS eligible clinician in accordance with applicable deadlines. We also are proposing that, to determine whether to apply reweighting to the affected performance category(ies), we will consider: whether the MIPS eligible clinician knew or had reason to know of the issue with its third party intermediary's submission of the clinician's data for the performance category(ies); whether the MIPS eligible clinician took reasonable efforts to correct the issue; and whether the issue between the MIPS eligible clinician and their third party intermediary caused no data to be submitted for the performance category(ies) in accordance with applicable deadlines. We believe these factors are necessary to ensure we are only granting these requests in circumstances where MIPS eligible clinicians would otherwise be unfairly penalized due to the actions or inactions of a third party intermediary. MIPS eligible clinicians could request reweighting under this proposed policy in circumstances where no data was submitted on their behalf by their third party intermediary through the help desk at *QPP@cms.hhs.gov*.

Under this proposed policy, MIPS eligible clinicians would be able to request reweighting for each performance category for which their third party intermediary, to which the MIPS eligible clinician delegated submission of their data, did not submit data for reasons outside of the control of the MIPS eligible clinician. We note that we are only proposing that this reweighting policy be available for the quality, improvement activities, and Promoting Interoperability performance categories because a MIPS eligible

[783] As set forth in § 414.1325(a), data is only required to be submitted for certain measures and activities as specified for certain performance categories. For example, MIPS eligible clinicians are not required to submit data for the cost performance category to receive a score for that category because cost measures are scored based on Medicare claims data. We refer readers to our data submission requirements at § 414.1325 and our proposal to modify these requirements in section IV.A.4.d. of this proposed rule.

clinician may delegate data submission to a third party intermediary only with respect to these three performance categories, and not the cost performance category. MIPS eligible clinicians do not submit data separately for measures for the cost performance category; we score cost measures based solely on Medicare claims data.

Under this proposed reweighting policy, the MIPS eligible clinician must submit reweighting requests beginning with the close of a relevant performance period's data submission period, only after it is confirmed that no data has been submitted in accordance with applicable deadlines. MIPS eligible clinicians would be able to submit reweighting requests on or before November 1st of the year preceding the associated MIPS payment year in order to allow time for CMS to re-calculate their final score and MIPS payment adjustment factor.

We would only approve reweighting requests with evidence of a written agreement between the MIPS eligible clinician and a third party intermediary. Such written agreement must provide that the MIPS eligible clinician delegated submission of their data to the third party intermediary, and that the third party intermediary agreed to submit data on their behalf in accordance with applicable deadlines, for the performance category or performance categories in question.

We would review requests and make determinations to reweight based on our assessment that data were not submitted outside the control of the MIPS eligible clinician. As discussed in this section of this proposed rule, we are proposing that we would determine whether to apply reweighting to the affected performance category(ies) under this policy based on our consideration of the following criteria: whether the MIPS eligible clinician knew or had reason to know of the issue with its third party intermediary's submission of the clinician's data for the performance category(ies); whether the MIPS eligible clinician took reasonable efforts to correct the issue; and whether the issue between the MIPS eligible clinician and their third party intermediary caused no data to be submitted for the performance category(ies) in accordance with applicable deadlines. These criteria would inform whether we would grant reweighting requests under our proposed policy at § 414.1380(c)(2)(i)(A)(*10*) and (c)(2)(i)(C)(*12*). Circumstances resulting in a clinician's data being inaccessible or unable to be submitted that would merit reweighting could include, but are not limited to, a critical systems failure, the third party intermediary going out of business, the third party intermediary having collected data on a MIPS eligible clinicians behalf and refusing to hand it over for the MIPS eligible clinician to submit, or other circumstances CMS determines to be outside the control of the MIPS eligible clinician.

This proposed reweighting policy is solely intended to mitigate the potentially adverse financial impact of no data being submitted during the MIPS data submission period for one or more performance categories on behalf of the MIPS eligible clinician due to the failure of a third party intermediary to fulfill its contractual responsibilities. Our determination to grant a reweighting request under this proposed policy does not indicate, and should not be interpreted to suggest, that the third party intermediary could not be held liable for the failure to perform the task as delegated, that is, to submit data on the performance category(ies) on behalf of the MIPS eligible clinician. In these circumstances where we determine that a third party intermediary failed to fulfill its agreement with the MIPS eligible clinician to submit their data, we believe it is appropriate to give the MIPS eligible clinician the opportunity to request reweighting of the affected performance category(ies), provided that all elements of our proposed policy are met.

We propose to apply reweighting only in cases when we receive documentation of a third party intermediary failing to submit data on behalf of a MIPS eligible clinician demonstrating that all elements of our proposed policy are met.

We propose that this policy would be effective beginning with CY 2024 performance period/2026 MIPS payment year. If finalized, this policy change would become effective prospectively, prior to the beginning of the data submission period for the CY 2024 performance period/2026 MIPS payment year, which will occur January 2, 2025, through March 31, 2025. We are proposing this effective date to provide relief to MIPS eligible clinicians, whose circumstances meet all requirements set forth in this proposed reweighting policy, as soon as feasible.

We propose to codify this new reweighting policy, including all proposed elements as described in section IV.A.4.i.(2) of this proposed rule, at § 414.1380(c)(2)(i)(A)(*10*) for the quality and improvement activities performance categories and at § 414.1380(c)(2)(i)(C)(*12*) for the Promoting Interoperability performance category.

We request public comments on this proposal.

j. Third Party Intermediaries General Requirements

(1) Requirements for CMS-Approved Survey Vendors

(a) Background

As codified at § 414.1305, a CMS-approved survey vendor means a survey vendor that is approved by CMS for a particular performance period to administer the Consumer Assessment of Healthcare Providers & Systems (CAHPS) for MIPS survey and to transmit survey measures data to CMS.

We refer readers to § 414.1400(d), the CY 2017 Quality Payment Program final rule (81 FR 77386), the CY 2018 Quality Payment Program final rule (82 FR 53818 and 53819), the CY 2019 PFS final rule (83 FR 59907 and 59908), and the CY 2022 PFS final rule (86 FR 65538 and 65539) for previously finalized standards and criteria for CMS-approved survey vendors.

(b) Requirement To Submit Cost of Services

In the CY 2017 Quality Payment Program final rule (81 FR 77386 and 77387), we established that CMS-approved survey vendors may transmit data collected from the CAHPS for MIPS survey to CMS for use in MIPS. Section 414.1400(d)(2) requires that CMS-approved survey vendors submit a survey vendor application to CMS in a form and manner specified by CMS for each MIPS performance period for which it wishes to transmit such data. We implemented this requirement through the Vendor Participation Form, which is available at *https://qpp.cms.gov/resources/resource-library*.

The CY 2017 Quality Payment Program final rule contained requirements applicable to other types of third party intermediaries, which varied based on whether the third party intermediary was a Qualified Clinical Data Registry (QCDR) or qualified registry. For example, we established requirements for QCDRs and qualified registries to ''sign a document verifying the QCDR's name, contact information, cost for MIPS eligible clinicians or groups to use the QCDR or qualified registry'' (81 FR 77368 and 77369; 81 FR 77385 and 77386). If QCDRs and qualified registries do not provide this information, CMS may exclude them from MIPS in a subsequent year. This requirement helps eligible clinicians determine which vendors to use prior to registration and provides transparency on the cost of program participation. Currently, CMS-approved survey

vendors are not required to provide cost information even though other third party intermediaries (QCDRs and qualified registries) are required to do so.

We are proposing under the current application submission requirement at § 414.1400(d)(2) that beginning with the CY 2026 performance period/2028 MIPS payment year, a survey vendor must include on its application the range of costs of its third party intermediary services. Ranges of cost estimates would vary based on different levels of service (*i.e.,* number of survey respondents, languages provided, etc.). With respect to a third party intermediary that is solely a CMS-approved survey vendor, the publishable costs would be limited to the cost of services related to the CAHPS for MIPS survey. CMS has received inquiries from MIPS participants regarding survey vendor costs but has not been able to provide any specific information in response to those requests. The cost information from survey vendors is not easily available to the MIPS eligible clinicians who are considering contracting for services. Having such information in the publicly-accessible QPP Resource Library (as part of the list of approved vendors) would make it easier for MIPS eligible clinicians to contract for services and educate themselves about the cost of using a third party intermediary survey vendor. In recent years, some participants who registered for the CAHPS for MIPS survey later withdrew their participation once they learned the costs of survey administration. Providing information on the cost of CMS-approved CAHPS for MIPS survey vendor services may support MIPS participants who are interested in the CAHPS for MIPS Survey but want to know what the costs of administering the survey would be, thus allowing them to make more informed decisions about whether to participate in the CAHPS for MIPS survey. This would also increase the consistency in requirements across different types of third party intermediaries.

If this proposal is finalized, the CAHPS for MIPS Survey Vendor Participation Form [784] and the CAHPS for MIPS Survey Minimum Business Requirements [785] in the QPP Resource Library would be updated to detail the required survey vendor cost estimate information. The CAHPS for MIPS Survey Vendor Participation Form submitted by vendors seeking CMS approval would be updated to include fields to report the cost information. The vendor-specific cost information would then be published in the list of CAHPS for MIPS Survey Approved Vendors which is also posted in the Resource Library. We refer readers to section V.B.8.c.(5) of this proposed rule for discussion on the burden estimates for this proposal.

We request comment on this proposal.

k. Overview of QP Determinations and the APM Incentive

(1) Overview

The Quality Payment Program provides incentives for eligible clinicians to engage in value-based, patient-centered care under Medicare Part B via MIPS and Advanced APMs. The structure of the Quality Payment Program enables the Department to advance accountability and encourage improvements in care. The Secretary has also adopted the closely related goal that all people with Original Medicare be in an accountable care relationship by 2030, so that their needs can be holistically assessed, and their care is coordinated within a broader total cost of care system. Our vision for increased participation among clinicians in Advanced APMs is driven by the belief that integrating individuals' clinical needs across a spectrum of clinicians and settings will improve patient care and population health.

As we continue to make improvements to the Quality Payment Program, we seek to develop, propose, and implement policies that encourage broad and meaningful clinician participation, including by specialists, in Advanced APMs.

In the CY 2017 Quality Payment Program final rule (81 FR 77450 through 77457), we finalized the payment amount method and patient count method for calculation of Threshold Scores used for QP determinations under the Medicare option and codified these methods at § 414.1435(a) and (b), respectively. The payment amount method is based on payments for Medicare Part B covered professional services, including certain supplemental service payments, while the patient count method is based on numbers of patients. Both methods use the ratio of ''Attributed beneficiaries'' to ''Attribution-eligible beneficiaries'', as defined at § 415.1305.

An attributed beneficiary is a beneficiary attributed to the APM Entity under the terms of the Advanced APM as indicated on the most recent available list of attributed beneficiaries at the time of a QP determination. An attribution-eligible beneficiary is a beneficiary who:

- Is not enrolled in Medicare Advantage or a Medicare cost plan;
- Does not have Medicare as a secondary payer;
- Is enrolled in both Medicare Parts A and B;
- Is at least 18 years of age;
- Is a United States resident; and
- Has a minimum of:

++ One claim for E/M services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period.

++ Or, for an Advanced APM that does not base attribution on E/M services and for which attributed beneficiaries are not a subset of the attribution-eligible beneficiary population based on the requirement to have at least one claim for E/M services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period, the attribution basis determined by CMS based upon the methodology the Advanced APM uses for attribution, which may include a combination of E/M and/or other services.

In this section, we propose to modify the definition of ''attribution-eligible beneficiary'' to include any beneficiary who has received a covered professional service (section 1833(z)(3)(A) of the Act; 42 CFR 414.1305; section 1848(k)(3)(A) of the Act) furnished by the eligible clinician (NPI) for whom we are making the QP determination. By no longer specifying evaluation and management (E/M) services as the default attribution basis, we also would eliminate the need to develop customized attribution bases for Advanced APMs that do not use E/M services as the basis for attribution. Therefore, our proposal would standardize the attribution methodology for QP determinations by making covered professional services the basis for attribution across all Advanced APMs.

(2) Payment Amount and Patient Count Methods

The payment amount method for calculating threshold scores is based on payments for Medicare Part B covered professional services, including certain supplemental service payments, while the patient count method is based on numbers of patients. Both methods use the ratio of ''attributed beneficiaries'' to

[784] 2024 CAHPS for MIPS Survey Vendor Participation Form, March 25, 2024. *https://qpp.cms.gov/resources/document/6386fe4b-49b9-42c8-9a2b-a1149f7b142a.*

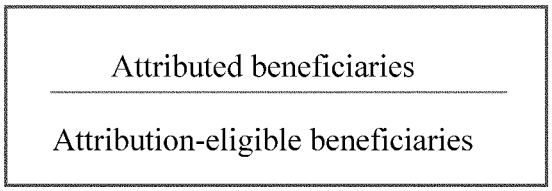
[785] 2024 CAHPS for MIPS Survey Vendor Minimum Business Requirements, March 11, 2024. *https://qpp.cms.gov/resources/document/02e6e596-51de-4336-a6a6-ab63fc639dbc.*

''attribution-eligible beneficiaries,'' as defined at § 415.1305.[786]

Attributed beneficiaries are those who are attributed to the APM Entity (or individual eligible clinician) under the terms of the Advanced APM as indicated on the most recent available list of attributed beneficiaries at the time of a QP determination. Attribution-eligible beneficiaries generally are those who, during the QP Performance Period, meet six criteria (listed below) specified in the definition of that term at § 414.1305 and described in section IV.A.4.m.(3) of this proposed rule.

When making QP determinations, we begin by calculating Threshold Scores using the payment amount and patient count methodologies. These Threshold Scores are percentages based on the ratio of the payment amounts or patient counts for attributed beneficiaries to the payment amounts or patient counts for attribution-eligible beneficiaries during the QP performance period. If the Threshold Score (using either the payment amount or patient count method) calculated at the APM Entity or individual eligible clinician level, as applicable, meets or exceeds the relevant QP threshold described at § 414.1430(a), the relevant eligible clinician or clinicians (either the individual eligible clinician or all those on the APM Entity's Participation List) achieve QP status for such year.

FIGURE 5: QP Determination Calculation



Our regulation at § 414.1435(b)(3) provides that a beneficiary may be counted only once in the numerator and denominator for a single APM Entity group, and at § 414.1435(b)(4) provides that a beneficiary may be counted multiple times in the numerator and denominator for multiple different APM Entity groups. In the CY 2021 PFS final rule (85 FR 84951 through 84952), we amended § 414.1435(c)(1)(i) to specify that beneficiaries who have been prospectively attributed to an APM Entity for a QP Performance Period will be excluded from the attribution-eligible beneficiary count for any other APM Entity that is participating in an APM where that beneficiary would be ineligible to be added to the APM Entity's attributed beneficiary list. This means that beneficiaries who have been attributed to one APM Entity and are thus barred under the terms of an Advanced APM from attribution to another APM Entity are removed from the denominator of both the payment amount method and patient count method in QP Threshold Score calculations for the APM Entity to which they cannot be attributed. In other words, we do not penalize an APM Entity in the QP Threshold Score calculation by including a beneficiary in its denominator when the terms of an Advanced APM do not permit such beneficiary to be attributed to such APM Entity.

(a) Attributed Beneficiary

An attributed beneficiary is a beneficiary attributed to the APM Entity under the terms of the Advanced APM as indicated on the most recent available list of attributed beneficiaries at the time of a QP determination. There may be beneficiaries on the most recent available list who do not meet the criteria to be attribution-eligible beneficiaries because the QP performance period does not align with the Advanced APM's performance period or attribution period, or for other reasons. There may also be cases where a beneficiary's status changes, for example by enrolling in a Medicare Advantage Plan. We exclude these beneficiaries from our Threshold Score calculations because they do not meet criteria to be attribution-eligible beneficiaries. Although APMs may have reconciliation processes in place to address changes in beneficiary status at various intervals, those processes do not necessarily coincide with the timeframe of QP determinations. Therefore, when calculating Threshold Scores for QP determinations, we exclude from the list of attributed beneficiaries any beneficiaries who do not meet the criteria to be attribution-eligible beneficiaries at that point in time.

(b) Attribution-Eligible Beneficiary

Under our regulation at § 414.1305, we define an attribution-eligible beneficiary as a beneficiary who:

- Is not enrolled in Medicare Advantage or a Medicare cost plan;
- Does not have Medicare as a secondary payer;
- Is enrolled in both Medicare Parts A and B;
- Is at least 18 years of age;
- Is a United States resident; and
- Has a minimum of one claim for E/M services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period or, for an Advanced APM that does not base attribution on E/M services and for which attributed beneficiaries are not a subset of the attribution-eligible beneficiary population based on the requirement to have at least one claim for E/M services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period, the attribution basis determined by CMS based upon the methodology the Advanced APM uses for attribution, which may include a combination of E/M and/or other services.

Our stated intent when we finalized the definition of attribution-eligible beneficiary (81 FR 77451 through 77452) was to have a definition that would, for purposes of QP determinations, allow us to be consistent across Advanced APMs in how we consider the population of beneficiaries served by an APM Entity. The criteria we used to define attribution-eligible beneficiary were aligned with the attribution

[786] For technical information on the QP calculation methodology, see the ''QP Methodology Fact Sheet'' that we publish annually, which can be found as part of the ''2024 Learning Resources for QP Status and APM Incentive Payment'' materials on the Quality Payment Program Resource Library at *qpp.cms.com*.

methodologies and rules for our then-contemporaneous Advanced APMs. The first five criteria are conditions that are required for a beneficiary to be attributed to any Advanced APM. The sixth criterion identifies beneficiaries who have received certain services from an eligible clinician who is associated with an APM Entity for any period during the QP Performance Period. We chose to refer to E/M services as the primary basis for purposes of attribution-eligibility because many Advanced APMs use E/M claims to attribute beneficiaries to their APM Entity groups. Over time, we have updated the list of services that are considered to be E/M services for purposes of identifying attribution-eligible beneficiaries and have published this list as part of the ''2024 Learning Resources for QP Status and APM Incentive Payment'' materials on the Quality Payment Program Resource Library at *qpp.cms.gov.*

We also included an exception in this sixth criterion to allow us to use an alternative approach for Advanced APMs that do not base attribution on E/M services, and thus for which attributed beneficiaries are not a subset of the attribution-eligible beneficiary population based on the requirement to have at least one claim for an E/M service. To date, we have implemented this alternative approach for four Advanced APMs:

- Bundled Payments for Care Improvement Advanced Model.
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track).
- Comprehensive ESRD Care Model (LDO arrangement and Non LDO Two Sided Risk Arrangement).
- Maryland Total Cost of Care Model (Care Redesign Program).

We have published links to the methodologies we use to identify attribution-eligible beneficiaries for these Advanced APMs in the ''2024 Learning Resources for QP Status and APM Incentive Payment'' materials on the Quality Payment Program Resource Library at *qpp.cms.gov*.

We adopted the general rule with flexibility to apply alternative methods for this criterion to ensure that, for the Advanced APMs for which attribution is based on services other than E/M services, the attributed beneficiary population is truly a subset of such Advanced APMs' attribution-eligible beneficiary populations and, ultimately, so that our way of identifying beneficiaries for purposes of Threshold Score calculations for QP determinations would be appropriate for such Advanced APMs. That said, our thinking when we developed these approaches was shaped by the form and nature of the Advanced APMs that existed at that time. We believed that, by affording sufficient flexibility within the program, we could both foster innovation in Advanced APMs and simplify our execution of the program. However, with our more narrowly defined default approach to beneficiary attribution (relying on claims for E/M services), we have increasingly needed to exercise the flexibility to identify an alternative approach to attribution eligibility for Advanced APMs that fell into the exception, which meant that we identified several individually-tailored ways of performing the attribution methodology for specific Advanced APMs. We anticipate that Advanced APMs will continue to evolve and use novel approaches to value-based care that may emphasize a broad range of covered professional services, and in that event the application of our current regulations may result in increased variability among the ways we define attribution-eligible when making QP determinations, which frustrates our goal of a consistent approach.

Further, we recognize that primary care practitioners generally furnish a higher proportion of E/M services than do specialists for the same beneficiary. The current reliance on E/M services for attribution in our Threshold Score calculations means that primary care practitioners may contribute more significantly to achieving QP status for an APM Entity group. As such, our current policy may have inadvertently encouraged APM Entities to prefer primary care practitioners over specialists in their Participation Lists.

As discussed in the CY 2024 PFS final rule (88 FR 79400 through 79406), we proposed but did not finalize to revise the definition of ''attribution-eligible beneficiary'' at § 414.1305 to use covered professional services as the basis for attribution for purposes of Threshold Score calculations for all Advanced APMs regardless of the attribution methodology used under the specific Advanced APMs in which the eligible clinician participates. We expressed concern that the current policy to use E/M services as the default basis for attribution, and to use an alternative approach for Advanced APMs that use a different attribution basis, could result in a complex set of unique attribution approaches for various Advanced APMs.

After further consideration and consultation with interested parties, we believe it would be appropriate to create a uniform basis for beneficiary attribution for purposes of Threshold Score calculations across all Advanced APMs. We are once again proposing to modify the sixth criterion of the definition of ''attribution-eligible beneficiary'' at § 414.1305 to include any beneficiary who has received a covered professional service furnished by the eligible clinician (NPI) for whom we are making the QP determination, beginning with the 2025 QP performance period. By no longer specifying a claim for E/M services as the default attribution basis in the sixth criterion, we also would eliminate the need to create unique attribution bases that are tied to a specific Advanced APM's attribution methodology. This would standardize the attribution methodology by basing attribution on covered professional services across all Advanced APMs.

The proposal would address the issue discussed earlier in this section whereby, under our current policy, beneficiary attribution for purposes of QP determinations in the default methodology is contingent upon the beneficiary receiving an E/M service, and as a result, beneficiaries who are actually furnished covered professional services by eligible clinicians on an APM Entity's Participation List are not attribution-eligible for purposes of the QP determination if none of the services are E/M services. Under our proposal, we would consider all covered professional services for purposes of attribution, and not solely the limited range of E/M services currently used for attribution. As a result, we would be able to include as attributed beneficiaries those who are receiving any services within the entire range of covered professional services through the Advanced APM. We believe this proposal would result in a QP calculation that, by including beneficiaries receiving any covered professional service, more accurately reflects eligible clinicians' actual participation in Advanced APMs and would be consistent across all Advanced APMs. Further, we believe that the proposal better aligns the QP determination methodology with the universe of services to which the Quality Payment Program (MIPS and APMs) applies, noting that its provisions generally pertain to covered professional services (for example, its financial incentives for both MIPS eligible clinicians and QPs are applied to covered professional services payments).

We note that the proposal would not change the dates of service used for purposes of QP determinations. As such, QP determinations at any given snapshot date (March 31, June 30, and

August 31, respectively) will be made by including all covered professional services furnished during the QP Performance Period for January 1 through the applicable snapshot date.

We believe that this change would more appropriately recognize the Advanced APM participation of the eligible clinicians for whom these determinations are being made. We further believe that this proposal would simplify and streamline QP determinations and address the challenges to Advanced APM participation reportedly faced by specialists who are less likely than primary care practitioners to provide E/M services. Finally, we believe that the proposal would standardize the approach to QP determinations across all Advanced APMs and conform more closely with the scope of services that are subject to the Quality Payment Program. We also acknowledge that, while this proposal would represent significant progress toward rationalizing attribution for the broader range of Advanced APMs, our continued analysis suggests there may be more work to be done in this area. We believe there still may be situations in which the proposed change in attribution policy would limit QP determinations in certain Advanced APMs, particularly in situations where an Advanced APM is focused on a limited set of services. We recognize the need to provide, consistent with statutory requirements, equitable opportunities to achieve QP status for participants in Advanced APMs that have different focus areas, goals, scopes, and design features. Further, in the case of CMS Innovation Center models, we recognize that there will be ongoing evolution and innovation in the model tests that are Advanced APMs, including the development of new approaches to attribution that apply within the models. We will continue to analyze these developments and issues with the goal to provide for an equitable, rational, transparent, and meaningful methodology for QP determinations across the full range of Advanced APMs.

We seek comment on this proposal to revise the sixth criterion of the definition of ''attribution-eligible beneficiary'' at § 414.1305 to include a beneficiary who has at least one claim for a covered professional service furnished by an eligible clinician who is on the Participation List for the APM Entity (or by the individual eligible clinician, as applicable) at any determination date during the QP Performance Period. We also invite comment more generally on potential approaches we could consider to make QP determinations in the most equitable, rational, transparent, and meaningful way for eligible clinicians across the broad range of Advanced APMs, including Advanced APMs that are focused on a limited set of services.

(3) QP Thresholds and Partial QP Thresholds

Section 1833(z)(2) of the Act specifies the thresholds for the level of participation in Advanced APMs required for an eligible clinician to become a QP for a year. The Medicare Option, based on Part B payments for covered professional services or counts of patients furnished covered professional services under Part B, has been applicable since payment year 2019 (performance period 2017). The All-Payer Combination Option, through which QP status is calculated using the Medicare Option in addition to an eligible clinician's participation in Other Payer Advanced APMs, has been applicable since payment year 2021 (performance period 2019). In the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77439), we finalized our policy for QP and Partial QP Thresholds for the Medicare Option as codified at § 414.1430(a) and for the All-Payer Combination Option at § 414.1430(b).

Section 304(a)(2) of Division G, Title I, Subtitle C, of the Consolidated Appropriations Act, 2024 (CAA, 2024) (Pub. L. 118–42, March 9, 2024) amended section 1833(z)(2) of the Act by extending for payment years 2025 and 2026 (performance periods 2023 and 2024) the applicable payment amount and patient count thresholds for an eligible clinician to achieve QP status. Specifically, section 304(a)(2) of the CAA, 2024, amended section 1833(z)(2) of the Act to continue the QP payment amount thresholds that applied in payment year 2025 (performance period 2023) to payment year 2026 (performance period 2024). Additionally, section 304(a)(2) of the CAA, 2024, amended section 1833(z)(2) of the Act to require that, for payment year 2026, the Secretary use the same percentage criteria for the QP patient count threshold that applied in payment year 2022. As such, the Medicare Option QP thresholds for payment year 2026 will remain at 50 percent for the payment amount method and 35 percent for the patient count method. Section 304(b) of the CAA, 2024, also amended section 1848(q)(1)(C)(iii) of the Act to extend through payment year 2026 the Partial QP thresholds that were established beginning for payment year 2021 under the Medicare Option. Therefore, the Partial QP thresholds for payment year 2026 (performance period 2024) will remain at 40 percent for the payment amount method and 25 percent for the patient count method.

Under the All-Payer Combination Option, the QP thresholds for payment year 2026 (performance period 2025) will remain at 50 percent for the payment amount method and 35 percent for the patient count method. The Partial QP thresholds for payment year 2026 (performance period 2024) will continue at 40 percent for the payment amount method and 25 percent for the patient count method. To become a QP through the All-Payer Combination Option, eligible clinicians must first meet certain minimum threshold percentages under the Medicare Option. For payment year 2026 (performance period 2024), the minimum Medicare Option threshold an eligible clinician must meet for the All-Payer Combination Option to become a QP is 25 percent for the payment amount method or 20 percent for the patient count method. For Partial QP status, the minimum Medicare Option threshold an eligible clinician must meet for the All-Payer Combination Option is 20 percent for the payment amount method or 10 percent for the patient count method.

To conform our regulation with the amendments made by the CAA, 2024, we propose to amend § 414.1430 by revising paragraphs (a) and (b) to reflect the statutory QP and Partial QP threshold percentages for both the payment amount and patient count under the Medicare Option and the All-Payer Option with respect to payment year 2026 (performance period 2024).

The proposed revisions to § 414.1430(a) and (b) for the Medicare Option and All-Payer Combination Option QP and Partial QP thresholds are as follows:

- Paragraph (a)(1)(v) to state that for 2026 the amount is 50 percent, and a new paragraph (a)(1)(vi) to state that for 2027and later, the amount is 75 percent.
- Paragraph (a)(2)(v) to state that for 2026 the amount is 40 percent, and a new paragraph (a)(2)(vi) to state that for 2027 and later, the amount is 50 percent.
- Paragraph (a)(3)(v) to state that for 2026 the amount is 35 percent, and a new paragraph (a)(3)(vi) to state that for 2027 and later, the amount is 50 percent.
- Paragraph (a)(4)(v) to state that for 2026 the amount is 25 percent, and a new paragraph (a)(4)(vi) to state that for 2027 and later, the amount is 35 percent.
- Paragraph (b)(1)(i)(A) to state that for 2021 through 2026 the amount is 50 percent, and paragraph (b)(1)(i)(B) to

state that for 2027 and later, the amount is 75 percent.

- Paragraph (b)(2)(i)(A) to state that for 2021 through 2026 the amount is 40 percent and paragraph (b)(2)(i)(B) to state that for 2027 and later, the amount is 50 percent.
- Paragraph (b)(3)(i)(A) to state that for 2021 through 2026 the amount is 35 percent, and paragraph (b)(3)(i)(B) to state that for 2027 and later, the amount is 50 percent.
- Paragraph (b)(4)(i)(A) to state that for 2021 through 2026 the amount is 25 percent, and paragraph (b)(4)(i)(B) to state that for 2027 and later, the amount is 35 percent.

TABLE 74: QP Threshold Score Updates

Medicare Option - Payment Amount Method								
QP Performance Period / Payment Year	2022/2024 (Percent)		2023/2025 (Percent)		2024/2026 (Percent)		2025/2027 and later (Percent)	
QP Payment Amount Threshold	50		50		50		75	
Partial QP Payment Amount Threshold	40		40		40		50	
Medicare Option - Patient Count Method								
QP Performance Period / Payment Year	2022/2024 (Percent)		2023/2025 (Percent)		2024/2026 (Percent)		2025/2027 and later (Percent)	
QP Patient Count Threshold	35		35		35		50	
Partial QP Patient Count Threshold	25		25		25		35	
All-Payer Combination Option - Payment Amount Method								
QP Performance Period / Payment Year	2022/2024 (Percent)		2023/2025 (Percent)		2024/2026 (Percent)		2025/2027 and later (Percent)	
QP Patient Count Threshold	50	25	50	25	50	25	75	25
Partial QP Patient Count Threshold	40	20	40	20	40	20	50	20
	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum
All-Payer Combination Option - Patient Count Method								
QP Performance Period / Payment Year	2022/2024 (Percent)		2023/2025 (Percent)		2024/2026 (Percent)		2025/2027 and later (Percent)	
QP Patient Count Threshold	35	20	35	20	35	20	50	20
Partial QP Patient Count Threshold	25	10	25	10	25	10	35	10
	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum

(4) APM Incentive Payment

Prior to amendments made by section 304(a)(1) of the CAA, 2024, section 1833(z)(1) of the Act provided for APM Incentive Payments for eligible clinicians who are QPs with respect to a year in each payment year from 2019 through 2025. Specifically, for each of the specified payment years, in addition to the amount of payment that would otherwise be made for covered professional services furnished by an eligible clinician who is determined to be a QP for such year, an additional lump sum APM Incentive Payment equal to 5 percent of the eligible clinician's estimated aggregate payment amounts for such covered professional services for the preceding year (which we defined as the ''base year'') in each payment year from 2019 through 2024, and 3.5 percent of such amounts in payment year 2025. Covered professional services is defined at § 414.1305, with reference to the statutory definition at section 1848(k)(3) of the Act, as services for which payment is made under, or based on, the PFS and which are furnished by an eligible clinician (physician; practitioner as defined in section 1842(b)(18)(C) of the Act; PT, OT, or speech-language pathologist; or qualified audiologist as defined under section 1861(ll)(4)(B) of the Act).

Section 304(a) of the CAA, 2024 amended section 1833(z)(1) of the Act to

provide that eligible clinicians who are QPs with respect to payment year 2026 (performance period 2024) will receive an APM Incentive Payment equal to 1.88 percent of their estimated aggregate payment amounts for Medicare Part B covered professional services in the preceding year. In effect, this statutory change extends the APM Incentive Payment for one additional year, at 1.88 percent.

Accordingly, we propose to incorporate the change made by the CAA, 2024, by amending the regulation text at § 414.1450 to add the payment year 2026 APM Incentive Payment amount of 1.88 percent of covered professional services payments. We propose to amend paragraph (b)(1) to state that the amount of the APM Incentive Payment for payment years 2019 through 2024 is equal to 5 percent, for payment year 2025, 3.5 percent, and for payment year 2026, 1.88 percent of the estimated aggregate payments for covered professional services furnished during the calendar year immediately preceding the payment year.

Beginning with the 2026 payment year, which relates to the 2024 QP Performance Period, section 1848(d)(1)(A) of the Act specifies that there shall be two separate PFS conversion factors, one for items and services furnished by an eligible clinician who is a QP for the year (the qualifying APM conversion factor), and the other for other items and services not furnished by a QP (the nonqualifying APM conversion factor). Each conversion factor will be equal to the conversion factor for the previous year multiplied by the applicable update for the year specified in section 1848(d)(20) of the Act. The update specified for the qualifying APM conversion factor for CY 2025 is 0.75 percent, while the update for the nonqualifying APM conversion factor is 0.25 percent.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement (as defined under 5 CFR 1320.3(c) of the PRA's implementing regulations) is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether a collection of information should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment (see section VI. of this proposed rule) on each of the aforementioned issues for the following sections of this document that contain information collection requirements (ICRs). Comments, if received, will be responded to within the subsequent final rule.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS) May 2023 National Occupational Employment and Wage Estimates for all salary estimates (*https://bls.gov/oes/2023/may/oes_nat.htm*). In this regard, Tables 75 and 76 presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage. There are many sources of variance in the average cost estimates, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Therefore, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

We note that the May 2023 BLS data does not include median hourly wage rates for a number of the physician occupation types listed in Table 76; in these cases, the BLS identifies that the median wage rate is equal to or greater than $115.00/hr or $239,200 per year. BLS data for prior years, such as the May 2021 and May 2022 data, provide similar notes for median wage rates for occupations that are above a given threshold ($100.00/hr or $208.000 per year for the May 2021 BLS data (*https://www.bls.gov/oes/2021/may/oes_nat.htm*), and $115.00/hr or $239,200 per year for the May 2022 BLS data (*https://www.bls.gov/oes/2022/may/oes_nat.htm*)). Therefore, for consistency with previous years for estimating physician wage rates, we have continued to use mean hourly wage rates across our wage estimates.

TABLE 75: National Occupational Employment and Wage Estimates (Excluding Physicians)

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
Billing and Posting Clerks	43-3021	22.66	22.66	45.32
Computer System Analysts	15-1211	53.27	53.27	106.54
Chief Executives	11-1011	124.47	124.47	248.94
Lawyers	23-1011	84.84	84.84	169.68
Licensed Practical and Licensed Vocational Nurses	29-2061	29.23	29.23	58.46
Medical and Health Services Managers	11-9111	64.64	64.64	129.28
Pharmacists	29-1051	64.81	64.81	129.62

For our purposes, BLS' May 2023 National Occupational Employment and Wage Estimates does not provide an occupation that we could use for ''Physician'' wage data. To estimate a Physician's costs, we are using an average conglomerate wage of $291.64/hr as demonstrated below in Table 76.

TABLE 76: National Occupational Employment and Wage Estimates (Physicians)

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
Anesthesiologists	29-1211	163.21	163.21	326.42
Family Medicine Physicians	29-1215	115.77	115.77	231.54
General Internal Medicine Physicians	29-1216	118.01	118.01	236.02
Obstetricians and Gynecologists	29-1218	133.97	133.97	267.94
Orthopedic Surgeons, Except Pediatric	29-1242	181.85	181.85	363.7
Pediatric Surgeons	29-1243	216.02	216.02	432.04
Pediatricians, General	29-1221	98.97	98.97	197.94
Physicians, All Other	29-1229	119.54	119.54	239.08
Psychiatrists	29-1223	123.53	123.53	247.06
Surgeons	29-1240	167.74	167.74	335.48
Surgeons, All Other	29-1249	165.38	165.38	330.76
Total				3,207.98
Average Physician Wage (3,207.98/11)				291.64

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-In of Payment Reductions (§ 414.504)

On November 17, 2023, section 502 of the Further Continuing Appropriations and Other Extensions Act, 2024 (Pub. L. 118–22) (FCAOEA, 2024) was passed and delayed data reporting requirements for CDLTs that are not ADLTs, and it also delayed the phase-in of payment reductions under the CLFS from private payor rate implementation under section 1834A of the Act. As described in section III.D of this proposed rule, under the Clinical Laboratory Fee Schedule, ''reporting entities'' must report to CMS during a ''data reporting period'' ''applicable information'' collected during a ''data collection period'' for their component ''applicable laboratories.'' We are proposing to revise § 414.504(a)(1) to account for a delay in reporting until January 1, 2025, through March 31, 2025. As stated in section 1834A(h)(2) of the Act, chapter 35 of title 44 U.S.C., which includes such provisions as the PRA, does not apply to information collected under section 1834A of the Act. Consequently, we are not setting out any proposed burden estimates under this section of this proposed rule. Please refer to section VII.XX. of this proposed rule for a discussion of the impacts associated with the proposed changes described in section III.D. of this proposed rule.

2. ICRs Regarding the Updates to the Medicare Diabetes Prevention Program

In section § 410.79(b), we are proposing to make conforming changes to our regulation Conditions of Coverage to align with the 2024 Centers for Disease Control and Prevention (CDC) Diabetes Prevention Recognition Program (DPRP) Standards.[787] We are proposing to amend § 410.79(b) to add a new term for MDPP, ''in-person with a distance learning component.'' The proposed ''in-person with a distance learning component'' code will reduce administrative burden and allow MDPP suppliers to streamline data reporting to CDC because they will only have to maintain one code if they are providing in-person and distance learning delivery. To further align with 2024 CDC DPRP Standards, we are also adding the term ''combination with an online component'' and revising the current ''online'' definition. We are also clarifying in § 410.79(d)(1) that MDPP make-up sessions can only be furnished using distance learning and in-person delivery modes, in alignment with the Extended flexibilities as defined in the CY 2024 PFS final rule (88 FR 79528). We are also proposing to amend § 410.79(e)(3)(iii)(C) in response to comments that beneficiaries are unable to take a picture while standing on their home scales due to risk of injury and physical health limitations (88 FR 79249). We are proposing revised language to specify that a beneficiary can self-report their weight for an MDPP distance learning session by sending 2 (two) date-stamped photos: one with their weight on the digital scale and one of the beneficiary visible in their home. Additionally, at § 414.84(c), to make it possible for Medicare Administrative Contractors (MACs) to process claims for same day make-up sessions in MDPP, we are proposing that suppliers be required to append an existing claim modifier (Current Procedural Terminology (CPT) Modifier 79) to any claim for G9886 or G9887 to indicate a

[787] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

make-up session that was held on the same day as a regularly scheduled MDPP session. We are proposing to remove the MDPP bridge payment in § 414.84(a), (d), and (e). This payment is no longer necessary in MDPP's CY 2024 fee for service payment structure and could introduce the potential for fraud, waste, or abuse. Finally, we are proposing to make minor edits throughout §§ 410.79, 424.205, and 414.84 to update outdated references and align with previous rulemaking pertaining to MDPP terminology, payment structure, and requirements. Section 1115A(d)(3) of the Act exempts Innovation Center model tests and expansions, which include the MDPP expanded model, from the provisions of the PRA. Accordingly, this collection of information section does not set out any burden for the provisions, including the collection of weights, per the CY 2024 PFS final rule.

3. ICRs Regarding the Medicare Shared Savings Program

Section 1899(e) of the Act provides that chapter 35 of title 44 U.S.C., which includes such provisions as the PRA, shall not apply to the Shared Savings Program. Accordingly, we are not setting out proposed Shared Savings Program burden estimates under this section of the preamble. Please refer to section VII.E.11. of this proposed rule for a discussion of the impacts associated with the changes to the Shared Savings Program as described in section III.G. of this proposed rule.

4. ICRs Regarding Rebate Reduction Requests Submitted Under Sections 11101 and 11102 of the Inflation Reduction Act

The following proposed changes will be submitted to OMB for review under control number 0938–NEW (CMS–10858).

As described in section III.I. of this proposed rule, to receive consideration for an inflation rebate reduction for a specific rebatable drug when the manufacturer believes there is a severe supply chain disruption or likely shortage, we are proposing that a manufacturer must submit a rebate reduction request form along with supporting documentation. We are proposing this because manufacturers hold some of the information and documentation that is needed to determine whether the rebate amount for a Part B or Part D rebatable drug should be reduced due to either a severe supply chain disruption or a likely shortage as required by sections 1847A(i)(3)(G)(ii), 1860D–14B(b)(1)(C)(ii), and 1860D–14B(b)(1)(C)(iii) of the Act.

In §§ 427.402(c)(4) and 428.302(c)(4), we are proposing the criteria that a Part B or Part D rebatable drug would have to meet for CMS to grant a severe supply chain disruption rebate reduction request. In §§ 427.402(c)(5) and 428.302(c)(5), we propose that if a manufacturer believes a severe supply chain disruption continues into a fifth consecutive calendar quarter for a Part B rebatable biosimilar biological product, or a second applicable period for a generic Part D rebatable drug or biosimilar after the start of the natural disaster or other unique or unexpected event, the manufacturer may request an extension of the rebate reduction one time by submitting a rebate reduction extension request and supporting documentation. In § 428.303(c)(4), we propose the criteria that a generic Part D rebatable drug would have to meet for CMS to grant a rebate reduction request because the generic Part D rebatable drug is likely to be in shortage, including the requirements for a one-time extension of a rebate reduction.

Outside of this proposed rule we have proposed additional submission requirements for rebate reduction requests under OMB control number: 0938–NEW (CMS–10858). At this time, the rebate reduction request forms are currently going through the PRA review and approval process. The 30-day notice appeared in the **Federal Register** on June 3, 2024 (89 FR 47563).

We believe that few manufacturers will submit a rebate reduction request form due to the statutory specifications regarding eligible rebatable drugs, as well as the policy criteria proposed in this proposed rule. Using the wage rates in Table 75 of this proposed rule, we anticipate collecting a total of 10 rebate reduction request forms per year. We estimate a total annual burden of 310 hours (31 hrs per form * 10 forms) and total annual cost of $37,378 ((160 hrs × $84.66/hr) + (80 hrs × $129.62/hr) + (50 hrs × $169.68/hr) + (20 hrs × $248.94/hr)).

Using the wage rates in Table 75 of this proposed rule, we also anticipate collecting a total of 10 rebate reduction extension request forms per year, and a total annual burden estimate of 310 hours (31 hr per form * 10 forms) at a cost of $37,378 ((160 hrs × $84.66/hr) + (80 hrs × $129.62/hr) + (50 hrs × $169.68/hr) + (20 hrs × $248.94/hr)).

5. ICRs Regarding Medicare Parts A and B Overpayment Provisions of the Affordable Care Act (§ 401.305(b)(1), (2), and (3))

Existing § 401.305(b)(1) specifies when a person who has received an overpayment must report and return an overpayment. We propose to amend this regulation to reference revised § 401.305(b)(2) and new § 401.305(b)(3). We are proposing a technical modification to the introductory language in § 401.305(b)(2) to acknowledge that this paragraph may be applicable after the suspension described in new § 401.305(b)(3) is complete. New proposed § 401.305(b)(3) would identify the circumstances under which the deadline for reporting and returning overpayments would be suspended to allow time for providers to investigate and calculate overpayments.

The proposed amendments for Medicare Parts A and B are associated with OMB control number 0938–1323 (CMS–10405); however, we are not making any revisions to the currently approved requirements and burden under this control number since we cannot predict if there will be any change to the number of overpayments identified or reported based on this rulemaking's proposed changes. We solicit comment on this assumption.

6. The Quality Payment Program (42 CFR Part 414 and Section IV of This Proposed Rule)

The following Quality Payment Program-specific ICRs reflect changes to our currently approved burden to capture proposed policy changes in this CY 2025 proposed rule as well as adjustments to the policies that have been previously finalized in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77008 and 82 FR 53568, respectively), and the CY 2019, CY 2020, CY 2021, CY 2022, CY 2023, and CY 2024 Physician Fee Schedule (PFS) final rules (83 FR 59452, 84 FR 62568, 85 FR 84472, 86 FR 64996, 87 FR 70131, and 88 FR 78818, respectively) due to revised assumptions based on updated data available at the time of the publication of this proposed rule.

As described in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77008 and 82 FR 53568, respectively), and the CY 2019, CY 2020, CY 2021, CY 2022, CY 2023, and CY 2024 Physician Fee Schedule (PFS) final rules (83 FR 59452, 84 FR 62568, 85 FR 84472, 86 FR 64996, 87 FR 70131, and 88 FR 78818, respectively), we have used an exhaustive approach for describing the burden associated with

the MIPS requirements for the Quality Payment Program. With the maturity and stabilization of the Quality Payment Program, we believe there may be opportunities to present streamlined annual burden estimates to account for changes, including changes due to proposed policies. We are soliciting public comment as part of this proposed rule on our exhaustive approach to presenting burden estimates associated with the Quality Payment Program.

a. Background

(1) ICRs Associated With Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs)

In this section of this proposed rule, we discuss a series of ICRs associated with the Quality Payment Program, including for MIPS and Advanced APMs. The following sections describe the changes in the estimated burden for the information collections relevant to the proposed revisions in the policies associated with the CY 2025 PFS proposed rule and proposed revisions to our currently approved information requests for MIPS and Advanced APM ICRs. The proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621). In the CY 2024 PFS final rule (88 FR 79446 and 79447), we provided updated burden estimates for the information collections under the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey PRA package. We have submitted these burden estimates to OMB for approval under control number 0938–1222 (CMS–10450): the 60-day notice appeared in the **Federal Register** on October 17, 2023 (88 FR 71573), while the 30-day notice appeared on January 16, 2024 (89 FR 2622). The updated information collections for the CAHPS for MIPS Survey discussed in section IV.A.4.j. of this proposed rule will be submitted to OMB for review under control number 0938–1222 (CMS–10450) if the related policy proposal is finalized in the CY 2025 PFS final rule, to be a requirement for CAHPS for MIPS survey vendors beginning with the CY 2026 performance period/2028 MIPS payment year. We note that we have received approval for the collection of information associated with the virtual election process under OMB control number 0938–1343 (CMS–10652).

(a) Summary of Annual Quality Payment Program Burden Estimates

Table 77 summarizes this proposed rule's total burden estimates for the Quality Payment Program for the CY 2025 performance period/2027 MIPS payment year. We provide details of the proposed policies, updated assumptions, and ICRs beginning in section V.B.8. of this proposed rule.

In the CY 2024 PFS final rule (87 FR 70169), the total estimated burden for the CY 2024 performance period/2026 MIPS payment year was 724,212 hours at a cost of $81,322,556 (see Table 77, row a). Accounting for updated wage rates and the subset of all Quality Payment Program ICRs outlined in this proposed rule compared to the CY 2024 PFS final rule, the total estimated annual burden of continuing policies and information set forth in the CY 2024 PFS final rule into the CY 2025 performance period/2027 MIPS payment year is 727,906 hours at a cost of $85,867,252 (see Table 77, row b). These represent an increase of 3,694 hours and an increase of $4,544,696.

To understand the burden implications of the policies proposed in this rulemaking, we provided an estimate of the total burden associated with continuing the policies and information collections set forth in the CY 2024 PFS final rule into the CY 2025 performance period/2027 MIPS payment year. The estimated burden of 657,110 hours at a cost of $77,779,594 (see Table 77, row c) reflects the availability of more accurate data to account for all potential respondents and submissions across all the performance categories and represents a decrease of 70,796 hours and $8,087,658 (see Table 77, row d).

Our total proposed burden estimate for the CY 2025 performance period/2027 MIPS payment year is 649,540 hours and $76,866,418 (see Table 77, row e), which represents a decrease of 78,366 hours and $9,000,834 from the CY 2024 PFS final rule estimate with updated wage rates and ICRs (see Table 77, row f). From these estimates, updated data and assumptions not related to policies proposed in this proposed rule would reduce burden by 70,796 hours and $8,087,658. We estimate that the policies proposed in this proposed rule would further reduce burden by 7,570 hours (−78,366 hours − −70,796 hours) and $913,176 (−$9,000,834 − −$8,087,658) (see Table 77, row g) between this estimate and the total burden shown in Table 78 is the decrease in burden associated with impacts of the policies proposed for the CY 2025 performance period/2027 MIPS payment year.

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TABLE 77: Summary of Burden Estimates and Requirements from the CY 2025 PFS Proposed Rule

Burden Estimate Description	Time (Hours)	Cost
Currently Approved Burden in CY 2024 PFS Final Rule (a)	724,212	$81,322,556
CY 2024 PFS Final Rule w/ Updated Wage Rates and ICRs (b)	727,906	$85,867,252
CY 2024 PFS Final Rule w/ Updated Data and Assumptions (c)	657,110	$77,779,594
Change in Burden Due to Updated Data and Assumptions (d) = (c) – (b)	**-70,796**	**-$8,087,658**
CY 2025 PFS Proposed Rule Total Burden (e)	649,540	$76,866,418
Total Change in Burden (f) = (e) – (b)	-78,366	-$9,000,834
Change in Burden Associated with Policies (g) = (f) – (d)	**-7,570**	**-$913,176**

TABLE 78: Summary of Quality Payment Program Burden Estimates and Requirements CMS-10621 (OMB 0938-1314)

Requirement	Currently Approved Responses	CMS-1807-P Responses	Change in Responses	Currently Approved Total Time (Hours)	CMS-1807-P Total Time (Hours)	Change in Total Time (Hours)
§ 414.1400 Qualified Clinical Data Registry (QCDR) Simplified Self-Nomination and other Requirements (see Tables 81 and 82)	44	39	-5	418	467	+49
§ 414.1400 QCDR Full Self-Nomination and other Requirements (see Tables 83 and 84)	12	17	+5	138	238	+100
§ 414.1400 Qualified Registry Simplified Self-Nomination and other Requirements (see Tables 85 and 86)	84	76	-8	42	38	-4
§ 414.1400 Qualified Registry Full Self-Nomination and other Requirements (see Tables 87 and 88)	27	30	+3	54	60	+6
§ 414.1400 Third Party Intermediary Plan Audits (see Tables 90 and 91)	126	89	-37	499	472	-27
Quality Payment Program Identity Management Application Process (see Tables 95 and 96)	6,500	6,237	-263	6,500	6,237	-263
§§ 414.1325 and 414.1335 Quality Performance Category: Medicare Part B Claims Collection Type (see Tables 97 and 98)	13,413	12,197	-1,216	190,465	173,197	-17,268
§§ 414.1325 and 414.1335 Quality Performance Category: QCDR/MIPS Clinical Quality Measure CQM Collection Type (see Tables 99 and 100)	16,632	17,008	+376	151,068	154,484	+3,416
§§ 414.1325 and 414.1335 Quality Performance Category: electronic Clinical Quality Measure eCQM Collection Type (see Tables 101 and 102)	28,714	27,179	-1,535	229,712	217,432	-12,280
§414.1365 MVP Registration (see Tables 103 and 104)	9,585	6,285	-3,300	2,396	1,571	-825
MVP Quality Submission (see Tables 105 and 106)	9,585	6,285	-3,300	61,662	40,193	-21,469
Call for Quality Measures (see Tables 107 and 108)	31	16	-15	171	88	-83

Requirement	Currently Approved Responses	CMS-1807-P Responses	Change in Responses	Currently Approved Total Time (Hours)	CMS-1807-P Total Time (Hours)	Change in Total Time (Hours)
§ 414.1380(c)(2) Reweighting Applications for MIPS Performance Categories (see Tables 109 and 110)	29,227	3,297	-25,930	7,307	824	-6,483
§ 414.1375 Data Submission for Promoting Interoperability Performance Category (see Tables 112 and 113)	25,990	18,609	-7,381	70,173	50,244	-19,929
§ 414.1360 Data Submission for the Improvement Activities Performance Category (see Tables 115 and 116)	50,289	38,433	-11,856	4,174	3,190	-984
§§ 414.1310(b) and 414.1430 Partial Qualifying APM Participant (QP) Elections (see Tables 117 and 118)	287	18	-269	72	5	-67
§ 414.1445 Other Payer Advanced APM Determinations: Payer-Initiated Process (see Tables 119 and 120)	15	10	-5	150	100	-50
§ 414.1445 Other Payer Advanced APM Determinations: Eligible Clinician-Initiated Process (see Tables 121 and 122)	15	10	-5	150	100	-50
§ 414.1440 Submission of Data for QP Determinations under the All-Payer Combination Option (see Tables 123 and 124)	551	120	-431	2,755	600	-2,155
TOTAL	**191,127**	**135,955**	**-55,172**	**727,906**	**649,540**	**-78,366**

Table 79 provides the reasons for changes in the estimated burden for the CY 2025 performance period/2027 MIPS payment year for information collections in the Quality Payment Program segment of this proposed rule. We divided the reasons for our change in burden into those related to proposed policies in the CY 2025 PFS proposed rule and those related to adjustments in burden continued from the CY 2024 PFS final rule policies that reflect updated data and revised methods.

TABLE 79: Reasons for Proposed Change in Burden Compared to The Currently Approved CY 2024 Information Collection Burden

ICR Title	Changes in Burden Due to CY 2025 Proposed Rule Policies	Adjustments in Burden Continued from CY 2024 PFS Final Rule Policies Due to Revised Methods or Updated Data
QCDR Simplified Self-Nomination and other Requirements (See Table 82)	None	Decrease in number of respondents and increase in the number of hours per respondent due to updated data. Net increase in the total number of hours due to updated data.
QCDR Full Self-Nomination and other Requirements (See Table 84)	None	Increase in number of respondents and increase in the number of hours per respondent due to updated data. Net increase in the total number of hours due to updated assumptions for the CY 2025 performance period/2027 MIPS payment year.
Qualified Registry Simplified Self-Nomination and other Requirements (See Table 86)	None	Decrease in number of respondents due to updated data.
Qualified Registry Full Self-Nomination and other Requirements (See Table 88)	None	Increase in number of respondents due to updated data.
Third Party Intermediary Plan Audits (see Table 91)	None	Decrease in number of respondents due to updated data.
Quality Payment Program Identity Management Application Process (see Table 96)	None	Decrease in number of respondents due to updated data.
Quality Performance Category: Medicare Part B Claims Collection Type (see Table 98)	Decrease in number of respondents due to the estimated increase in the number of respondents submitting for the MVP quality performance category via the claims collection type due to the proposed addition of 6 new MVPs.	Decrease in the number of respondents due to updated data.

ICR Title	Changes in Burden Due to CY 2025 Proposed Rule Policies	Adjustments in Burden Continued from CY 2024 PFS Final Rule Policies Due to Revised Methods or Updated Data
Quality Performance Category: QCDR/MIPS CQM Collection Type (see Table 100)	Decrease in number of respondents due to the estimated increase in the number of respondents submitting for the MVP quality performance category via the QCDR and MIPS CQM collection type due to proposed addition of new MVPs.	Increase in the number of respondents due to updated data.
Quality Performance Category: eCQM Collection Type (see Table 102)	Decrease in number of respondents due to the estimated increase in the number of respondents submitting for the MVP quality performance category via the eCQM collection type due to proposed addition of 6 new MVPs.	Decrease in the number of respondents due to updated data.
MVP Registration (see Table 104)	Increase in number of respondents due to proposed addition of 6 new MVPs.	Decrease in the number of respondents due to updated data.
MVP Quality Submission (see Table 106)	Increase in number of respondents due to proposed addition of 6 new MVPs.	Decrease in the number of respondents due to updated data.
Call for Quality Measures (see Table 108)	None	Decrease in number of respondents due to updated data.
Reweighting Applications for MIPS Performance Categories (see Table 110)	None	Decrease in number of respondents due to updated data.
Data Submission for the Promoting Interoperability Performance Category (see Table 113)	None	Decrease in number of respondents due to updated data.
Data Submission for the Improvement Activities Performance Category (see Table 116)	None.	Decrease in number of respondents due to updated data.
Partial QP Elections (see Table 118)	None	Decrease in number of respondents due to updated data.
Other Payer Advanced APM Determinations: Payer-Initiated Process (see Table 120)	None	Decrease in number of respondents due to updated data.
Other Payer Advanced APM Determinations: Eligible Clinician-Initiated Process (see Table 122)	None	Decrease in number of respondents due to updated data.
Submission of Data for QP Determinations under the All-Payer Combination Option (see Table 124)	None	Decrease in number of respondents due to updated data.

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(2) Summary of Proposed Changes for the Quality Payment Program: MIPS

We have included the change in the estimated burden for the CY 2025 performance period/2027 MIPS payment year due to the proposed policies and information collections in this proposed rule. The proposed policies in this proposed rule impact the burden estimates for the CY 2025 performance period/2027 MIPS payment year.

The following five MIPS ICRs show changes in burden due to the proposed policies in this proposed rule: (1) Quality performance category data submission by Medicare Part B claims

collection type; (2) Quality performance category data submission by qualified clinical data registry (QCDR) and MIPS clinical quality measure (CQM) collection type; (3) Quality performance category data submission by electronic clinical quality measure (eCQM) collection type; (4) MIPS Value Pathways (MVP) quality performance category submission, and (5) MVP registration. In aggregate, we estimate the proposed policies would result in a net decrease in burden of 7,570 hours and $913,176 for the CY 2025 performance period/2027 MIPS payment year. The remaining changes to our currently approved burden estimates are proposed adjustments due to the revised burden assumptions based on the updated data available at the time of preparation of this proposed rule.

We are not proposing any changes or adjustments to the following ICRs: Registration for virtual groups; CAHPS survey vendor requirements; CAHPS beneficiary burden; group registration for the CAHPS survey; call for Improvement Activities; Open Authorization (OAuth) credentialing and token request process; nomination of MVPs; subgroup registration; and opt-out of performance data display on Compare Tools for voluntary participants. See section V.B.8.a.(1). of this proposed rule for a summary of the ICRs, the overall burden estimates, and a summary of the assumption and data changes affecting each ICR.

We incorporate submission data from CY 2022 performance period/2024 MIPS payment year to calculate the total burden for data submission under the quality, Promoting Interoperability, and improvement activities performance categories. The accuracy of our estimates of the total burden for data submission for those performance categories may be impacted by several primary factors. First, we are unable to predict with absolute certainty who will be a Qualifying APM Participant (QP) for the CY 2025 performance period/2027 MIPS payment year. Newly eligible clinician participants in Advanced APMs who become QPs will be excluded from MIPS payment adjustments, and as such, are unlikely to report under MIPS; while some current Advanced APM participants may end participation such that the APM Entity's eligible clinicians may not be QPs for a year based on § 414.1425(c)(5), and thus be required to report under MIPS. Second, it is difficult to predict whether Partial QPs, who can elect to report to MIPS, will choose to participate in the CY 2025 performance period/2027 MIPS payment year compared to the CY 2022 performance period/2024 MIPS payment year. Therefore, the actual number of Advanced APM participants and how they elect to submit data may differ from our estimates. However, we believe our estimates are the most appropriate given the available data. We will continue to revise our estimates as updated data becomes available.

In the CY 2024 PFS final rule, we finalized requirements to align the Shared Savings Program's certified electronic health record technology (CEHRT) requirements with MIPS Promoting Interoperability (88 FR 79124 through 79131), codified at § 425.507(a) and (b). For performance years beginning on or after January 1, 2025, unless otherwise excluded, an Accountable Care Organization (ACO) participant, ACO provider/supplier, and (ACO) professional that is a MIPS eligible clinician, Qualifying APM Participant (QP) and Partial Qualifying APM Participant (Partial QP), regardless of track must report the MIPS Promoting Interoperability measures and requirements to MIPS according to § 414(o) at the individual, group, virtual group, or APM entity level, and earn a MIPS performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level, barring an applicable exclusion defined at § 425.507(b). We refer readers to the CY 2024 PFS final rule (88 FR 79124 through 79131) for details. We note we are not updating burden estimates for the Promoting Interoperability performance category to reflect requirements for ACO participants who are not MIPS eligible clinicians. Section 1899(e) of the Act provides that chapter 35 of title 44 of the U.S.C., which includes such provisions as the PRA, shall not apply to the Shared Savings Program. In section V.B.8.e.(7). of this proposed rule, we provide our burden estimates for the Promoting Interoperability performance category for MIPS eligible clinicians.

(3) Summary of Quality Payment Program Changes: Advanced APMs

For these ICRs, we are proposing adjustments to the currently approved burden estimates for the CY 2025 performance period/2027 MIPS payment year based on updated submission trends: Partial QP elections; Other Payer Advanced APM determinations: Payer-Initiated and Eligible Clinician-initiated processes; and submission of Data for QP Determinations under the All-Payer Combination Option.

(4) Framework for Understanding the Burden of MIPS Data Submission

Because of the wide range of information collection requirements under MIPS, Table 80 presents a framework for understanding how the organizations permitted or required to submit data on behalf of clinicians vary across the types of data, and whether the clinician is a MIPS eligible clinician or other eligible clinician voluntarily submitting data, MIPS APM participant, or an Advanced APM participant. In Table 80, MIPS eligible clinicians and other clinicians voluntarily submitting data to MIPS may submit data as individuals, groups, or virtual groups for the quality, Promoting Interoperability, and improvement activities performance categories. Note that virtual groups are subject to the same data submission requirements as groups, and therefore, we will refer only to groups for the remainder of this section, unless otherwise noted.

Beginning with the CY 2023 performance period/2025 MIPS payment year, clinicians could also participate as subgroups for reporting measures and activities in an MVP. We note that the subgroup reporting option is not available for clinicians participating in traditional MIPS. We finalized in the CY 2022 PFS final rule that for the CY 2023 and 2024 MIPS performance periods/2025 and 2026 MIPS payment years, a subgroup reporting measures and activities in an MVP will submit its affiliated group's data for the Promoting Interoperability performance category and in the scenario that a subgroup does not submit its affiliated group's data, the subgroup will receive a zero score for the Promoting Interoperability performance category (86 FR 65413 and 65414). As discussed in section IV.A.4.b.(1)(4). of this proposed rule, we are proposing to clarify that we intend for the policy to apply beyond the CY 2023 and 2024 performance periods/2025 and 2026 MIPS payment years. We refer readers to section V.B.8.g.(3). of this proposed rule for our burden estimates for the Promoting Interoperability performance category.

Because MIPS eligible clinicians are not required to submit any additional information for assessment under the cost performance category, the administrative claims data used to calculate the scores for the cost performance category is not represented in Table 80.

For MIPS eligible clinicians participating in MIPS APMs, the organizations submitting data on behalf of MIPS eligible clinicians will vary

between performance categories and, in some instances, between MIPS APMs. We previously finalized in the CY 2021 PFS final rule that the APM Performance Pathway (APP) is available for clinicians who participate in a MIPS APM for both ACO participants and non-ACO participants to submit quality data (85 FR 84859 through 84866). Due to data limitations and our inability to determine who will use the APP versus the traditional MIPS submission mechanism for the CY 2025 performance period/2027 MIPS payment year, we assume Shared Savings Program ACO APM Entities will submit quality data through the APP as required, and MIPS eligible clinicians in non-Shared Savings Program ACO APM Entities will participate through traditional MIPS or MVPs, submitting as an individual or group rather than as an APM Entity. Per section 1899(e) of the Act, submissions received from eligible clinicians in ACOs are not included in burden estimates for this proposed rule because quality data submissions to fulfill requirements of the Shared Savings Program are not subject to the PRA. Accordingly, this burden is not included in Quality Payment Program burden estimates.

In the CY 2021 PFS final rule (85 FR 84860 and 84861), we adopted the current APP quality measure set. As discussed in section IV.A.4.c.(2). of this proposed rule, we are proposing to create the APP Plus quality measure set that would allow for alignment of the APP with the Adult Universal Foundation measures. Under this proposal, Shared Savings Program ACOs would be required to report the APP Plus quality measure beginning with the CY 2025 performance period/2027 MIPS payment year. We are not proposing to modify the existing APP quality measure set of six quality measures; instead, we are proposing to create the APP Plus measure set that would be optional, with exception to the Shared Savings Program ACOs, beginning in the CY 2025 performance period/2027 MIPS payment year. Under this proposal, each MIPS eligible clinician, group, or APM Entity that elects to report the APP may choose to report either the APP quality measure set or the APP Plus quality measure set. MIPS APM participants may also elect to report via traditional MIPS or MVPs.

We are proposing to adopt five new quality measures for the APP Plus quality measure set incrementally over several performance periods/MIPS payment years, as detailed in Tables 55, 56, and 57 in section IV.A.4.c.(3)(f): two new quality measures beginning with the CY 2025 performance period; one new quality measure beginning with the CY 2026 performance period, and two new quality measures beginning with the CY 2028 performance period. We refer readers to section IV.A.4.c.(3). of this proposed rule for additional details on the proposed measures and collection types of the APP Plus quality measure set. As noted in section IV.A.4.c.(3). of this proposed rule, we are proposing to establish that all measures in the APP Plus quality measure set must be reported. As detailed in Table 53, the current APP quality measure set consists of six measures: two administrative claims measures, the CAHPS for MIPS survey, and three measures that MIPS eligible clinicians reporting the APP must actively report to CMS via the Medicare CQM (Shared Savings Program ACOs only), eCQM, CQM, or Part B claims collection types. MIPS eligible clinicians, groups, or APM Entities reporting the proposed APP Plus quality measure set would report via the available collection types: eight measures for the CY 2025 performance period/2027 MIPS payment year; nine measures for the CY 2026 and 2027 performance periods/2028 and 2029 MIPS payment years; and eleven measures for the CY 2028 performance period/2030 MIPS payment period.

The quality performance category burden for MIPS eligible clinicians who elect to report the proposed APP Plus quality measure set varies compared to the current APP quality measure set, traditional MIPs, and MVPs. We assume MIPS eligible clinicians incur no burden for reporting the two administrative claims quality measures currently required under the APP quality measure set, as similar to cost measures, we automatically calculate scores from administrative claims reporting. Additionally, burden estimates for the CAHPS for MIPS registration and patient reporting are provided in the CAHPS for MIPS PRA package under OMB control number 0938–1222 (CMS–10450); we do not assume that MIPS eligible clinicians incur additional reporting burden for reporting this measure under the current APP quality measure set. Therefore, we assume that MIPS eligible clinicians reporting the proposed APP Plus quality measure set would incur burden for actively submitting their quality performance category data via the available collection types—eCQM, CQM/QCDR, and Medicare Part B claims. We note, these assumptions for actively submitting to assess clinician reporting burden may differ from MIPS scoring policy. This active submission of quality performance data would include five of the eight quality measures for the CY 2025 performance period/2027 MIPS payment year, six of the nine quality measures for the CY 2026 and 2027 performance periods/2028 and 2029 MIPS payment years, and eight of the eleven measures for the CY 2028 performance period/2030 MIPS payment year. Continuing this burden comparison for MIPS eligible clinicians reporting the proposed APP Plus quality measure set for the CY 2025 performance period/2027 MIPS payment year, clinicians would need to actively submit quality performance category data for one less quality measure than clinicians participating in traditional MIPS (six measures), two more quality measures than clinicians participating via the APP (three measures), and one more quality measure than clinicians participating via MVPs (four measures). For the CY 2026 and 2027 performance periods/ 2028 and 2029 MIPS payment years, clinicians reporting the proposed APP Plus quality measure set would need to actively submit quality performance category data for the same number of quality measures as clinicians participating in traditional MIPS (six measures); they would need to report three more quality measures than clinicians participating via the APP (three measures), and two more quality measures than clinicians participating via MVPs (four measures). Beginning in the CY 2028 performance period/2030 MIPS payment year, clinicians reporting the proposed APP Plus quality measure set would need to actively submit quality performance category data for two more quality measures than clinicians reporting via traditional MIPS (six measures), five more quality measures that clinicians participating via the APP (three measures), and four more measures than clinicians participating via MVPs (four measures). For this comparison of MIPS reporting requirements, we assume that clinicians reporting via traditional MIPS and MVPs will report eCQM, CQM, and Part B Claims measures, and will not elect to report the CAHPS for MIPS survey. As proposed in section IV.A.4.c.(2). of this proposed rule, all Shared Savings Program ACOs would be required to report the APP Plus measure set for the CY 2025 performance period/2027 MIPS payment year. Per section 1899(e) of the Act, submissions received from eligible clinicians in ACOs are not included in burden estimates for this proposed rule because quality data submissions to fulfill requirements of the Shared Savings Program are not subject to the

PRA. As the APP Plus is a new measure set, and optional, with exception to the Shared Savings Program ACOs, we are unable to estimate how many MIPS eligible clinicians would submit quality measures via the APP Plus at this time via individual, group, or non-Shared Savings Program ACO Entity reporting. We will update these estimates as additional data are available. We refer readers to section VII.E.17.e.(2)(h). of this proposed rule for additional discussion.

For the Promoting Interoperability performance category, group TINs may submit data on behalf of eligible clinicians in MIPS APMs, or eligible clinicians in MIPS APMs may submit data individually. Additionally, APM Entities may report the Promoting Interoperability performance category at the APM Entity level beginning with the CY 2023 performance period/2025 MIPS payment year (87 FR 70087 and 70088). In the CY 2017 Quality Payment Program final rule (81 FR 30132), we codified at § 414.1380(b)(3)(i) that individual MIPS eligible clinicians participating in APMs (as defined in section 1833(z)(3)(C) of the Act) for a performance period will earn at least 50 percent for the improvement activities performance category. We also stated that MIPS eligible clinicians participating in an APM for a performance period may receive an improvement activity score higher than 50 percent (81 FR 30132). To provide clarity for APM participants not scored under the APP in the CY 2024 PFS final rule (88 FR 79365 through 79367), we revised § 414.1380(b)(3)(i) to state that a MIPS eligible clinician participating in an APM receives an improvement activities performance category score of at least 50 percent if the MIPS eligible clinician reports a completed improvement activity or submits data for the quality and Promoting Interoperability performance categories.

MIPS eligible clinicians who attain Partial QP status may incur additional burden if they elect to participate in MIPS, which is discussed in more detail in the CY 2018 Quality Payment Program final rule (82 FR 53841 through 53844).

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TABLE 80: Clinicians or Organizations Submitting MIPS Data on Behalf of Clinicians, by Type of Data and Category of Clinician

Type of Data Submitted	Category of Clinician
Quality Performance Category	Individual clinician (MIPS eligible, voluntary, opt-in), group, virtual group, subgroup, or APM Entity. Subgroup reporting is only available for clinicians participating in MVP reporting. Voluntary reporting and virtual group reporting are only available for clinicians participating in traditional MIPS. Opt-in reporting is only available for clinicians participating in traditional MIPS and the APM Performance Pathway.
Promoting Interoperability Performance Category	Individual clinician (MIPS eligible, voluntary, opt-in), group, virtual group, subgroup, or APM Entity. Each eligible clinician in an APM Entity could report data for the Promoting Interoperability performance category at the individual level, or as part of their group TIN, or under their APM Entity TIN. The burden estimates for this proposed rule assume group TIN-level reporting.
Improvement Activities Performance Category	Individual clinician (MIPS eligible, voluntary, opt-in), group, virtual group, subgroup, or APM Entity. For eligible clinicians in an APM Entity, the burden estimates for this proposed rule assume individual or group TIN-level reporting.
Reweighting Applications for extreme and uncontrollable circumstances, significant hardship, or other exceptions	Clinicians who submit an application may be eligible for a reweighting of the approved performance category to zero percent under specific circumstances as set forth in § 414.1380(c)(2), including, but not limited to, extreme and uncontrollable circumstances, significant hardship, or another exception. Certain types of MIPS eligible clinicians are automatically eligible reweighting for the Promoting Interoperability performance category to zero percent as described in § 414.1380(c)(2)(i)(C).
MVP and Subgroup Registration	An MVP participant, as described at § 414.1305, electing to submit data for the measures and activities in an MVP must register. Clinicians who choose to participate as a subgroup for reporting an MVP must also register.
Partial QP Election	Eligible clinicians who attain Partial QP status and choose to participate in MIPS must submit a partial QP election form.
Registration for the CAHPS for MIPS Survey	Groups electing to use a CMS-approved survey vendor to administer the CAHPS for MIPS Survey must register.
Virtual Group Registration	Virtual groups must register via email. Virtual group participation is limited to MIPS eligible clinicians, specifically, solo practitioners who are MIPS eligible and groups consisting of 10 eligible clinicians or fewer that have at least one MIPS eligible clinician.
APM Performance Pathway (APP)	Clinicians in MIPS APMs electing the APP. The burden estimates for this proposed rule assume that Shared Savings ACO APM Entities will submit data through the APP via the APP Plus measure set beginning in CY 2025 performance period/2027 MIPS payment year, and non-Shared Savings Program ACO APM Entities will participate through traditional MIPS, submitting as an individual or group rather than as an APM Entity.

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The policies finalized in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77008 and 82 FR 53568), the CY 2019, CY 2020, CY 2021, CY 2022, CY 2023, and CY 2024 PFS final rules (83 FR 59452, 84 FR 62568, 85 FR 84472, 86 FR 64996, 87 FR 70131, and 88 FR 78818), and continued in this proposed rule create some additional data collection requirements not listed in Table 80. These additional data collections, some of which are currently approved by OMB under the control number 0938–1314 (Quality Payment Program/MIPS, CMS–10621) or pending renewal under 0938–1222 (CAHPS for MIPS, CMS–10450), are as follows:

Additional ICRs related to MIPS third party intermediaries (see sections V.B.8.c. and V.B.8.d. of this proposed rule):

- Self-nomination of new QCDRs (81 FR 77507 and 77508, 82 FR 53906 through 53908, and 83 FR 59998 through 60000) (OMB 0938–1314).
- Simplified self-nomination process of returning QCDRs (88 FR 79426 and 79427) (OMB 0938–1314).
- Self-nomination of new qualified registries (81 FR 77507 and 77508, 82 FR 53906 through 53908, and 83 FR 59997 and 59998) (OMB 0938–1314),
- Simplified self-nomination process of returning qualified registries (88 FR 79429) (OMB 0938–1314).
- Third party intermediary plan audits (87 FR 70140 through 70144) (OMB 0938–1314).

• Approval process for new and returning CAHPS for MIPS survey vendors (82 FR 53908) (OMB 0938–1222).
• Open Authorization Credentialing and Token Request Process (OMB 0938–1314) (85 FR 84969 and 84970).

Additional ICRs related to the data submission and the quality performance category (see section V.B.8.e. of this proposed rule):

• CAHPS for MIPS Survey completion by beneficiaries (81 FR 77509, 82 FR 53916 and 53917, and 83 FR 60008 and 60009) (OMB 0938–1222).
• Quality Payment Program Identity Management Application Process (82 FR 53914 and 83 FR 60003 and 60004) (OMB 0938–1314).

Additional ICRs related to the Promoting Interoperability performance category (see section V.B.8.g. of this proposed rule):

• Reweighting Applications for MIPS performance categories (82 FR 53918 and 83 FR 60011 and 60012) (OMB 0938–1314).

Additional ICRs related to call for new MIPS measures and activities (see sections V.B.8.i., V.B.8.f., and V.B.8.j. of this proposed rule):

• Nomination of improvement activities (82 FR 53922 and 83 FR 60017 and 60018) (OMB 0938–1314).
• Call for MIPS quality measures (83 FR 60010 and 60011) (OMB 0938–1314).
• Nomination of MVPs (85 FR 84990 through 84991) (OMB 0938–1314).

Additional ICRs related to MIPS (see section V.B.8.n. of this proposed rule):

• Opt out of performance data display on Compare Tools for voluntary reporters under MIPS (82 FR 53924 and 53925 and 83 FR 60022) (OMB 0938–1314).

Additional ICRs related to APMs (see sections V.B.8.l. and V.B.8.m. of this proposed):

• Partial QP Election (81 FR 77512 and 77513, 82 FR 53922 and 53923, and 83 FR 60018 through 60019) (OMB 0938–1314).
• Other Payer Advanced APM determinations: Payer Initiated Process (82 FR 53923 and 53924 and 83 FR 60019 through 60020) (OMB 0938–1314).
• Other Payer Advanced APM determinations: Eligible Clinician Initiated Process (82 FR 53924 and 83 FR 60020) (OMB 0938–1314).
• Submission of Data for All-Payer QP Determinations (83 FR 60021) (OMB 0938–1314).

b. ICRs Regarding the Virtual Group Election (§ 414.1315)

This rulemaking is not proposing any new or revised collection of information requirements or burden related to the virtual group election. The virtual group election requirements and burden are currently approved by OMB under control number 0938–1343 (CMS–10652). Consequently, we are not proposing any changes under that control number.

c. ICRs Regarding Third Party Intermediaries (§ 414.1400)

In sections V.B.8.c.(2)., V.B.8.c.(3)., V.B.8.c.(4)., and V.B.8.c.(5). of this proposed rule, we identify proposed adjustments to the estimated burden for ICRs regarding third party intermediaries that will be submitted to OMB for review under control number 0938–1314 (CMS–10621), as summarized in Tables 78 and 79. We note that these proposed adjustments to estimated burden are due to the availability of updated data and related assumptions as identified per ICR, rather than proposed policies or statute changes in section IV.A.4. of this proposed rule.

(1) Background

Under MIPS, the quality, Promoting Interoperability, and improvement activities performance category data may be submitted via relevant third party intermediaries, such as QCDRs and qualified registries. Data on the CAHPS for MIPS Survey, which counts as either one quality performance category measure, or towards an improvement activity, can be submitted via CMS-approved survey vendors. We refer readers to § 414.1400 for details on third party intermediary requirements. Entities seeking approval to submit data on behalf of clinicians as a QCDR, qualified registry, or survey vendor must complete a self-nomination process annually. The processes for self-nomination of entities seeking approval as QCDRs and qualified registries are similar with the exception that QCDRs have the option to nominate QCDR measures for CMS consideration for the reporting of quality performance category data. Therefore, the difference between the QCDR and qualified registry self-nomination is associated with the preparation of QCDR measures for CMS consideration. As established in the CY 2024 PFS final rule (88 FR 79425), we continue to estimate burden separately for the simplified and full self-nominations of QCDRs and qualified registries, to more accurately capture the distinct number of estimated respondents and burden per self-nomination for the different processes. In the CY 2024 PFS final rule (88 FR 79390 and 79391), we eliminated the category of health information technology (IT) vendors from MIPS third party intermediaries beginning with the CY 2025 performance period/2027 MIPS payment period.

(2) QCDR Self-Nomination Applications

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77507 and 77508, and 82 FR 53906 through 53908, respectively), and the CY 2019, CY 2020, CY 2021, CY 2022, CY 2023, and CY 2024 PFS final rules (83 FR 59998 through 60000, 84 FR 63116 through 63121, 85 FR 84964 through 84969, 86 FR 65569 through 65573, 87 FR 70138 and 70139, and 88 FR 79426 through 79429 respectively) for our previously finalized requirements and estimated burden for self-nomination of QCDRs and nomination of QCDR measures.

We are proposing to adjust burden for QCDR self-nomination applications based on updated assumptions for the number of applications and QCDR measure submissions that we expect to receive during the CY 2024 self-nomination period for the CY 2025 performance period/2027 MIPS payment year. As discussed later in this section, we are proposing to adjust our estimates for: (1) the number of QCDRs that will submit applications under the simplified and full self-nomination processes; (2) the number of QCDR measures (existing or borrowed and new measures) submitted by a QCDR; and (3) the average time required for a QCDR to submit the QCDR measure information.

(a) Simplified Self-Nomination Process and Other Requirements

We estimate that 39 existing QCDRs will submit applications under the simplified self-nomination process for the CY 2025 performance period/2027 MIPS payment year. We derive this estimate from the number of applications received during the CY 2023 QCDR self- nomination period for the CY 2024 performance period/2026 MIPS payment year, while anticipating that: (1) some QCDRs may face remedial action or termination during the CY 2024 performance period/2026 MIPS payment year, and (2) some intermediaries may electively discontinue participating as a QCDR. This estimate is a decrease of 5 respondents from the currently approved estimate of 44 for the QCDR simplified self-nomination process (88 FR 79426 and 79427).

In line with these assumptions and QCDR measure submission trends, we estimate that simplified QCDR applicants will propose 14 QCDR measures, on average, for the CY 2025 performance period/2027 MIPS

payment year, consisting of approximately 3 new QCDR measures and 11 existing or borrowed QCDR measures per QCDR. This is an increase of 1 new QCDR measure and 1 borrowed QCDR measure per QCDR from the currently approved aggregated estimate of 12 QCDR measures in the CY 2024 PFS final rule (88 FR 79426). Due to this change, we propose to adjust the estimated weighted average time required for each QCDR to submit a QCDR measure from 0.75 hours to 0.82 hours [((3 new QCDR measures × 2 hr) + (11 existing or borrowed QCDR measures × 0.5 hr)) ÷ total # of QCDR measures (14)]. We are continuing our currently approved estimated response times to submit a new QCDR measure (2 hr/response) and an existing or borrowed QCDR measure (0.5 hr/response). We are also continuing our currently approved response time of 0.5 hours required for existing QCDRs that do not submit QCDR measures under the simplified self-nomination process.

For existing QCDRs that submit QCDR measures as part of their self-nomination application, we estimate that it will take 11.98 hours [0.5 hr for the simplified self-nomination process + (14 QCDR measures × 0.82 hr/measure for QCDR measure submission)] for a QCDR to submit an application under the simplified self-nomination process. We note that this proposed change will result in an increase of 2.48 hours (11.98 hr adjusted estimate − 9.5 hr currently approved estimate) for each applicant to complete the simplified QCDR self-nomination process (88 FR 79426 and 79427).

From these assumptions, we estimate the total annual burden associated with a QCDR self-nominating to be considered ''qualified'' to submit data on behalf of MIPS eligible clinicians. As shown in Table 81, we assume that the staff involved in the simplified QCDR self-nomination process will continue to be computer systems analysts or their equivalent, who have an average adjusted labor rate of $106.54/hr. We estimate the burden per application will be $1,276.35 (11.98 hr × $106.54/hr). In aggregate and inclusive of the 2.48 hr adjustment for the CY 2025 performance period/2027 MIPS payment year, we estimate an annual burden of 467 hours (39 applications × 11.98 hr/application) at a cost of $49,778 (39 applications × $1,276.35/application) for the simplified QCDR self-nomination process.

TABLE 81: Adjusted Burden for Simplified QCDR Self-Nomination and QCDR Measure Submission

Burden and Respondent Descriptions	Burden Estimate
# of Simplified QCDR Self-Nomination Applications Submitted (a)	39
Annual Hours Per QCDR for Simplified Process (b)	11.98
Total Annual Hours for Self-Nomination (c) = (a) × (b)	**467**
Cost per Application at Labor Cost for Computer Systems Analyst at $106.54/hr (d) = $106.54/hr × (b)	$1,276.35
Total Annual Cost (e) = (a) × (d)	**$49,778**

In Table 82, we illustrate the proposed net change in estimated burden for simplified QCDR self-nomination and QCDR measure submission using the currently approved burden in the CY 2024 PFS final rule (88 FR 79426 and 79427). In aggregate, using our currently approved estimates for responses and time per response, the proposed decrease in the number of simplified QCDR self-nomination applications and the increase in the estimated burden hours per simplified QCDR self-nomination will result in a total annual adjustment of +49 hours at a cost of +$5,244 for the CY 2025 performance period/2027 MIPS payment year.

TABLE 82: Change in Estimated Burden for Simplified QCDR Self-Nomination and QCDR Measure Submission

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Time (hr) (a)	418
Total Annual Time (hr) for Respondents in CY 2025 PFS Proposed Rule (b) (See Table **81**, row (c))	467
Difference in Annual Hours (c) = (b) − (a)	**+49**
Total Currently Approved Annual Cost (d)	$44,534
Total Annual Cost for Respondents in CY 2025 PFS Proposed Rule (e) (See Table **81**, row (e))	$49,778
Difference in Annual Cost (f) = (e) − (d)	**+$5,244**

(b) Full QCDR Self-Nomination Process and Other Requirements

We estimate that 17 QCDRs will submit applications under the full self-nomination process for the CY 2025 performance period/2027 MIPS payment year. We derive this estimate from the number of applications received during the CY 2023 QCDR self-nomination period for the CY 2024 performance period/2026 MIPS payment year, while anticipating that: (1) some existing QCDRs may face remedial action and would need to complete the full self-nomination

process for the CY 2025 performance period/2027 MIPS payment year, and (2) several new QCDR self-nominations. This estimate is an increase of 5 respondents (17 revised − 12 active applications) for the QCDR full self-nomination process (88 FR 79427).

As estimated for the QCDR simplified self-nomination process in section V.B.8.c.(2)(a). of this proposed rule, we estimate that QCDR applicants completing the full self-nomination process will propose on average 14 QCDR measures for the CY 2025 performance period/2027 MIPS payment year, consisting of approximately 3 new QCDR measures and 11 existing or borrowed QCDR measures per QCDR. This is an increase of 1 new QCDR measure and 1 borrowed QCDR measure per QCDR from the currently approved aggregated estimate of 12 QCDR measures in the CY 2024 PFS final rule (88 FR 79427). Due to this change, we also propose to adjust the estimated weighted average time required for each QCDR to submit a QCDR measure from 0.75 hours (10 existing QCDR measures × 0.5 hr + 2 new QCDR measures × 2 hr) ÷ 12 total QCDR measures) to 0.82 hours (11 existing QCDR measures × 0.5 hours + 3 new QCDR measures × 2 hours) ÷ 14 total QCDR measures). We are continuing our currently approved time of 2.5 hours required for new QCDRs that do not submit QCDR measures under the full self-nomination process, and our estimated per response times for a QCDR to submit a new QCDR measure (2 hr/response) and an existing or borrowed QCDR measure (0.5 hr/response).

Due to the estimated (−5 applications = 44 active − 39 new estimate) increase in the average number of existing or borrowed QCDR measures (+1) and new QCDR measures (+1) submitted with the full self-nomination application, we estimate that it will take 13.98 hours [2.5 hr for the full self-nomination process + (14 QCDR measures × 0.82 hr/measure for QCDR measure submission)] for a QCDR to submit an application under the full self-nomination process. This proposed change will result in an overall increase of 2.48 hours (13.98 hr revised − 11.5 hr active) required for the full QCDR self-nomination application (88 FR 79428 and 79429).

From these updated assumptions, we provide an estimate of the total annual burden associated with a QCDR self-nominating to be considered ''qualified'' to submit data on behalf of MIPS eligible clinicians. In Table 83, we assume that the staff involved in the full QCDR self-nomination process will continue to be computer systems analysts or their equivalent who have an average adjusted labor rate of $106.54/hr. We estimate the burden per application will be $1,489.43 (13.98 hr × $106.54/hr). In aggregate, for the CY 2025 performance period/2027 MIPS payment year, we estimate an annual burden of 238 hours (17 applications × 13.98 hr) at a cost of $25,320 (17 applications × $1,489.43/application) for the full QCDR self-nomination process.

TABLE 83: Estimated Burden for Full QCDR Self-Nomination and QCDR Measure Submission

Burden and Respondent Descriptions	Burden Estimate
# of Full QCDR Self-Nomination Applications Submitted (a)	17
Annual Hours Per QCDR for Full Process (b)	13.98
Total Annual Hours for Full Self-nomination (c) = (a) × (b)	**238**
Cost per Application at Labor Cost for Computer Systems Analyst at $106.54/hr (d) = $106.54/hr × (b)	$1,489.43
Total Annual Cost (e) = (a) × (d)× (d)	**$25,320**

In Table 84, we use the currently approved burden as the baseline for calculating the proposed net change in burden for the full QCDR self-nomination process (88 FR 79427). For the CY 2025 performance period/2027 MIPS payment year, the proposed adjustment in the number of applicants and time per applicant results in a total annual adjustment of +100 hours at a cost of +$10,617 for the CY 2025 performance period/2027 MIPS payment year.

TABLE 84: Change in Estimated Burden for Full QCDR Self-Nomination and QCDR Measure Submission

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Time (hr) (a)	138
Total Annual Time (hr) for Respondents in CY 2025 PFS Proposed Rule (b) (See Table 83, row (c))	238
Difference in Annual Hours (c) = (b) − (a)	**+100**
Total Currently Approved Annual Cost (d)	$14,703
Total Annual Cost for Respondents in CY 2025 PFS Proposed Rule (e) (See Table 83, row (e))	$25,320
Difference in Annual Cost (f) = (e) − (d)	**+$10,617**

(3) Qualified Registry Self-Nomination Process and Other Requirements

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77507 and 77508, and 82 FR 53906 through 53908, respectively), and the CY 2019, CY 2020, CY 2021, CY 2022, CY 2023, and CY 2024 PFS final rules (83 FR 59997 and 59998, 84 FR 63114 through 63116, 85 FR 84968 and 84969, 86 FR 65573 through 65576, 87 FR 70139 and 70140, and 88 FR 79429 and 79430 respectively) for our previously finalized requirements and estimated burden for self-nomination of qualified registries.

In the CY 2024 PFS final rule (88 FR 79390 through 79391), we established the elimination of the health IT vendor category amid MIPS third party intermediary beginning with the CY 2025 performance period/2027 MIPS payment year. We believe that many third party intermediaries serve as both health IT vendors and qualified registries for the purposes of submitting data for MIPS eligible clinicians. As with our burden assumptions in the CY 2024 PFS final rule (88 FR 79425), we are not proposing any adjustments to the number of qualified registries that will submit applications for the qualified registry self-nomination process during the CY 2025 performance period/2027 MIPS payment year.

We are proposing to adjust burden for qualified registry self-nomination applications based on the number of applications we expect to receive for the CY 2025 performance period/2027 MIPS payment year. We note these proposed changes are not due to proposed policies discussed in section IV.A. of this proposed rule.

(a) Simplified Qualified Registry Self-Nomination Process

For this proposed rule, we estimate that 76 qualified registries will complete the simplified self-nomination process in CY 2025 performance period/2027 MIPS payment year. We derive this estimate from the number of applications received during the CY 2023 qualified registry self- nomination period for the CY 2024 performance period/2026 MIPS payment year, while anticipating that: (1) some qualified registries may face remedial action or termination during the CY 2024 performance period/2026 MIPS payment year, and (2) some intermediaries may electively discontinue participating as a qualified registry. This estimate is a decrease of eight applications from the currently approved estimate of 84 in the CY 2024 PFS final rule (88 FR 79429). We note that we are continuing the currently approved time of 0.5 hours for the simplified qualified registry self-nomination process.

Based on these assumptions, we estimate the total annual burden associated with a qualified registry self-nominating to be considered ''qualified'' to submit data on behalf of MIPS eligible clinicians. In Table 85, we assume that the staff involved in the simplified qualified registry self-nomination process will continue to be computer systems analysts or their equivalent, who have an average adjusted labor rate of $106.54/hr. We estimate the burden per response will be $53.27 (0.5 hr × $106.54/hr) for the simplified self-nomination process. In aggregate, we estimate that the annual burden for the simplified qualified registry self-nomination process will be 38 hours (76 applications × 0.5 hr) at a cost of $4,049 (76 applications × $53.27/application) for the CY 2025 performance period/2027 MIPS payment year.

TABLE 85: Estimated Burden for Simplified Qualified Registry Self-Nomination

Burden and Respondent Descriptions	Burden Estimate
# of Simplified Self-Nomination Applications Submitted (a)	76
Annual Hours Per Qualified Registry for Simplified Process (b)	0.5
Total Annual Hours for Simplified Self-Nomination (c) = (a) × (b)	**38**
Cost per Application at Labor Cost for Computer Systems Analyst at $106.54/hr(d) = $106.54/hr × (b)	$53.27
Total Annual Cost (e) = (a)× (d)	**$4,049**

In Table 86, we illustrate the proposed net change in estimated burden for the simplified qualified registry self-nomination using the currently approved burden in the CY 2024 PFS final rule (88 FR 79429). In aggregate, using our proposed adjustment to the number of applications results in a total annual change of minus 4 hours (42 hr active − 38 hr revised) and minus $426 ($4,475 − $4,049) for the CY 2025 performance period/2027 MIPS payment year.

TABLE 86: Change in Estimated Burden for Simplified Qualified Registry Self-Nomination

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Time (hr) (a)	42
Total Annual Time (hr) for Respondents in CY 2025 PFS Proposed Rule (b) (See Table 85, row (c))	38
Difference in Annual Hours (c) = (b) − (a)	**-4**
Total Currently Approved Annual Cost (d)	$4,475
Total Annual Cost for Respondents in CY 2025 PFS Proposed Rule (e) (See Table 85, row (e))	$4,049
Difference in Annual Cost (f) = (e) − (d)	**-$426**

(b) Full Qualified Registry Self-Nomination Process

We estimate that 30 qualified registries will submit applications under the full self-nomination process for the CY 2025 performance period/2027 MIPS payment year. We derive this estimate from the number of applications received during the CY 2023 qualified registry self- nomination period for the CY 2024 performance period/2026 MIPS payment year, while anticipating: (1) that some existing qualified registries may face remedial action during the CY 2025 performance period/2026 MIPS payment year and may need to submit full self-nomination applications, and (2) several new qualified registry applicants. This is an increase of 3 respondents from the currently approved estimate of 27 in the CY 2024 PFS final rule (88 FR 79430). We note we are continuing our currently approved per response time estimate of 2 hours for the full qualified registry self-nomination process.

Based on the assumptions discussed in this section, we provide an estimate of the total annual burden associated with a qualified registry self-nominating to be considered ''qualified'' to submit data on MIPS eligible clinicians.

In Table 87, we assume the staff involved in the qualified registry self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor rate of $106.54/hr. We estimate the burden per response will be $213.08 (2 hr × 106.54/hr) for the full qualified registry self-nomination process. In aggregate, for the CY 2025 performance period/2027 MIPS payment year, we estimate that the annual burden for the full qualified registry self-nomination process will be 60 hours (30 applications × 2 hr) at a cost of $6,392 (30 applications × $213.08/application).

TABLE 87: Estimated Burden for Full Qualified Registry Self-Nomination

Burden and Respondent Descriptions	Burden Estimate
# of Qualified Registry Full Self-Nomination Applications submitted (a)	30
Annual Hours Per Qualified Registry for Full Process (b)	2
Total Annual Hours for Full Self-Nomination (c) = (a) × (b)	**60**
Cost per Application at Labor Cost for Computer Systems Analyst at $106.54/hr (d) = $106.54/hr × (b)	$213.08
Total Annual Cost (e) = (a) × (d)	**$6,392**

In Table 88, we illustrate the proposed net change in estimated burden for the full qualified registry self-nomination process using the currently approved burden in the CY 2024 PFS final rule (88 FR 79429). In aggregate, the proposed adjustments result in a total annual adjustment of +6 hours (+3 applications × 2 hr/response) at a cost of +$639 (3 applications × $213.08/application) for the full qualified registry self-nomination process for the CY 2025 performance period/2027 MIPS payment year.

TABLE 88: Change in Estimated Burden for Full Qualified Registry Self-Nomination

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Time (hr) (a)	54
Total Annual Time (hr) for Respondents in CY 2025 PFS Proposed Rule (b) (See Table 87, row (c))	60
Difference in Annual Hours (c) = (b) − (a)	**+6**
Total Currently Approved Annual Cost (d)	$5,753
Total Annual Cost for Respondents in CY 2025 PFS Proposed Rule (e) (See Table 87, row (e))	$6,392
Difference in Annual Cost (f) = (e) − (d)	**+$639**

(4) Third Party Intermediary Plan Audits

The following proposed burden adjustments are due to the availability of updated data and assumptions, rather than proposed policy changes.

(a) Targeted Audits

In the CY 2022 PFS final rule (86 FR 65547 and 65548), we finalized that beginning with the CY 2021 performance period/CY 2023 MIPS payment year, the QCDR or qualified registry must conduct targeted audits in accordance with requirements at § 414.1400(b)(3)(vi). Consistent with our assumptions in the CY 2022 PFS, CY 2023 PFS, and CY 2024 PFS final rules for the QCDRs (86 FR 65574, 87 FR 70141, and 88 FR 79431 and 79432 respectively) and qualified registries (86 FR 65571, 87 FR 70141, and 88 FR 79431 and 79432 respectively) that would submit the results of targeted audits, we estimate that the time required for a QCDR or qualified registry to submit a targeted audit ranges between 5 and 10 hours for the simplified and full self-nomination process, respectively. We assume the staff involved in submitting the targeted audits will continue to be computer systems analysts or their equivalent, who have an average labor rate of $106.54/hr.

Due to an increase in data issues among third party intermediaries during the CY 2023 performance period/2025 MIPS payment year, we estimate that 35 third party intermediaries will submit targeted audits for the CY 2025 performance period/2027 MIPS payment year (see Table 89). We estimate that the cost for a QCDR or a qualified registry to submit a targeted audit will range from $532.70 (5 hr × $106.54/hr) to $1,065.40 (10 hr × $106.54/hr). In aggregate for the CY 2025 performance period/2027 MIPS payment year, we estimate an annual burden ranging from 175 hours (35 responses × 5 hr/audits × 5 hr/audit) and $18,645 (35 targeted audits × $532.70/audit) to 350 hours (35 audits × 10 hr/audit) and $37,289 (35 targeted audits × $1,065.40/audit) (see Table 90 for the cost per audit).

(b) Participation Plans

In the CY 2022 PFS final rule (86 FR 65546), we finalized requirements for approved QCDRs and qualified registries that did not submit performance data and therefore will need to submit a participation plan as part of their self-nomination process. We refer readers to § 414.1400(e) for to submit a participation plan as part of their self-nomination process. We refer readers to § 414.1400(e) for additional details on policies for remedial action and termination of third party intermediaries. In the CY 2020 PFS final rule (82 FR 63074), we finalized requirements for QCDRs to submit a QCDR measure participation plan in instances where a QCDR believes the low-reported QCDR measure that did not meet benchmarking thresholds is still important and relevant to a specialist's practice. We refer readers to § 414.1400(b)(4)(iii)(B)(*10*) for additional details on policies for QCDR measure participation plans.

Consistent with our assumptions in the CY 2024 PFS final rule (88 FR 79431), we estimate that it will take 2 hours for a QCDR or qualified registry to submit a participation plan. We assume the staff involved in submitting the participation plans will continue to be computer systems analysts or their equivalent, who have an average labor rate of $106.54/hr.

As shown in Table 89, following additional review of the MIPS data submission reports, we estimate that 28 third party intermediaries will submit self-nomination or QCDR measure participation plans for the CY 2025 performance period/2027 MIPS payment year. This is a decrease of 36 participation plans from the currently approved estimate of 64 (88 FR 79431). Many QCDRs submitted a QCDR measure participation plan in their self-nomination for CY 2024 performance period/2026 MIPS payment year, and therefore we anticipate limited QCDR measure participation plan for QCDR self-nominations for the CY 2025 performance period/2027 MIPS payment year.

In Table 90, we estimate that the cost for a QCDR or a qualified registry to submit a participation plan is $213.08 (2 hr × $106.54/hr). In aggregate for the CY 2025 performance period/2027 MIPS payment year, we estimate the total impact associated with QCDRs and qualified registries to submit participation plans will be 56 hours (28 participation plans × 2 hr/plan) at a cost of $5,966 ((28 participation plans × $213.08/plan) (see Table 90 for the cost per audit).

(c) Corrective Action Plans (CAPs)

In the CY 2017 Quality Payment Program final rule, we established the process for corrective action plans (CAPs) (81 FR 77386 through 77389). We refer readers to § 414.1400(e)(1)(i) for third party intermediary requirements for submitting CAPs.

We have observed a decrease in the number of CAPs required from third party intermediaries due to non-compliance with MIPS program requirements. Accordingly, we estimate 20 third party intermediaries will submit CAPs for the CY 2025 performance period/2027 MIPS payment year. This is a decrease of 4 respondents from the currently approved estimate of 24 (88 FR 79431). We are continuing our currently approved estimate of 3 hours for a QCDR or qualified registry to submit a CAP. We also assume the staff involved in submitting the CAP will continue to be computer systems analysts or their equivalent, who have an average labor rate of $106.54/hr. In Table 90, we estimate that the cost for a QCDR or a qualified registry to submit a CAP is $319.62 (3 hr × $106.54/hr). In aggregate for the CY 2025 performance period/2027 MIPS payment year, we estimate

the total impact associated with QCDRs and qualified registries to CAPs would be 60 hours (20 CAPs × 3 hr/plan) at a cost of $6,392 (20 CAPs × $319.62/plan).

(d) Transition Plans

We established a policy at § 414.1400(a)(3)(iv) that states a condition of approval for the third party intermediary is to agree that prior to discontinuing services to any MIPS eligible individual clinician, group, virtual group, subgroup, or APM Entity during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, virtual group, subgroup, or APM Entity to an alternate third party intermediary, submitter type, or, for any measure on which data has been collected, collection type according to a CMS approved transition plan. In this proposed rule, we estimate that we will receive 6 transition plans for the CY 2025 performance period/2027 MIPS payment year. This adjustment would result in a decrease of 3 transition plans from the currently approved estimate of 9 transition plans (88 FR 79431). We continue to estimate it will take 1 hour for a computer system analyst or their equivalent at a labor rate of $106.54/hr to develop a transition plan on behalf of each QCDR or qualified registry during the self-nomination period. However, we are unable to estimate the burden for implementing the actions in the transition plan because the level of effort may vary for each QCDR or qualified registry. In aggregate for the CY 2025 performance period/2027 MIPS payment year, we estimate the impact associated with QCDRs and qualified registries completing transition plans is 6 hours (6 transition plans × 1 hr/plan) at a cost of $639 (6 transition plans × $106.54/plan).

(e) Estimated Burden for Third Party Intermediary Plan Audits

In aggregate, as shown in Table 89, we assume that 89 third party intermediaries will submit plan audits for the CY 2025 performance period/2027 MIPS payment year (35 targeted audits, 28 participation plans, 20 CAPs, and 6 transition plans).

TABLE 89: Estimated Number of Respondents to Submit Plan Audits

Burden and Respondent Descriptions	# of Respondents
# of Targeted Audits (a)	35
# of Participation Plans (b)	28
# of Corrective Action Plans (CAPs) (c)	20
# of Transition Plans (d)	6
Total Respondents (e) = (a) + (b) + (c) + (d)	**89**

As shown in in Table 90, we assume that the staff involved in the submission of the plan audits during the third party intermediary self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor rate of $106.54/hr. For the CY 2025 performance period/2027 MIPS payment year, in aggregate, the proposed estimated annual burden for the submission of third party intermediary plan audits will range from 297 hours to 472 hours at a cost ranging from $31,642 and $50,286.

TABLE 90: Estimated Burden for Third Party Intermediary Plan Audits

Burden and Respondent Descriptions	Simplified Process	Full Process
# of Hours per Completion of Targeted Audit (a)	5	10
Total Annual Hours for Completion of 35 Targeted Audits (b)	**175 (5 x 35)**	**350 (10 x 35)**
# of Hours per Submission of Participation Plan (c)	2	2
Total Annual Hours for Submission of 28 Participation Plans (d)	**56 (2 x 28)**	**56 (2 x 28)**
# of Hours per Submission CAP (e)	3	3
Total Annual Hours for Submission of 20 CAPs (f)	**60 (3 x 20)**	**60 (3 x 20)**
# of Hours per Submission of Transition Plan (g)	1	1
Total Annual Hours for Submission of 6 Transition Plans (h)	**6 (6 x 1)**	**6 (6 x 1)**
Total Annual Hours for Submission of Plan Audits ((i) = (b) + (d) + (f) + (h)	**297**	**472**
Cost Per Targeted Audit (Computer Systems Analyst's Labor Rate of $106.54/hr) (j) = (a) × $106.54/hr	$532.70	$1,065.40
Cost Per Participation Plan (Computer Systems Analyst's Labor Rate of $106.54/hr) (k) = (c) × $106.54/hr	$213.08	$213.08
Cost per CAP (Computer Systems Analyst's Labor Rate of $106.54/hr)) (l) = (e) × $106.54/hr	$319.62	$319.62
Cost per Transition Plan (Computer Systems Analyst's Labor Rate of $106.54/hr (m) = (g) × $106.54/hr	$106.54	$106.54
Total Cost of Targeted Audits (n) = (j) × 35	$18,645	$37,289
Total Cost of Participation Plans (o) = (k) × 28	$5,966	$5,966
Total Cost of CAPs (p) = (l) × 20	$6,392	$6,392
Total Cost of Transition Plans (q) = (m) × 6	$639	$639
Total Annual Cost (r) = (n) + (o) + (p) + (q) (simplified) and (r) = (n) + (o) + (p) + (q) (full)	**$31,642**	**$50,286**

As shown in Table 91, for the CY 2025 performance period/2027 MIPS payment year, the change in the number of respondents for third party intermediary plan audits results in an adjustment of −57 hours at a cost of −$12,303 under the simplified self-nomination process and −27 hours at a cost of −$2,878 under the full self-nomination process. We note for the purposes of calculating estimated change in burden in Tables 77 through 79 of this proposed rule, we use only estimated burden for the plan audits submitted under the full self-nomination process.

TABLE 91: Change in Estimated Burden for Third Party Intermediary Plan Audits

Burden and Respondent Descriptions	Simplified Process	Full Process
Total Currently Approved Annual Hours (a)	354	499
Total Annual Hours for Respondents in CY 2025 PFS Proposed Rule (b) (See Table 90, row (i))	297	472
Difference in Annual Hours (c) = (b) − (a)	**-57**	**-27**
Total Currently Approved Annual Cost (d)	$43,945	$53,164
Total Annual Cost for Respondents in CY 2025 PFS Proposed Rule (e) (See Table **90**, row (r))	$31,642	$50,286
Difference in Annual Cost (f) = (e) − (d)	**-$12,303**	**-$2,878**

(5) Survey Vendor Requirements

The following proposed changes associated with CAHPS survey vendors to submit data for eligible clinicians will be submitted to OMB for review under control number 0938–1222 (CMS–10450) if the policy proposal described in section IV.A.4.j. of this proposed rule is finalized in the CY 2025 PFS final rule. We would plan to make the revised files available for public review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices.

We refer readers to § 414.1400(d) for the requirements for CMS-approved survey vendors that may submit data on the CAHPS for MIPS Survey.

In section IV.A.4.j.(1)(b). of this proposed rule, we are proposing under the current application submission requirement at § 414.1400(d)(2) that beginning with the CY 2026 performance period/2028 MIPS payment year, a survey vendor must include on its application the range of cost of its third party intermediary services (cost estimates would vary based on the level of services provided). With respect to a third party intermediary that is solely a CMS-approved survey vendor, the publishable costs would be limited to the cost of services related to the CAHPS for MIPS survey. If this proposal is finalized, we would update the CAHPS for MIPS Survey Vendor Participation Form. We would also update the CAHPS for MIPS Survey Minimum Business Requirements to detail the required survey vendor cost information. We refer readers to section IV.A.4.j.(1). of this proposed rule for additional detail.

We anticipate that the proposed fields for cost information would request cost information that is readily available to survey vendors. Therefore, we are not proposing any adjustments in burden because we assume the additional cost requirement would not add significant burden to the currently approved 10 hours per application first established in the CY 2018 Quality Payment Program final rule (82 FR 30216). We also assume this change would not affect survey vendor participation. We note that we proposed updates to our estimated burden under control number 0938–1222 (CMS–10450) as discussed in the CY 2024 PFS final rule (88 FR 79433 and 79434). The 60-day notice appeared in the **Federal Register** on October 17, 2023 (88 FR 71573), while the 30-day notice appeared on January 16, 2024 (89 FR 2622). The status for OMB's approval of the changes can be monitored at: *https://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=0938-1222*. We are not proposing any additional updates under this control number due to policies proposed in this rulemaking. We refer readers to section VII.E.17.e(2)(a) of this proposed rule for additional discussion.

The proposed change, if finalized, would result in updates to the CAHPS for MIPS Survey Vendor Participation Form and the CAHPS for MIPS Survey Minimum Business Requirements. The instrument and requirements guide are currently approved by OMB under control number 0938–1222 (CMS–10450). The CAHPS for MIPS Survey Vendor Participation Form and the CAHPS for MIPS Survey Minimum Business Requirements guide reflecting these proposed changes will be updated if the policy proposal is finalized in the CY 2025 PFS final rule as a requirement for CAHPS for MIPS survey vendors beginning in the CY 2026 performance period/2028 MIPS payment year. We will make the updated files available for public review through a stand-alone non-rule **Federal Register** notice that is expected to appear in the **Federal Register** in CY 2025 performance period/2027 MIPS payment period.

d. ICRs Regarding Open Authorization (OAuth) Credentialing and Token Request Process

This rulemaking is not proposing any new or revised collection of information requirements or burden related to the OAuth credentialing and token request process for the CY 2025 performance period/2027 MIPS payment year. The requirements and burden for the OAuth credentialing and token request process are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes to the burden for the OAuth credentialing and token request process under that control number.

e. ICRs Regarding Quality Data Submission (§§ 414.1318, 414.1325, 414.1335, and 414.1365)

(1) Background

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77502 and 77503 and 82 FR 53908 through 53912, respectively), the CY 2019, CY 2020, CY 2021, CY 2022, CY 2023, and CY 2024 PFS final rules (83 FR 60000 through 60003, 84 FR 63121 through 63124, 85 FR 84970 through 84974, 86 FR 65576 through 65588, 87 FR 70145 through 70154, and 88 FR 79434 through 79442, respectively) for our previously finalized estimated burden associated with data submission for the quality performance category.

Under our current policies, two groups of clinicians submit data for the quality performance category under MIPS: those who submit data as MIPS eligible clinicians, and those who submit data voluntarily but are not subject to MIPS payment adjustments. Clinicians are ineligible for MIPS payment adjustments if they are newly enrolled to Medicare; are QPs; are partial QPs who elect to not participate in MIPS; are not one of the clinician types included in the definition for MIPS eligible clinician; or do not exceed the low-volume threshold as an individual or as a group.

(2) Changes and Adjustments to Quality Performance Category Respondents

To determine QPs that are excluded from MIPS, we used the Advanced APM payment and patient percentages from the APM Participant List for the final snapshot date for the 2022 QP Performance period. From this data, we calculated the QP determinations as described in the Qualifying APM Participant (QP) definition at § 414.1305 for the CY 2025 performance period/2027 MIPS payment year. Due to data limitations, we could not identify specific clinicians who have not yet enrolled in Advanced APMs, but who may become QPs in the future for the CY 2025 performance period/2027 MIPS payment year (and therefore will no longer need to submit data to MIPS); hence, our model may underestimate or overestimate the number of respondents.

In this proposed rule, we use submissions data from the CY 2022 performance period/2024 MIPS payment year to estimate the number of respondents that will submit data for the CY 2025 performance period/2027 MIPS payment year. We have adjusted the estimated number of respondents that will submit data for the CY 2025 performance period/2027 MIPS payment year from the currently approved estimates, as our burden estimates for the CY 2024 PFS final rule (88 FR 79434) did not incorporate all data updates in the CY 2024 PFS final rule regulatory impact analysis model (88 FR 79503 through 79505) due to the timing of data availability. These estimates in this proposed rule reflect updated performance category submissions for the CY 2022 performance period/2024 MIPS payment year. We refer readers to sections V.B.8.e., V.B.8.g.(3)., and V.B.8.h. of this proposed rule for additional details per performance category and collection type.

We assume 100 percent of ACO APM Entities will submit quality data to CMS as required under their models. While we do not believe there is additional quality reporting for ACO APM entities, consistent with assumptions used in the CY 2021, CY 2022, CY 2023, and CY 2024 PFS final rules (85 FR 84972, 86 FR 65567, 87 FR 70145, and 88 FR 79434, respectively), we include all quality data voluntarily submitted by MIPS APM participants at the individual or TIN-level in our respondent estimates. As stated in section V.B.8.a.(4). of this proposed rule, we assume non-Shared Savings Program ACO APM Entities will participate through traditional MIPS or

MVPs and submit as an individual or group rather than as an entity. To estimate who will be a MIPS APM participant in the CY 2025 performance period/2027 MIPS payment year, we used the Advanced APM payment and patient percentages from the APM Participant List for the final snapshot date for the 2022 QP performance period. We elected to use this data source because the overlap with the data submissions for the CY 2022 performance period/2024 MIPS payment year enabled the exclusion of Partial QPs that elected to not participate in MIPS and required fewer assumptions as to who is a QP or not. Based on this information, if we determine that a MIPS eligible clinician will not be scored as a MIPS APM, then their reporting assumption is based on their reporting as a group or individual for the CY 2022 performance period/ 2024 MIPS payment year.

Our burden estimates for the quality performance category do not include the burden for the quality data that Shared Savings Program APM Entities submit to fulfill the requirements of their APMs. The associated burden is excluded from this collection of information section but is discussed in the regulatory impact analysis section of this proposed rule because sections 1899(e) and 1115A(d)(3) of the Act (42 U.S.C. 1395jjj(e) and 1315a(d)(3), respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models tested under section 1115A of the Act (or section 3021 of the Affordable Care Act) are not subject to the PRA.[788]

For the CY 2025 performance period/ 2027 MIPS payment year, respondents would have the option to submit quality performance category data via Medicare Part B claims, direct, and log in and upload submission types. We estimate the burden for collecting data via collection type: Medicare Part B claims, QCDR and MIPS CQMs, and eCQMs. We do not estimate burden for administrative claims quality measures; similar to cost measures, we automatically calculate scores for individuals, groups, virtual groups, or APM Entities that meet requirements to be scored on individual measures due to their administrative claims reporting. Additionally, we capture the burden for clinicians who choose to submit via these collection types for the quality performance category of MVPs. We believe that, while estimating burden by submission type may be better aligned with the way clinicians participate with the Quality Payment Program, it is more important to reduce confusion and enable greater transparency by maintaining consistency with previous rulemaking. In the CY 2019 PFS final rule (83 FR 59752), we finalized proposals to limit the Medicare Part B claims collection type to small practices beginning with the CY 2019 performance period/2021 MIPS payment year and to allow clinicians in small practices to report Medicare Part B claims as a group or as individuals.

Because MIPS eligible clinicians may submit data for multiple collection types for a single performance category, the estimated numbers of individual clinicians and groups to collect via the various collection types are not mutually exclusive and reflect the occurrence of individual clinicians or groups that collected data via multiple collection types during the CY 2022 performance period/2024 MIPS payment year. We captured the burden of any eligible clinician that may have historically collected via multiple collection types, as we assume they will continue to collect via multiple collection types and that our MIPS scoring methodology will take the highest score where the same measure is submitted via multiple collection types.

We are not proposing changes to the quality performance category submission burden due to the proposals discussed in section IV.A. of this proposed rule. We discuss below in this section these proposed policies and our reasons for not changing the currently approved burden for the relevant ICRs.

For the quality performance category, we are proposing to adopt minimum criteria for a qualifying data submission for a MIPS performance period. Specifically, we are proposing to specify what we consider to be a data submission at § 414.1325(a)(1)(i) to state that, for the quality performance category, a data submission must include numerator and denominator data for at least one MIPS quality measure from the final list of MIPS quality measures. Additionally, we are proposing to codify our existing policies governing our treatment of multiple data submissions received for the quality performance category at § 414.1325(f)(1). We refer readers to sections IV.A.4.d.(2)(b) and IV.A.4.d.(3)(b) for details. These proposals, if finalized, would not affect the requirements for MIPS eligible clinicians and groups that submit data for the quality performance category. We assume these proposals, if finalized, would not affect the number of quality submissions, as the intent is to eliminate certain issues with the scoring of an unintended data submission affecting payment adjustments for individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities. Therefore, we are not proposing any adjustments to our currently approved estimated burden for this ICR due to these policy proposals.

As described in the CY 2017 Quality Payment Program final rule (81 FR 77125 and 77126), to ensure that data submitted on quality measures are complete enough to accurately assess each MIPS eligible clinician's quality performance, we established a data completeness requirement. For the CY 2024 and CY 2025 performance periods/ 2026 and 2027 MIPS payment years, we increased the data completeness criteria threshold from at least 70 percent to at least 75 percent (87 FR 70049 through 70052). We maintained the data completeness criteria threshold of at least 75 percent for the CY 2026 performance period/2028 MIPS payment year (88 FR 79334 through 79337). In section IV.A.4.e.(1)(c)(i). of this proposed rule, we are proposing to maintain the data completeness criteria threshold of at least 75 percent for the CY 2027 and CY 2028 performance periods/2029 and 2030 MIPS payment years. As this data completeness threshold proposal is consistent with the existing data completeness criteria, this proposal will not affect burden for the applicable interested parties. We refer readers to section IV.A.4.e.(1)(c)(i). of this proposed rule for additional information on this proposal.

In this proposed rule, we are not proposing any new or revised collection of information requirements or burden related to the submission of Medicare Part B claims data, QCDR and MIPS CQMs, and eCQMs for the quality performance category. Several factors drive the proposed changes and adjustments for the number of clinicians submitting quality data for MIPS using each collection type. First, we incorporated the updated submission data available for the CY 2022 performance period/2024 MIPS payment year as discussed in section V.B.8.e.(7)(a). of this proposed rule. Second, our updated estimates for MVP participation impact the number of estimated clinicians submitting quality data using each collection type. In section V.B.8.e.(7)(a) of this rulemaking, we propose to adjust our estimates for the number of participants in previously finalized MVPs, due to the availability of updated data. We then propose to update this estimate to account for increased MVP participation due to the

[788] Our estimates do reflect the burden on MIPS APM participants of submitting Promoting Interoperability or improvement activities performance category data, which is outside the requirements of their APMs.

proposed addition of six new MVPs. With this approach, any proposed adjustments to increase the number of MVP participants will reduce the number of estimated submissions for each quality performance category collection type via traditional MIPS. Similarly, any proposed decreases to the number of MVP participants will increase the number of estimated submissions for each quality performance category collection type via traditional MIPS. We refer readers to sections V.B.8.e.(4)., V.B.8.e.(5)., and V.B.8.e.(6). of this proposed rule for estimated burden on each quality performance category collection type.

Table 92 uses similar methods to estimate the number of MIPS eligible clinicians that will submit data as individual clinicians via each collection type in the CY 2025 performance period/2027 MIPS payment year. For the CY 2025 performance period/2027 MIPS payment year, we estimate that approximately 13,522 clinicians will submit data as individuals using the Medicare Part B claims collection type; approximately 12,056 clinicians will submit data as individuals using MIPS CQM and QCDR collection type; and approximately 23,600 clinicians will submit data as individuals using eCQMs collection type. Based on the availability of updated data for the CY 2022 performance period/2024 MIPS payment year and updated assumptions for MVP reporting as described in section V.B.8.e.(7)(a). of this proposed rule, these are decreases of 1,216 and 1,657 respondents from the currently approved estimates of 13,413 and 22,897 for the Medicare Part B claims and eCQM collection types, respectively and an increase of 168 respondents for MIPS CQM and QCDR collection type from the currently approved estimate of 10,682.

TABLE 92: Estimated Number of Clinicians Submitting Quality Performance Category Data as Individuals by Collection Type

Burden and Respondent Description	Medicare Part B Claims	QCDR/MIPS CQM	eCQM	Total
2025 MIPS Performance Period (Excludes QPs) (a)	13,552	12,056	23,600	49,208
MVP Adjustment (10%) (b) = (a) × 0.10	-1,355	-1,206	-2,360	-4,921
2025 MIPS Performance Period (Excludes QPs and Adjusted for MVP) (c)= (a) – (b)	**12,197**	**10,850**	**21,240**	**44,287**
Currently Approved 2024 MIPS Performance Period (Excludes QPs) (d)	13,413	10,682	22,897	46,992
Difference in # of Clinicians (e) = (c) – (d)	**-1,216**	**+168**	**-1,657**	**-2,705**

Consistent with the policy finalized in the CY 2018 Quality Payment Program final rule, we established that for MIPS eligible clinicians who collect measures via Medicare Part B claims, MIPS CQM, eCQM, or QCDR collection types and submit more than the required number of measures (82 FR 53735 and 54736), we will score the clinician on the required measures with the highest assigned measure achievement points and thus, the same clinician may be counted as a respondent for more than one collection type. Therefore, our columns in Table 92 are not mutually exclusive.

Table 93 provides our estimates for the number of groups or virtual groups that will submit quality data on behalf of clinicians for each collection type in the CY 2025 performance periods/2027 MIPS payment year. We assume clinicians who submitted quality data as groups in the CY 2022 performance period/2024 MIPS payment year will continue to submit data for the quality performance category either as groups, or virtual groups for the same collection types for the CY 2025 performance period/2027 MIPS payment years. We used the same methodology described in the CY 2022 PFS final rule (86 FR 65577) on our assumptions related to the use of an alternate collection type for groups that submitted data via the CMS Web Interface collection type for the CY 2022 performance period/2024 MIPS payment year.

As shown in Table 93, for the CY 2025 performance period/2027 MIPS payment year, we estimate that 6,158 groups and virtual groups will submit data for the MIPS CQM and QCDR collection type and 5,939 groups and virtual groups will submit for the eCQM collection type. These are increases of 208 and 122 respondents from the currently approved estimates of 5,950, and 5,817 for the groups and virtual groups that will submit data using MIPS CQM and QCDR, and eCQM collection types, respectively.

TABLE 93: Estimated Number of Groups and Virtual Groups Submitting Quality Performance Category Data by Collection Type

Burden and Respondent Description	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM	Total
2025 MIPS Performance Period (Excludes QPs) (a) Prior to Adjustments	0	6,842	6,599	13,441
Adjustment for MVPs (10%) (b) = (a) × 0.10	0	-684	-660	-1,344
2025 MIPS Performance Period (Excludes QPs and) Adjusted for MVP). (c) = (a) – (b)	**0**	**6,158**	**5,939**	**12,097**
Currently Approved 2024 MIPS Performance Period (Excludes QPs) (d)	0	-5,950	-5,817	-11,767
Difference in # of Groups and Virtual Groups (e) = (c) − (d)	**0**	**+208**	**+122**	**+330**

The burden associated with the submission of quality performance category data has some limitations. We believe it is difficult to quantify the burden accurately because clinicians and groups may have different processes for integrating quality data submission into their practices' workflows. Moreover, the time needed for a clinician to review quality measures and other information, select measures applicable to their patients and the services they furnish, and incorporate the use of quality measures into the practice workflows is expected to vary along with the number of measures that are potentially applicable to a given clinician's practice and by the collection type. For example, clinicians submitting data via the Medicare Part B claims collection type need to integrate the capture of quality data codes for each encounter whereas clinicians submitting via the eCQM collection types may have quality measures automated as part of their electronic health record (EHR) implementation.

We believe the burden associated with submitting quality measures data will vary depending on the collection type selected by the clinician, group, or third party intermediary. As such, we separately estimate the burden for clinicians, groups, and third party intermediaries to submit quality measures data by the collection type used. For the purposes of our burden estimates for the Medicare Part B claims, MIPS CQM and QCDR, and eCQM collection types, we also assume that, on average, each clinician or group will submit 6 quality measures. Additionally, as finalized in the CY 2022 PFS final rule (86 FR 65394 through 65397), group tax identification numbers (TINs) could also choose to participate as subgroups for MVP reporting beginning with the CY 2023 performance period/2025 MIPS payment year. We refer readers to the CY 2022 PFS final rule for additional details on MVP quality reporting requirements (86 FR 65411 and 65412).

In terms of the quality measures available for clinicians and groups to report for the CY 2025 performance period/2027 MIPS payment year, we are proposing a measure set of 196 quality measures. The new MIPS quality measures proposed for inclusion in MIPS for the CY 2025 performance period/2027 MIPS payment year and future years are found in Table Group A of Appendix 1; MIPS quality measures with substantive changes can be found in Table Group D of Appendix 1; and MIPS quality measures proposed for removal can be found in Table Group C of Appendix 1. These measures are stratified by collection type in Table 94, as well as counts of new, removed, and substantively changed measures. There are no changes to the remaining measures not included in Appendix 1. We refer readers to Appendix 1 of this proposed rule for additional information.

TABLE 94: Summary of Quality Measure Inventory Proposed for the CY 2025 Performance Period

Collection Type	# Measures Proposed as New*	# Measures Proposed for Removal*	# Measures Proposed with a Substantive Change*	# Measures Proposed for CY 2025*
Medicare Part B Claims	0	-2	10	25
MIPS CQMs Specifications	+8	-11	60	170
eCQM Specifications	+1	-1	16	47
Survey – CSV	0	0	0	1
Administrative Claims	0	0	1	4
Total*	**+9****	**-11****	**66**	**196*****

*A measure may be specified under multiple collection types but is only counted once in the total.

**Note that one new measure and one measure removal included above were finalized in the CY 2024 PFS final rule with a 1-year delay to the CY 2025 performance period/2027 MIPS payment year.

***Three of the 196 quality measures are only available in MVPs.

For the CY 2025 performance period/2027 MIPS payment year, we are proposing 196 measures, a net decrease of 2 quality measures compared to the currently approved estimate of 198 measures. Specifically, as discussed in section IV.A.4.e.(1)(d). of this rulemaking, we are proposing to add 9 new MIPS quality measures, remove 11 MIPS quality measures, and make substantive updates to 66 MIPS quality measures. We do not anticipate our provision to remove these measures will increase or decrease the reporting burden on clinicians and groups as respondents generally are still required to submit quality data for 6 measures in traditional MIPS reporting or submit quality data for 4 measures in an MVP.

(3) Quality Payment Program Identity Management Application Process

This rulemaking does not propose any new or revised collection of information requirements or burden related to the identity management application process. We are adjusting our currently approved estimates based on updated data and assumptions. The proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

In the CY 2023 and CY 2024 PFS final rules (87 FR 70148 and 88 FR 79437), we estimated the number of eligible clinicians, groups, or third party intermediaries that register for new accounts by applying a rolling average of the number of respondents registering for new accounts. The Quality Payment Program requires users to utilize HCQIS Access Roles and Profiles (HARP), a secure identity management portal, to log into the Quality Payment Program portal. To assess the incremental change for new Quality Payment Program Identity Management application registrations, we will assess the number of unique TINs associated with new Quality Payment Program user accounts that signed into the Quality Payment Program portal for the first time in a given year. Based on this approach and new data available from March 2022 to February 2023, we propose to adjust our estimates from 6,500 to 6,237 for the number of unique TINs accessing the Quality Payment Program portal for the first time in the CY 2025 performance period/2027 MIPS payment year. This proposed adjustment will result in a decrease of 263 registrations. We do not propose to adjust the currently approved estimated time of 1 hour per response to obtain a new account. As shown in Table 95, it will take 1 hour at $106.54/hr for a computer systems analyst (or their equivalent) to obtain a HARP account, required to access the Quality Payment Program portal. In aggregate we estimate an annual burden of 6,237 hours (6,237 registrations × 1 hr/registration) at a cost of $664,490 (6,237 registrations × $106.54/registrations).

TABLE 95: Estimated Burden for Quality Payment Program Identity Management Application Process

Burden and Respondent Descriptions	Burden Estimate
# of New TINs Completing the Identity Management Application Process (a)	6,237
Total Hours Per Application (b)	1
Total Annual Hours for Completing the Identity Management Application Process (c) = (a) [x] (b)	6,237
Cost per Applicant at Computer Systems Analyst's Labor Rate of $106.54/hr(d) = $106.54/hr × (b)	$106.54
Total Annual Cost (e) = (a) × (d)	$664,490

In Table 96, we illustrate the proposed net change in estimated burden for the Quality Payment Program Identity Management Application Process using the currently approved burden in the CY 2023 PFS final rule (87 FR 70148 and 70149). In aggregate, using the currently approved per response time estimate, the proposed decrease of respondents results in a total annual adjustment of −263 hours (−263 responses × 1 hr/response) at a cost of −$28,020 (−263 responses × $106.54/response) for the CY 2025 performance period/2027 MIPS payment year.

TABLE 96: Change in Estimated Burden for Quality Payment Program Identity Management Application Process

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Time (hr) (a)	6,500
Total Annual Time (hr) for Respondents in CY 2025 PFS Proposed Rule(b) (See Table 95, row (c))	6,237
Difference in Annual Hours (c) = (b) − (a)	-263
Total Currently Approved Annual Cost (d)	$692,510
Total Annual Cost for Respondents in CY 2025 PFS Proposed Rule (e) (See Table 95, row (e))	$664,490
Difference in Annual Cost (f) = (c) − (d)	-$28,020

(4) Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type

The following proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621). In this section of this proposed rule, we propose updates to the estimated burden for the Quality Data Submission by Individuals and Groups Using Medicare Part B Claims-Based Collection Type that will be submitted to OMB for review under control number 0938–1314 (CMS–10621). As noted in Table 79, the proposed change in burden reflects adjustments for updated data and assumptions, and as well as the proposal for additional MVPs as outlined in section V.B.8.e.(4). of this proposed rule. In Table 95, we identify the changes in burden to this ICR due to the proposed policies.

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77501 through 77504 and 82 FR 53912, respectively), the CY 2019, CY 2020, CY 2021, CY 2022, CY 2023, and CY 2024 PFS final rules (83 FR 60004 and 60005, 84 FR 63124 through 63126, 85 FR 84975 and 84976, 86 FR 65582 through 65584, 87 FR 70149 through 70151, and 88 FR 79437 through 79439 respectively) for our previously finalized requirements and burden for quality data submission via the Medicare Part B claims collection type.

In this proposed rule, we are not proposing any new or revised collection of information requirements related to the submission of Medicare Part B claims data for the quality performance category. We refer readers to section V.B.8.e.(2). of this proposed rule for the factors affecting the proposed changes and adjustments for each quality performance collection type. We refer readers to Table 92 of this section for the estimated change in associated burden for quality data submissions using Medicare Part B claims data related to MVP and subgroup reporting in CY 2025 performance period/2027 MIPS payment year.

As noted in Table 92, based on updated data available for the CY 2022 performance period/2024 MIPS payment year and updated MVP reporting assumptions, we estimate that 12,197 individual clinicians will collect and submit quality data via the Medicare Part B claims collection type, a decrease of 1,216 from the currently approved estimate of 13,413 (88 FR 79437 and 79438).

In Table 97, consistent with our currently approved per response time figures and using the updated wage rates in Table 75 of this proposed rule, we continue to estimate the burden of quality data submission using Medicare Part B claims will range from 0.15 hours (9 minutes) at a cost of $15.98 (0.15 hr × $106.54) for a computer systems analyst to 7.2 hours at a cost of $767.09 (7.2 hr × $106.54/hr). The burden estimate also accounts for the effort to become familiar with MIPS quality measure specifications.

Consistent with our currently approved per response time estimates and using the updated wage rates in Table 75 of this proposed rule, we believe that the start-up cost for a clinician's practice to review measure specifications is 7 hours, consisting of 3 hours for a medical and health services manager at $129.28/hr, 1 hour for a computer systems analyst at $106.54/hr, 1 hour for a Licensed Practical Nurse (LPN) at $58.46/hr, 1 hour for a billing and posting clerk at $45.32/hr, and 1 hour for a physician at $291.64/hr.

In Table 97, considering both data submission and start-up requirements for our adjusted number of clinicians, the estimated time (per clinician using the Medicare Part B claims collection type) ranges from a minimum of 7.15 hours (0.15 hr + 7 hr) to a maximum of 14.2 hours (7.2 hr + 7 hr). In aggregate, the estimated total annual time for the CY 2025 performance period/2027 MIPS payment year ranges from 87,209 hours (7.15 hr/response × 12,197 responses) to 173,197 hours (14.2 hr/response × 12,197 responses). The total annual cost for the CY 2025 performance period/2027 MIPS payment year ranges from a minimum of $11,047,799 (12,197 responses × $905.78/response) to a maximum of $20,209,087 (12,197 responses × $1,656.89/response). For purposes of calculating total burden associated with this proposed rule as shown in Tables 77 through 79, only the maximum burden is used.

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TABLE 97 : Estimated Burden for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

Burden and Respondent Descriptions	Minimum Burden Estimate	Median Burden Estimate	Maximum Burden Estimate
# of Clinicians (a)	12,197	12,197	12,197
Hours Per Computer Systems Analyst to Submit Quality Data (b)	0.15	1.05	7.2
# of Hours Medical and Health Services Manager Review Measure Specifications (c)	3	3	3
# of Hours Computer Systems Analyst Review Measure Specifications (d)	1	1	1
# of Hours LPN Review Measure Specifications (e)	1	1	1
# of Hours Billing Clerk Review Measure Specifications (f)	1	1	1
# of Hours Physician Review Measure Specifications (g)	1	1	1
Annual Hours per Clinician (h) = (b) + (c) + (d) + (e) + (f) + (g)	7.15	8.05	14.2
Total Annual Hours (i) = (a) × (h)	**87,209**	**98,186**	**173,197**
Cost to Submit Quality Data (Computer Systems Analyst's Labor Rate of $106.54/hr at varying times) (j)	$15.98	$111.87	$767.09
Cost to Review Measure Specifications (Medical and Health Services Manager's Labor Rate of $129.28/hr for 3 hr) (k)	$387.84	$387.84	$387.84
Cost to Review Measure Specifications (Computer Systems Analyst's Labor Rate of $106.54/hr for 1 hr) (l)	$106.54	$106.54	$106.54
Cost to Review Measure Specifications (LPN's Labor Rate of $58.46/hr for 1 hr) (m)	$58.46	$58.46	$58.46
Cost to Review Measure Specifications (Billing Clerk's Labor Rate of $45.32/hr) (n)	$45.32	$45.32	$45.32
Cost to Review Measure Specifications (Physician's Labor Rate of $291.64/hr) (o)	$291.64	$291.64	$291.64
Total Annual Cost Per Clinician (p) = (j) + (k) + (l) + (m) + (n) + (o)	$905.78	$1,001.67	$1,656.89
Total Annual Cost (q) = (a) × (p)	**$11,047,799**	**$12,217,369**	**$20,209,087**

In Table 98, we illustrate the net change in estimated burden for quality data submissions from clinicians using the Medicare Part B Claims-based collection type using the currently approved burden in the CY 2024 PFS final rule (88 FR 79438 and 79439). In aggregate, using our currently approved per response time estimates, the decrease in number of responses from 13,413 to 12,197 (−1,216) (Table 92) will result in a total maximum adjustment of −17,268 hours at a cost of −$2,014,779 for the CY 2025 performance period/2027 MIPS payment year. For purposes of calculating total burden associated with this proposed rule as shown in Tables 77 through 79, only the maximum burden is used.

TABLE 98: Change in Estimated Burden for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	190,465
Total Annual Hours for Respondents in CY 2025 PFS Proposed Rule (b) (see Table 97, row (i))	173,197
Difference in Annual Hours (c) = (b) − (a)	**-17,268**
Total Currently Approved Annual Cost (d)	$22,223,866
Total Annual Cost for Respondents in CY 2025 PFS Proposed Rule (e) (see Table 97, row (q))	$20,209,087
Difference in Annual Cost (f) = (d) − (e)	**-$2,014,779**

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(5) Quality Data Submission by Individuals and Groups Using MIPS CQM and QCDR Collection Types

In this section, we identify proposed updates to the estimated burden for the Quality Data Submission by Individuals and Groups Using MIPS CQM and QCDR Collection Types ICR that will be submitted to OMB for review under control number 0938–1314 (CMS–10621). As noted in Table 79, the proposed change in burden reflects adjustments for updated data and assumptions, and as well as the proposal for additional MVPs as outlined in section V.B.8.e.(4). of this proposed rule. In Table 146 (section VII.E.17.e.(1).), we identify the changes in burden to this ICR due to the proposed policies.

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77504 and 77505 and 82 FR 53912 and 53914, respectively), the CY 2019, CY 2020, CY 2021, CY 2022, CY 2023, and CY 2024 PFS final rules (83 FR 60005 and 60006, 84 FR 63127 and 63128, 85 FR 84977 through 84979, 86 FR 65584 through 65586, and 87 FR 70151 through 70153, and 88 FR 79439 through 79441, respectively) for our previously finalized requirements and burden for quality data submission via the MIPS CQM and QCDR collection types. We refer readers to Table 105 for the estimated change in associated burden for quality data submission using MIPS CQM and QCDR collection types related to MVP and subgroup reporting in the CY 2025 performance period/2027 MIPS payment year. We refer readers to section V.B.8.e.(2). of this proposed rule for the factors affecting the proposed changes and adjustments for each quality performance collection type.

As noted in Tables 92 and 93, based on updated data available from the CY 2022 performance period/2024 MIPS payment year and updated MVP reporting assumptions, for the CY 2025 performance period/2027 MIPS payment year, we estimate that 17,008 clinicians (10,850 individuals and 6,158 groups and virtual groups) will submit quality data as individuals or groups using MIPS CQM or QCDR collection types. This is an increase of 376 clinicians from the currently approved estimate of 16,632 clinicians provided in the CY 2024 PFS final rule (88 FR 79439 through 79441). Given the number of measures required for clinicians and groups is the same, we expect the burden to be the same for each respondent collecting data via MIPS CQM or QCDR, whether the clinician is participating in MIPS as an individual or group.

Under the MIPS CQM and QCDR collection types, the individual clinician or group may either submit the quality measures data directly to us, log in and upload a file, or utilize a third party intermediary to submit the data to us on the clinician's or group's behalf. We estimate that the burden associated with the QCDR collection type is similar to the burden associated with the MIPS CQM collection type; therefore, we discuss the burden for both collection types together. For MIPS CQM and QCDR collection types, we estimate an additional time for respondents (individual clinicians and groups) to become familiar with MIPS quality measure specifications and, in some cases, specialty measure sets and QCDR measures. Therefore, we believe the burden for an individual clinician or group to review measure specifications and submit quality data is a total of 9 hours at a cost of $1,088.98 per response. This consists of 3 hours at $106.54/hr for a computer systems analyst (or their equivalent) to submit quality data along with 2 hours at $129.28/hr for a medical and health services manager, 1 hour at $106.54/hr for a computer systems analyst, 1 hour at $58.46/hr for a LPN, 1 hour at $45.32/hr for a billing clerk, and 1 hour at $291.64/hr for a physician to review measure specifications. Additionally, clinicians and groups who do not submit data directly will need to authorize or instruct the qualified registry or QCDR to submit quality measures' results and numerator and denominator data on quality measures to us on their behalf. We estimate the time and effort associated with authorizing or instructing the quality registry or QCDR to submit this data will be approximately 5 minutes (0.083 hr) at $106.54/hr for a computer systems analyst at a cost of $8.84 (0.083 hr × $106.54/hr). Overall, we estimate 9.083 hr/response (3 hr + 2 hr + 1 hr + 1 hr + 1 hr + 1 hr + 0.083 hr) at a cost of $1,088.98/response [(3 hr × $106.54/hr) + (2 hr × $129.28/hr) + (1 hr × $106.54/hr) + (1 hr × $58.46/hr) + (1 hr × $45.32/hr) + (1 hr × $291.64/hr) + (0.083 hr × $106.54/hr)].

In Table 99, for the CY 2025 performance period/2027 MIPS payment year, in aggregate, we estimate a burden of 154,484 hours (9.083 hr/response × 17,008 responses) at a cost of $18,521,372 (17,008 responses × $1,088.98/response).

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TABLE 99: Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM and QCDR Collection Type

Burden and Respondent Descriptions	Burden Estimate
# of Clinicians Submitting as Individuals (a)	10,850
# of Groups Submitting via QCDR or MIPS CQM on Behalf of Individual Clinicians (b)	6,158
Total # of Respondents (c) = (a) + (b)	**17,008**
# of Hours Per Respondent to Report Quality Data (d)	3
# of Hours per Medical and Health Services Manager to Review Measure Specifications (e)	2
# of Hours for Computer Systems Analyst to Review Measure Specifications (f)	1
# of Hours for LPN to Review Measure Specifications (g)	1
# of Hours for Billing Clerk to Review Measure Specifications (h)	1
# of Hours for Physician to Review Measure Specifications (i)	1
# of Hours Per Respondent to Authorize Qualified Registry to Report on Respondent's Behalf (j)	0.083
Annual Hours Per Respondent (k)= (d) + (e) + (f) + (g) + (h) + (i) + (j)	9.083
Total Annual Hours (l) = (c)×(k)	**154,484**
Cost Per Respondent to Submit Quality Data (at Computer Systems Analyst's Labor Rate of $106.54/hr) (m) = $106.54/hr × (d)	$319.62
Cost to Review Measure Specifications (at Medical and Health Services Manager's Labor Rate of $129.28/hr) (n) = $129.28/hr × (e)	$258.56
Cost per Computer System's Analyst Review of Measure Specifications (at Computer Systems Analyst's Labor Rate of $106.54/hr) (o) = $106.54/hr × (f)	$106.54
Cost per LPN to Review Measure Specifications (at LPN's Labor Rate of $58.46/hr) (p) = $58.46/hr × (g)	$58.46
Cost per Billing Clerk to Review Measure Specifications at Clerk's Labor Rate of $45.32/hr) (q) = $45.32/hr × (h)	$45.32
Cost for Physician to Review Measure Specifications (at Physician's Labor Rate of $291.64/hr) (r) = $291.64/hr × (i)	$291.64
Cost for Respondent to Authorize Qualified Registry/QCDR to Report on Respondent's Behalf (at Computer Systems Analyst's Labor Rate of $106.54/hr) (s) = $106.54/hr × (j)	$8.84
Total Annual Cost Per Respondent (t) = (m) + (n) + (o) + (p) + (q) + (r) + (s)	$1,088.98
Total Annual Cost (u) = (c) × (t)	**$18,521,372**

In Table 100, we calculated the net change in estimated burden for quality performance category submissions using the MIPS CQM and QCDR collection type by using the currently approved burden in the CY 2024 PFS final rule (88 FR 79439 through 79441). In aggregate, using the unchanged currently approved time per response estimate, the increase of 376 respondents from 16,632 to 17,008 for the CY 2025 performance period/2027 MIPS payment year results in an increase of 3,416 hours at a cost of +$409,457.

TABLE 100: Change in Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM and QCDR Collection Type

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	151,068
Total Annual Hours for Respondents in CY 2025 PFS Proposed Rule (b) (see Table 99, row (l))	154,484
Difference in Annual Hours (c) = (b) − (a)	**+3,416**
Total Currently Approved Annual Cost (d)	$18,111,915
Total Annual Cost for Respondents in CY 2025 PFS Proposed Rule (e) (see Table 99, row (u))	$18,521,372
Difference in Annual Cost (f) = (e) − (d)	**+$409,457**

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(6) Quality Data Submission by Clinicians and Groups: eCQM Collection Type

In this section, we identify proposed updates to the estimated burden for the Quality Data Submission by Individuals and Groups Using eCQM Collection Type ICR that will be submitted to OMB for review under control number 0938–1314 (CMS–10621). As noted in Table 79, this proposed change in burden reflects adjustments for updated data and assumptions, and as well as the proposal for additional MVPs as outlined in section V.B.8.e.(4). of this proposed rule. In Table 146 (section VII.E.17.e.(1).of this proposed rule), we identify the changes in burden to this ICR due to the proposed policies.

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77505 and 77506 and 82 FR 53914 and 53915), CY 2019, CY 2020, CY 2021, the CY 2022 PFS, the CY 2023, and the CY 2024 PFS final rule (83 FR 60006 and 60007, 84 FR 63128 through 63130, 85 FR 84979 and 84980, 86 FR 65586 through 65588, 87 FR 70153 and 70154, and 88 FR 79441 through 79443 respectively) for our previously finalized requirements and burden for quality data submission via the eCQM collection types. For the change in associated burden for quality data submission related to the provisions introducing MVP and subgroup reporting beginning in the CY 2025 performance period/2027 MIPS payment year, we refer readers to Table 105. We refer readers to section V.B.8.e.(2). of this proposed rule for the factors affecting the proposed changes and adjustments for each quality performance collection type.

As noted in Tables 92 and 93, based on updated data available from the CY 2022 performance period/2024 MIPS payment year and updated MVP reporting assumptions, we assume that 27,179 clinicians (21,240 individual clinicians and 5,939 groups and virtual groups) will submit quality data using the eCQM collection type for the CY 2025 performance period/2027 MIPS payment year. This is a decrease of 1,535 clinicians from the currently approved estimate of 28,714 clinicians in the CY 2024 PFS final rule (88 FR 78818)). We assume the burden to be the same for each respondent using the eCQM collection type, whether the clinician is participating in MIPS as an individual or group.

Under the eCQM collection type, the individual clinician or group may either submit the quality measures data directly to us from their eCQM, log in and upload a file, or utilize a third party intermediary to derive data from their certified electronic health record technology (CEHRT) and submit it to us on the clinician's or group's behalf.

To prepare for the eCQM collection type, the clinician or group must review the quality measures on which we will be accepting MIPS data extracted from eCQMs, select the appropriate quality measures, extract the necessary clinical data from their CEHRT, and submit the necessary data to a QCDR/qualified registry to submit the data on behalf of the clinician or group. We assume the burden for collecting quality measures data via eCQM is similar for clinicians and groups who submit their data directly to us from their CEHRT and clinicians and groups who use a QCDR or qualified registry to submit the data on their behalf. This includes extracting the necessary clinical data from their CEHRT and submitting the necessary data to a QCDR/qualified registry. We note that the CY 2024 PFS final rule eliminated the category of health IT vendors for the Quality Payment Program beginning in the CY 2025 performance period/2027 MIPS payment period (88 FR 79390 and 79391).

We estimate that it will take no more than 2 hours at $106.54/hr for a computer systems analyst or their equivalent to submit the data file. The burden will also involve becoming familiar with MIPS quality measure specifications. In this regard, we estimate it will take 6 hours for a clinician or group to review measure specifications. Of that time, we estimate 2 hours at $129.28/hr for a medical and health services manager, 1 hour at $291.64/hr for a physician, 1 hour at $106.54/hr for a computer systems analyst, 1 hour at $58.46/hr for an LPN, and 1 hour at $45.32/hr for a billing clerk. Overall, we estimate a cost of $973.60/response [(2 hr × $106.54/hr) + (2 hr × $129.28/hr) + (1 hr × $106.54/hr) + (1 hr × $58.46/hr) + (1 hr × $45.32/hr) + (1 hr × $4291.64/hr)].

In Table 101, for the CY 2025 performance period/2027 MIPS payment year, in aggregate, we estimate a burden of 217,432 hours (8 hr × 27,179 responses) at a cost of $26,461,474 (27,179 responses × $973.60/response).

TABLE 101: Estimated Burden for Quality Performance Category: Clinicians (Submitting Individually or as Part of a Group) Using the eCQM Collection Type

Burden and Respondent Descriptions	Burden Estimate
# of Clinicians Submitting as Individuals (a)	21,240
# of Groups Submitting via EHR on Behalf of Individual Clinicians (b)	5,939
Total # of Respondents (c)=(a)+(b)	**27,179**
# of Hours Per Respondent to Submit MIPS Quality Data File (d)	2
# of Hours Per Medical and Health Services Manager to Review Measure Specifications (e)	2
# of Hours Per Computer Systems Analyst to Review Measure Specifications (f)	1
# of Hours Per LPN to Review Measure Specifications (g)	1
# of Hours Per Billing Clerk to Review Measure Specifications (h)	1
# of Hours Per Physician to Review Measure Specifications (i)	1
Annual Hours Per Respondent (j) = (d) + (e) + (f) + (g) + (h) + (i)	8
Total Annual Hours (k) = (c) × (j)	**217,432**
Cost Per Respondent to Submit Quality Data (at Computer Systems Analyst's Labor Rate of $106.54/hr) (l) = $106.54/hr × (d)	$213.08
Cost to Review Measure Specifications (at Medical and Health Services Manager's Labor Rate of $129.28/hr) (m) = $129.28/hr × (e)	$258.56
Cost to Review Measure Specifications (at Computer System's Analyst's Labor Rate of $106.54/hr) (n) = $106.54/hr × (f)	$106.54
Cost to Review Measure Specifications (at LPN's Labor Rate of $58.46/hr) (o) = $58.46/hr × (g)	$58.46
Cost to Review Measure Specifications (at Clerk's Labor Rate of $45.32/hr) (p) = $45.32/hr) × (h)	$45.32
Cost to Review Measure Specifications (at Physician's Labor Rate of $291.64/hr) (q) = $291.64/hr × (i)	$291.64
Total Cost Per Respondent (r)=(l)+(m)+(n)+(o)+(p)+(q)	$973.60
Total Annual Cost (s) = (c) × (r)	**$26,461,474**

In Table 102, we illustrate the net change in burden for submissions in the quality performance category using the eCQM collection type from the currently approved burden in the CY 2024 PFS final rule (88 FR 79441 and 79442). In aggregate, using our currently approved time per response burden estimate, the decrease of 1,535 respondents from 28,714 to 27,179 for the CY 2025 performance period/2027 MIPS payment year results in a decrease of 12,280 hours (1,535 responses × 8 hr/response) at a cost of −$1,494,476 (−1,535 response) at a cost of −$1,494,476 (−1,535 responses × $973.60/response).

TABLE 102: Change in Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the eCQM Collection Type

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	229,712
Total Annual Hours for respondents in CY 2025 PFS Proposed Rule (b) (see Table 101, row (k))	217,432
Difference in Annual Hours (c) = (b) − (a)	**-12,280**
Total Currently Approved Annual Cost (d)	$27,955,950
Total Annual Cost for Respondents in CY 2025 PFS Proposed Rule (e) (see Table 101, row (s))	$26,461,474
Difference in Annual Cost (f) = (e) − (d)	**-$1,494,476**

(7) ICRs Regarding Burden for MVP Reporting

The following proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

(a) Burden for MVP Reporting Requirements

In the CY 2022 PFS final rule, we finalized an option for clinicians choosing to report MVPs to participate through subgroups beginning with the CY 2023 performance period/2025 MIPS payment year (86 FR 65392 through 65394). We refer readers to the CY 2022, CY 2023, and CY 2024 PFS final rules for our previously finalized burden assumptions and requirements for submission data for the MVP performance category, and for the estimated number of clinicians participating as subgroups in the CY 2024 performance period/2026 MIPS payment year (86 FR 65590 through 65592, 87 FR 70155, and 88 FR 79443).

As discussed in section II.G.2. of this proposed rule, we are proposing to make payment for advanced primary care management(APCM) services furnished by a physician or other qualified health care professional who is responsible for all primary care (for example, physicians and non-physician practitioners, including nurse practitioners, physician assistants, certified nurse-midwives and clinical nurse specialists), and serve as the continuing focal point for all needed health care services during a calendar month. This proposed payment would incorporate several specific, existing care management and communication technology-based services into a bundle and require reporting the Value in Primary Care MVP by clinicians billing for APCM services beginning in the CY 2025 performance period/2027 MIPS payment year. We are proposing that billing practitioners who are not MIPS eligible clinicians (as defined at § 414.1305) would not be required to report the MVP in order to furnish and bill for APCM services. Based on our approach for estimating MVP as a percentage of previous traditional MIPS quality submissions discussed in section V.B.8.e.(7)(a)(i).of this proposed rule, we are unable to determine how many additional clinicians or practices would report the Value in Primary Care MVP for the CY 2025 performance period/2027 MIPS payment year above our current MVP submission estimates. Similarly, we cannot assess what participation levels clinicians or practices who may use these APCM codes, if finalized, have reported MIPS in the past (for example, eligibility requirements and special statuses, participation at the individual, group, virtual group, or Alternative Payment Model (APM) Entity level, or reporting via traditional MIPS, the APM Performance Pathway (APP), or MVPs), or if they will be MIPS eligible clinicians in future years. We refer readers to section II.G.2. of this proposed rule for details on this proposal, and section VII.E.17.e.(2)(f) for additional discussion on burden impacts to the Quality Payment Program.

In the CY 2024 PFS final rule (88 FR 79442), we conducted an analysis to calculate the average quality measure submission rate for each newly proposed MVP for the CY 2024 performance period/2026 MIPS payment period, using measures submissions in the CY 2021 performance period/2023 MIPS payment year for clinicians with relevant clinical specialties for each proposed MVP. The total of these average quality measure submissions for each MVP was equivalent to about 2 percent of total quality measure submissions in the CY 2021 performance period/2023 MIPS payment year. We added this incremental increase of 2 percentage points to the previously approved estimate in the CY 2023 PFS final rule that 12 percent of clinicians who participated in MIPS for the CY 2021 performance period/2023 MIPS payment year will submit data for the quality performance category through MVP reporting in the CY 2023 performance period/2025 MIPS payment year (88 FR 79443).

With updated submission data available for the CY 2022 performance period/2024 MIPs payment year as discussed in section V.B.8.e.(3). of this proposed rule and updated quality measure list revisions within the MVP inventory for the CY 2024 performance period/2026 MIPS payment year (88 FR 79978 through 80047), we conducted the analysis identified in the preceding paragraph for the 16 MVPs approved for the CY 2024 performance period/2026 MIPS payment year. The total of these average quality measure submissions for each approved MVP was equivalent to 6 percent of the total quality measure submissions in the CY 2022 performance period/2024 MIPS payment year. This is a decrease from the 14 percent estimate provided in the CY 2024 PFS final rule (88 FR 79443).

As discussed in section IV.A.4.a.(1). of this proposed rule, we are proposing modifications to the 16 MVPs approved for the CY 2024 performance period/2026 MIPS payment year reporting with the addition and removal of measures and improvement activities based on the MVP development criteria (85 FR 84849 through 84854). We are proposing to consolidate the previously finalized Optimal Care for Patients with Episodic Neurological Conditions MVP and Supportive Care for Neurodegenerative Conditions MVP into a consolidated neurological MVP titled Quality Care for Patients with Neurological Conditions. We are also proposing to add six (6) new MVPs to the MVP inventory. These proposals would provide 21 MVPs for the CY 2025 performance period/2027 MIPS payment year.

For each newly proposed MVP, we similarly calculated the average quality measure submission rate across the measures available in each MVP for the CY 2022 performance period/2024 MIPS payment year. Using updated data available from the CY 2022 performance period/2024 MIPS payment year, we calculated that the total of these average quality measure submissions for each proposed MVP was equivalent to about 4 percent of total quality measure submissions. We assume there would not be any changes to MVP submissions due to the proposal to consolidate the measures in the Optimal Care for Patients with Episodic Neurological Conditions MVP and Supportive Care for Neurodegenerative Conditions MVP into the Quality Care for Patients with Neurological Conditions MVP. That is, we assume clinicians who would have submitted the Optimal Care for Patients with Episodic Neurological Conditions MVP or the Supportive Care for Neurodegenerative Conditions MVP would instead submit the Quality Care for Patients with Neurological Conditions MVP. Therefore, we estimate the proposed changes to the MVP inventory in this proposed rule will result in an additional 4 percent of MIPS clinicians moving from traditional MIPS to MVP reporting.

Taking together the aforementioned analyses where we assessed the MVP participation rate for the 16 established MVPs at 6 percent using updated quality measure submission data from the CY 2022 performance period/2024 MIPS payment year, and the assessment that 4 percent of MIPS clinicians may move to the six proposed MVPs due to quality measure submission trends for the CY 2022 performance period/2024 MIPS payment year, we estimate that a total of 10 percent of the clinicians will participate in MVP reporting in the CY 2025 performance period/2027 MIPS payment year. This is a decrease of 4 percentage points from the currently approved estimate of 14 percent in the

CY 2024 PFS final rule (88 FR 79443). This decrease reflects the updated analysis of MVP submissions for established MVPs (from 14 percent to 4 percent) to account for the latest available MIPS submission data, and the additional 6 percent of MIPS clinicians we believe may report the 6 newly proposed MVPs due to updated quality measure submission data.

Continuing our approach used in the CY 2022, CY 2023, and CY 2024 PFS final rules (86 FR 65589 and 65590, 87 FR 70156 and 701566, and 88 FR 79443 and 79444, respectively), we assume that the number of MVP registrations will equal our estimated MVP quality submissions. We note the MVP registration window for the 12 MVPs available for the CY 2023 performance period/2025 MIPS payment year closed on November 30, 2023. As noted in section IV.A.3.b.(2). of this proposed rule, we received over 750 MVP registrations for the CY 2023 performance period/2025 MIPS payment year. MIPS submission data for the CY2023 performance period/2025 MIPS payment year was unavailable while preparing these burden estimates. We will reassess our approach as needed in future rules when both MVP registration and submission data are available for the same performance period.

(i) Burden for MVP Registration: Individuals, Groups and APM Entities

We refer readers to the CY 2024 PFS final rule (88 FR 79443 and 79444) for our previously finalized burden relevant to MVP registration for clinicians participating as an individual and/or group for MVP reporting.

In the CY 2022 PFS final rule (86 FR 65414), we finalized at § 414.1365(c)(4)(ii) that an MVP Participant is scored on one population health measure in accordance with § 414.1365(d)(1). Since the MVP population health measures are administrative claims-based, they do not require data submission from clinicians and do not contribute to reporting burden. To track which population health measure an MVP Participant intends to report, we finalized in the CY 2022 PFS final rule (86 FR 65417) at § 414.1365(b)(2)(i) that MVP Participants are required to select one population health measure at the time of MVP registration.

MVP Participants currently select one population measure during registration (86 FR 65589), via a drop-down list. In section IV.A.4.b.(1)(b) of this proposed rule, we are proposing to update the registration process and scoring policies for population health measures in the quality performance category. We are proposing to revise § 414.1365(d)(3)(i)(A) to state that for the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, MVP Participants will be scored on the selected population health measure and beginning in the CY 2025 performance period/2027 MIPS payment year, we would use the highest score of all available population health measures. To apply this policy to subgroups reporting an MVP, we also propose to update § 414.1365(d)(3)(i)(A)(*1*) to provide that for the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, subgroups will be scored on the selected population health measure based on its affiliated group score, if available, and beginning in the CY 2025 performance period/2027 MIPS payment year a subgroup is scored on the highest score of all available population health measures based on its affiliated group score, if available. We propose to revise § 414.1365(b)(2)(i) to provide that beginning in the CY 2025 performance period/2027 MIPS payment year, each MVP Participant must select an MVP and any outcomes-based administrative claims-based measure on which the MVP Participant intends to be scored. We refer readers to section IV.A.4.b.(1) of this rulemaking for details on this proposal and scoring implications. This proposal would remove the requirement for the MVP Participant to select a population health measure during MVP registration. We assume the associated reduction in burden per application would be minimal. Therefore, we are not adjusting the burden per MVP registration from the currently approved registration time of 15 minutes (0.25 hr) (88 FR 79443 and 79444).

As discussed, we estimate that approximately 10 percent of the clinicians that currently participate in MIPS will submit data for the measures and activities in an MVP. For the CY 2025 performance period/2027 MIPS payment year, we assume that the total number of individual clinicians, groups, subgroups and APM Entities that will complete the MVP registration process is 6,285. In Table 103, we estimate that it will take 1,571 hours (6,285 responses × 0.25 hr/response) at a cost of $167,432 (6,285 registrations × $26.64/registration) for individual clinicians, groups and APM Entities to register for MVP reporting in the CY 2025 performance period/2027 MIPS payment year.

TABLE 103: Estimated Burden for MVP Registration (Individuals, Groups, Subgroups, and APM Entities)

Burden and Respondent Descriptions	Burden Estimate
Estimated # of Individual Clinicians, Groups, Subgroups and APM Entities Registering (a)	6,285
Estimated Time Per Registration (hr) (b)	0.25
Estimated Total Annual Time for MVP Registration (c) = (a) × (b)	**1,571**
Computer Systems Analyst's Labor Rate (d)	$106.54/hr
Estimated Cost Per Registration (e) = (d) × (b)	$26.64
Estimated Total Annual Cost for MVP Registration ((f) = (a) × (e)	**$167,432**

In Table 104, we illustrate the net change in burden for MVP registration using the currently approved burden in the CY 2024 PFS final rule (88 FR 79443 and 79444). In aggregate, for the CY 2025 performance period/2027 MIPS payment year, the change in the number of respondents expected to register for MVP reporting from 9,585 to 6,285 will result in a decrease of 3,300 responses. In aggregate, when combined with the currently approved per response time estimate, this will result in a decrease of 825 hours (−3,300 responses × 0.25hr/

response) at a cost of −$87,912 (−3,300 responses × $26.64/response).

TABLE 104: Change in Estimated Burden for MVP Registration (Individuals, Groups, Subgroups, and APM Entities)

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	2,396
Total Annual Hours for Respondents in CY 2025 PFS Proposed Rule (b) (See Table 103, row (c))	1,571
Difference in Annual Hours (c) = (b) − (a)	**-825**
Total Currently Approved Annual Cost (d)	$255,344
Total Annual Cost for Respondents in CY 2025 PFS Proposed Rule (e) (See Table 103, row (e))	$167,432
Difference in Annual Cost (f) = (e) − (d)	**-$87,912**

(ii) Burden for Subgroup Registration

We are not proposing any changes to our currently approved subgroup registration burden (86 FR 65590) of 10 annual hours (20 responses at 0.5hr/response). As discussed in section V.B.8.e.(7)(a) of this proposed rule, we assume the proposal to remove the selection of a population health measure at the time of registration, as detailed in section IV.A.4.b.(1)(b). of this proposed rule, will not significantly impact the currently approved burden for MVP registration. We continue this assumption to subgroup registration. Therefore, we are continuing our currently approved burden for subgroup registration time of 30 minutes (0.5 hr).

We expect clinician participation in subgroups will be relatively low for the CY 2025 performance period/2027 MIPS payment year due to the voluntary subgroup reporting option and the additional burden involved for groups to organize clinicians into subgroups. Therefore, we are not proposing any adjustments to our previously finalized estimate in the CY 2022 PFS final rule (86 FR 65590) that 20 subgroups will participate in MVP reporting.

As identified in section IV.A.3.c.(1) of this proposed rule, we finalized a mandatory subgroup reporting requirement for multispecialty groups choosing to report as an MVP Participant beginning in the CY 2026 performance period/2028 MIPS payment year (§ 414.1305; 86 FR 65394 through 65397). Section IV.A.3.d. of this proposed rule includes a Request for Information (RFI) to obtain feedback on what guidance/parameters are needed for multispecialty groups to place clinicians into subgroups for reporting an MVP relevant to the scope of care provided. Absent available submission data on MVP reporting as discussed in section V.B.8.e.(7)(a). of this proposed rule, we are unable to estimate the effect of this established policy on reporting for the CY 2026 performance period/2028 MIPS payment. We refer readers to section VII.E.17.e.(2)(g). of this proposed rule for additional discussion on burden impacts of this established policy to the Quality Payment Program.

The burden relevant to the subgroup registration requirement is currently approved by OMB under control number 0938–1314 (CMS–10621). Since this rulemaking is not proposing any new or revised subgroup registration requirements or burden, we are not proposing any changes under that control number.

(iii) Burden for MVP Quality Performance Category Submission

In the CY 2022 PFS final rule (86 FR 65411 through 65415), we finalized the reporting requirements for the MVP quality performance category at § 414.1365(c)(1)(i).

In sections IV.A.4.d.(2)(b). and IV.A.4.d.(3).(b). of this proposed rule, we are proposing to adopt minimum criteria for a qualifying data submission for a MIPS performance period for the quality performance category and to codify our existing policies governing our treatment of multiple submissions received for the quality performance category. In accordance with our discussion of this policy proposal relevant to traditional MIPS quality reporting in section V.B.8.e.(2). of this proposed rule, these proposed policies will not introduce new requirements to submit data for the quality performance category of MVPs. Therefore, we are continuing our currently approved per response time estimates for submitting the MVP quality performance category data due to this proposal.

As described in section V.B.8.e.(7)(a) of this proposed rule, we estimate that 10 percent of the clinicians who participated in MIPS for the CY 2022 performance period/2024 MIPS payment year will submit data for the quality performance category of MVP in the CY 2025 performance period/2027 MIPS payment year. We also estimate there will be 20 subgroup reporters in the CY 2025 performance period/2027 MIPS payment year. In Table 105, we estimate that 3,020 clinicians and 10 subgroups will submit data using eCQMs collection type at $644.93/response (see line q for eCQMs); 1,890 clinicians and 10 subgroups will submit data using MIPS CQM and QCDR collection type at $716.31/response (see line q for CQM and QCDRs); and 1,355 clinicians and 0 subgroups will submit data for the MVP quality performance category using the Medicare Part B claims collection type at $1,101.24/response (see line q for claims). For the CY 2025 performance period/2027 MIPS payment year, using our currently approved per response time estimates for the clinicians and subgroups submitting data for the MVP quality performance category, we estimate a burden of 16,059 hours [5.3 hr × 3,030 (3,020 + 10) responses] at a cost of $1,954,138 (3,030 responses × $644.93/response) for the eCQM collection type, 11,343 hours [5.97 hr × 1,900 (1,890 + 10 responses)] at a cost of $1,360,989 (1,900 responses × $716.31/response) for the MIPS CQM and QCDR collection type, and 12,791 hours (9.44 hr × 1,355 clinician responses) at a cost of $1,492,180 (1,355 responses ×

$1,101.24/response) for the Medicare Part B claims collection type.

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TABLE 105: Estimated Burden for MVP Quality Performance Category Submission

Burden and Respondent Descriptions	eCQM Collection Type	CQM and QCDR Collection Type	Claims Collection Type
# of Submissions from Pre-existing collection types (a)	3,020	1,890	1,355
# of Subgroup Reporters (b)	10	10	0
Total MVP Participants (c) = (a) + (b)	**3,030**	**1,900**	**1,355**
Hours Per Computer Systems Analyst to Submit Quality Data (d)	1.33	2	4.8
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	1.33	1.33	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	0.66	0.66	0.66
# of Hours LPN Review Measure Specifications (g)	0.66	0.66	0.66
# of Hours Billing Clerk Review Measure Specifications (h)	0.66	0.66	0.66
# of Hours Physician Review Measure Specifications (i)	0.66	0.66	0.66
Annual Hours per Clinician Submitting Data for MVPs (j) = (d) + (e) + (f) + (g) + (h) + (i)	5.3	5.97	9.44
Total Annual Hours (k) = (c) × (j)	**16,059**	**11,343**	**12,791**
Cost to Submit Quality Data (at Computer Systems Analyst's Labor Rate of $106.54/hr) (l) = $106.54/hr × (d) varying times	$141.70	$213.08	$511.39
Cost to Review Measure Specifications (at Medical and Health Services Manager's Labor Rate of $129.28/hr) (m) = $129.28/hr × (e) varying times	$171.94	$171.94	$258.56
Cost to Review Measure Specifications (at Computer Systems Analyst's Labor Rate of $106.54/hr) (n) = $106.54/hr × (f)	$70.32	$70.32	$70.32
Cost to Review Measure Specifications (at LPN's Labor Rate of $58.46/hr) (o) = $58.46/hr × (g)	$38.58	$38.58	$38.58
Cost to Review Measure Specifications (at Billing Clerk's Labor Rate of $45.32/hr) (p) = $45.32/hr × (h)	$29.91	$29.91	$29.91
Cost to Review Measure Specifications (at Physician's Labor Rate of $291.64/hr) (q) = $291.64/hr × (i)	$192.48	$192.48	$192.48
Total Annual Cost Per Submission (r) = (l) + (m) + (n) + (o) + (p) + (q)	$644.93	$716.31	$1,101.24
Total Cost (s) = (c) × (r)	**$1,954,138**	**$1,360,989**	**$1,492,180**

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Table 106 illustrates the changes in estimated burden for clinicians who will submit the MVP quality performance category utilizing the

eCQM, MIPS CQM and QCDR, and Medicare Part B claims collection types in the CY 2025 performance period/2027 MIPS payment year. We note we used the currently approved burden in the CY 2024 PFS final rule (88 FR 79444 through 79446) as the baseline to determine the net change in burden. In aggregate, when combined with our currently approved per response time estimate, the decrease in 3,300 respondents who will submit data for the MVP quality performance category will result in a change of −8,766 hours and −$1,066,714 for the eCQM collection type, −4,877 hours and −$585,225 for the CQM and QCDR collection type, and −7,826 hours and −$912,928 for the Medicare Part B claims collection type.

TABLE 106: Change in Estimated Burden for MVP Quality Performance Category Submission

Burden and Respondent Descriptions	eCQM Collection Type	CQM and QCDR Collection Type	Claims Collection Type
Total Currently Approved Annual Hours (a)	24,825	16,220	20,617
Total Annual Hours for Respondents in CY 2025 PFS Proposed Rule (b) (See Table 105, row (k))	16,059	11,343	12,791
Difference in Annual Hours (c) = (b) − (a)	**-8,766**	**-4,877**	**-7,826**
Total Currently Approved Annual Cost (d)	$3,020,852	$1,946,214	$2,405,108
Total Annual Cost for Respondents in CY 2025 PFS Proposed Rule (e) (See Table 105, row (s))	$1,954,138	$1,360,989	$1,492,180
Difference in Annual Cost (f) = (e) − (d)	**-$1,066,714**	**-$585,225**	**-$912,928**

(8) Beneficiary Responses to CAHPS for MIPS Survey

We are not proposing any new or revised collection of patient experience information from survey respondents during the administration of the CAHPS for MIPS Survey for the CY 2025 performance period/2027 MIPS payment year. We note that we proposed updates to our estimated burden under control number 0938–1222 (CMS–10450) as discussed in the CY 2024 PFS final rule (88 FR 79446 and 79447), which were submitted under the standard non-rule PRA package. The 60-day notice for public comment for this PRA package appeared in the **Federal Register** on October 17, 2023 (88 FR 71573), and the 30-day notice for public comment appeared in the **Federal Register** on January 16, 2024 (89 FR 2622). Since this rulemaking is not proposing any new or revised CAHPS for MIPS survey requirements or burden for this ICR, we are not proposing any changes for this ICR under that control number.

(9) Group Registration for CAHPS for MIPS Survey

We are not proposing any new or revised collection of information requirements or burden related to group registration for the CAHPS for MIPS Survey for the CY 2025 performance period/2027 MIPS payment year. We note that we proposed updates to our estimated burden under control number 0938–1222 (CMS–10450) as discussed in the CY 2024 PFS final rule (88 FR 79447 and 79448), which were submitted under the standard non-rule PRA package. The 60-day notice for this PRA package appeared in the **Federal Register** on October 17, 2023 (88 FR 71573), while the 30-day notice appeared on January 16, 2024 (89 FR 2622). Since this rulemaking is not proposing any new or revised CAHPS for MIPS survey requirements or burden for this ICR, we are not proposing any changes for this ICR under that control number.

f. ICRs Regarding the Call for MIPS Quality Measures

In this section of this proposed rule, we identify proposed adjustments to the estimated burden for the Call for MIPS Quality Measures ICR, that will be submitted to OMB for review under control number 0938–1314 (CMS–10621). These proposed adjustments are summarized in Tables 78 and 79. We are not proposing any new or revised collection of information requirements related to the call for MIPS quality measures. However, based on quality measure submissions received for CMS' consideration during the 2023 MIPS Annual Call for Quality Measures, we are adjusting our burden estimates for the CY 2025 performance period/2027 MIPS payment year. In the CY 2024 PFS proposed rule (88 FR 52662) and the CY 2024 PFS final rule (88 FR 79448), we inadvertently noted we that we derived our estimates of 31 responses from submissions during the 2023 MIPS Annual Call for Quality Measures; we derived these estimated response from data for the 2022 MIPS Annual Call for Quality Measures. The proposed estimates in this proposed rule reflect submission changes from the 2022 and 2023 MIPS Annual Call for Quality Measures, and do not reflect proposed policies or statute changes in this proposed rule.

In this proposed rule, we estimate that we will receive 16 quality measure submissions during the 2025 MIPS Annual Call for Quality Measures, a decrease of 15 from the currently approved number of quality measure submissions for consideration (88 FR 79448 and 79449). We are not proposing any changes to the 5.5 hour (2.4 hr for practice administrator + 3.1 hr for clinician) per response time estimate for quality measure submissions.

In Table 107, we estimate an annual burden of 88 hours (16 measure submissions × 5.5 hr/measure) at a cost of $19,430 (16 measure submissions × $1,214.35/submission for the CY 2025 performance period/2027 MIPS payment year).

TABLE 107: Estimated Burden for Call for Quality Measures

Burden and Respondent Descriptions	Burden Estimate
# of New Quality Measures Submitted for Consideration (a)	16
# of Hours per Practice Administrator to Identify, Propose and Link Measure (b)	2.4
# of Hours per Clinician to Identify and Link Measure (c)	1.1
# of Hours per Clinician to Complete Peer Review Article Form (d)	2
Annual Hours Per Response (e) = (b) + (c) + (d)	5.5
Total Annual Hours (f)=(a)×(e)	**88**
Cost to Identify and Submit Measure (at Medical and Health Services Manager's Labor Rate of $129.28/hr) (g) = $129.28/hr × (b)	$310.27
Cost to Identify Quality Measure and Complete Peer Review Article Form (at Clinician's Labor Rate of $291.64/hr) (h) = $291.64/hr × [(c) + (d)]	$904.08
Total Annual Cost Per Submitted Measure (i) = (g) + (h)	$1,214.35
Total Annual Cost (j)=(a)×(i)	**$19,430**

In Table 108, we illustrate the net change in estimated burden for the call for quality measures using the currently approved burden in the CY 2024 PFS final rule (88 FR 79448 and 79449). In aggregate, the estimated decrease in the number of quality measure submissions will result in an adjustment of −83 hours (−15 measure submissions × 5.5 hr/measure submission) at a cost of −$18,215 (−15 measure submissions × $1,214.35/measure submission) for the CY 2025 performance period/2027 MIPS payment year.

TABLE 108: Change in Estimated Burden for Call for Quality Measures

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours for Respondents (a)	171
Total Annual Hours for Respondents in CY 2025 PFS Proposed Rule (b) (See Table 107, row (f))	88
Difference in Annual Hours (c) = (b) − (a)	**-83**
Total Currently Approved Annual Cost for Respondents (d)	$37,645
Total Annual Cost for Respondents in CY 2025 PFS Proposed Rule (e) (See Table 107, row (j))	$19,430
Difference in Annual Cost (f) = (e) − (d)	**-$18,215**

g. ICRs Regarding Promoting Interoperability Data (§§ 414.1375 and 414.1380)

(1) Background

For the CY 2025 performance period/2027 MIPS payment year, MIPS eligible clinicians, groups, subgroups, and APM Entities can submit Promoting Interoperability performance category data through direct log in and upload or log in and attest submission types. We note that the log in and attest submission type is only available for the Promoting Interoperability performance category and is not available for the quality performance category. With the exception of submitters who elect to use the log in and attest submission type for the Promoting Interoperability performance category, we anticipate that MIPS eligible individual clinicians, groups, subgroups, and APM Entities will use the same data submission type for both the quality and Promoting Interoperability performance categories and that the clinicians, practice managers, and computer systems analysts involved in supporting the quality data submission will also support the Promoting Interoperability data submission process. The following burden estimates show only incremental hours required above and beyond the time already accounted for in the quality data submission process. We note that this analysis assesses burden by performance category and submission type and emphasizes that MIPS is a consolidated program. We analyzed data submitted by MIPS eligible clinicians, groups, subgroups and APM Entities, and assessed clinician performance based on all the four MIPS performance categories, as applicable.

(2) Reweighting Applications for MIPS Performance Categories

The following proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77240 through 77243), CY 2018 Quality Payment Program final rule (82 FR 53918 and 53919), and the CY 2019, CY 2020, CY 2021, CY 2022, CY 2023, and CY 2024 PFS final rules (83 FR

60011 and 60012, 84 FR 63134 and 63135, 85 FR 84984 and 84985, 86 FR 65596 through 65598, 87 FR 70160 through 70162, and 88 FR 79449 and 97450, respectively) for our previously finalized requirements for, and our analysis of the information collection and reporting burden associated with, reweighting applications for the four MIPS performance categories.

As established in the CY 2017 and CY 2018 Quality Payment Program final rules, MIPS eligible clinicians may submit an application requesting reweighting to zero percent for the Promoting Interoperability, quality, cost, and/or improvement activities performance categories under specific circumstances as set forth in § 414.1380(c)(2), including, but not limited to, extreme and uncontrollable circumstances, significant hardship, or other exceptions (81 FR 77240 through 77243, 82 FR 53680 through 53686, and 82 FR 53783 through 53785).

Respondents (MIPS eligible individual clinicians, groups, or APM Entities) who apply for reweighting of the quality, cost, and/or improvement activities performance categories have the option of applying for reweighting of the Promoting Interoperability performance category on the same online form. We assume respondents applying for a reweighting of the Promoting Interoperability performance category due to extreme and uncontrollable circumstances will also request a reweighting of at least one of the other performance categories simultaneously and not submit multiple reweighting applications.

In section IV.A.4.i.(2) of this proposed rule, we are proposing to adopt a new reweighting policy at § 414.1380(c)(2)(i)(A)(*10*) and (c)(2)(i)(C)(*12*). Specifically, we are proposing that, beginning with the CY 2024 performance period/2026 MIPS payment year, that we may reweight one or more of the performance categories (that is, quality, improvement activities, or Promoting Interoperability) where we determine, based on information submitted to us on or before November 1st of the year preceding the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because the MIPS eligible clinician delegated submission of the data to their third party intermediary, evidenced by a written agreement between the MIPS eligible clinician and third party intermediary, and the third party intermediary did not submit the data for the performance category(ies) on behalf of the MIPS eligible clinician in accordance with applicable deadlines. Since MIPS eligible clinicians do not submit data separately for measures in the cost performance category and we score cost measures based solely on Medicare claims data, the proposed reweighting policy does not apply to the cost performance category. We also are proposing that, to determine whether to apply reweighting to the affected performance category(ies), we would consider: whether the MIPS eligible clinician knew or had reason to know of the issue with its third party intermediary's submission of the clinician's data for the performance category(ies); whether the MIPS eligible clinician took reasonable efforts to correct the issue; and whether the issue between the MIPS eligible clinician and their third party intermediary caused no data to be submitted for the performance category(ies) in accordance with applicable deadlines. Because we believe these occurrences would be rare based on our experience with related requests for reweighting, and the extent and source of documentation provided to us for each event may vary considerably, we are not proposing any changes to our currently approved burden estimates for this proposal. We refer readers to section VII.E.17.e.(2)(e). of this proposed rule for additional discussion on these burden estimates.

Table 109 summarizes our analysis of the estimated burden, including for MIPS eligible clinicians to apply for reweighting of one or more of the MIPS performance categories to zero percent due to an extreme or controllable circumstance, significant hardship, or other exception as provided in § 414.1380(c)(2)(i).

We are updating our burden estimates relevant to this ICR based on the number of reweighting applications received for the CY 2023 performance period/2025 MIPS payment year by January 2, 2024, that do not cite the public health emergency (PHE) for COVID–19 (PHE for COVID–19) as the basis for reweighting. The Federal PHE for COVID–19 under section 319 of the Public Health Service Act ended on May 11, 2023.[789] As a result of the end of the PHE, MIPS eligible clinicians will no longer be able to submit a reweighting application citing hardships from the PHE for COVID–19; therefore, we are excluding reweighting applications citing the PHE for COVID–19 in our estimate for CY 2025 performance period/2027 MIPS payment year reweighting applications. In this proposed rule, we estimate that we will receive a total of 3,297 applications to request reweighting for any or all of the four MIPS performance categories for the CY 2025 performance period/2027 MIPS payment year. Of the 3,297, we estimate that 2,490 MIPS eligible clinicians or groups will submit a request that includes reweighting the Promoting Interoperability performance category to zero percent due to a significant hardship or other exception as provided in § 414.1380(c)(2)(i)(C). and we estimate that 802 MIPS eligible clinicians or groups will submit a request to reweight one or more of the MIPS performance categories as provided in § 414.1380(c)(2)(i). Additionally, we estimate 5 APM Entities will submit an extreme and uncontrollable circumstances exception application to reweight one or more MIPS performance category for the CY 2025 performance period/2027 MIPS payment year. This adjustment, due to both updated data and the end of the PHE for COVID–19, results in a decrease of 25,930 respondents compared to our currently approved estimate of 29,227 respondents (88 FR 79449 and 79450). We note the currently approved estimate included reweighting applications citing the PHE for COVID–19.

Consistent with our assumptions in the CY 2024 PFS final rule (88 FR 79449 and 79450), we continue to estimate it will take 0.25 hours at $106.54/hr for a computer system analyst to complete and submit the reweighting application. In Table 109, we estimate an annual burden of 824 hours (3,297 applications × 0.25 hr/application) at a cost of $87,832 (3,297 applications × $26.64/application) for the CY 2025 performance period/2027 MIPS payment year.

[789] *https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html.*

TABLE 109: Estimated Burden for Reweighting Applications for MIPS Performance Categories

Burden and Respondent Descriptions	Burden Estimate
# of Eligible Clinicians or Groups Applying Due to Significant Hardship and Other Exceptions or Extreme and Uncontrollable Circumstances (a)	3,292
# APM Entities Requesting Extreme and Uncontrollable Circumstances Exception (b)	5
Total Applications Submitted (c)	**3,297**
Annual Hours Per Applicant per Application Submission (d)	0.25
Total Annual Hours (e) = (c) × (d)	**824**
Cost to Submit a Reweighting Application at Computer Systems Analyst's Labor Rate of $106.54/hr (f) = (d) × $106.54/hr (f)	$26.64
Total Annual Cost (g) = (c) × (f)	**$87,832**

In Table 110, we illustrate the net change in estimated burden for submission of reweighting applications for MIPS performance categories using the currently approved burden in the CY 2024 PFS final rule (88 FR 79449 and 79450). The adjustment in the estimated number of respondents, from 29,227 to 3,297 respondents, results in a decrease of 25,930 respondents. In aggregate, using our currently approved per response time estimate, as shown in Table 110, the decrease in 25,930 respondents results in an adjustment of −6,483 hours and −$690,775 the CY 2025 performance period/2027 MIPS payment year.

TABLE 110: Change in Estimated Burden for Reweighting Applications for MIPS Performance Categories

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours in CY 2024 PFS Final Rule (a)	7,307
Total Annual Hours for Respondents in CY 2025 PFS Proposed Rule (b) (See Table 109, row (e))	824
Difference in Annual Hours (c) = (b) − (a)	**-6,483**
Total Currently Approved Annual Cost in CY 2024 PFS Final Rule (d)	$778,607
Total Annual Cost for Respondents in CY 2025 PFS Proposed Rule (e) (See Table 109, row (g))	$87,832
Difference in Annual Cost (f) = (e) − (d)	-$690,775

(3) Submitting Promoting Interoperability Data

The following proposed changes relevant to the submission of Promoting Interoperability data requirements and burden will be submitted to OMB for review under OMB under control number 0938–1314 (CMS–10621).

We note that we adjusted the burden estimates from the currently approved CY 2024 PFS final rule (88 FR 79451 through 79453) to incorporate updated available MIPS submission data for the CY 2022 performance period/2024 MIPS payment year, as discussed in section V.B.8.e.(3). of this proposed rule. We are not proposing changes based on the proposals discussed in section IV.A. of this proposed rule. In the following paragraphs, we discuss these proposed policies and our rationale for maintaining the currently approved burden for the submission of Promoting Interoperability data requirements.

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77509 through 77511, and 82 FR 53919 and 53920, respectively), and the CY 2019, CY 2020, CY 2021, CY 2022, CY 2023, and CY 2024 PFS final rules (83 FR 60013 and 60014, 84 FR 63135 through 63137, 85 FR 84985 through 84987, 86 FR 65598 through 65600, 87 FR 70162 through 70164, and 88 FR 79451 through 79453, respectively) for our previously finalized requirements and burden for submission of data for the Promoting Interoperability performance category. We refer readers to § 414.1375 for our previously established policies regarding reporting for the Promoting Interoperability performance category. We also refer readers to § 414.1305 for the definition of attestation, § 414.1325 for data submission requirements, and § 414.1380(b)(4) for Promoting Interoperability performance category scoring. We refer readers to § 414.1380(c)(2)(i)(C) for our previously finalized policies regarding scoring of data submission in the Promoting Interoperability performance category after an approved reweighting for the performance category.

In section IV.A.4.d.(2)(d) of this proposed rule, we are proposing to adopt minimum criteria for a qualifying data submission for the Promoting Interoperability performance category at § 414.1325(a)(1)(iii). Currently, an incomplete data submission would void an approved reweighting of the Promoting Interoperability performance category in accordance with § 414.1380(c)(2)(i)(C). This proposal would clarify what counts as a data submission for MIPS eligible clinicians

and it would potentially avoid partial data submissions from overriding an approved reweighting or a previously scored submission for the Promoting Interoperability performance category. Specifically, we propose that a qualifying data submission for the Promoting Interoperability performance category must include all the following elements: (1) performance data, including any claim of an applicable exclusion, for the measures in each objective, as specified by CMS; (2) required attestation statements, as specified by CMS; specified by CMS; (3) CMS EHR Certification ID (CEHRT ID) from the Certified Health IT Product List (CHPL); and (4) the start date and end date for the applicable performance period as set forth in § 414.1320. If we receive a qualifying data submission meeting the proposed minimum criteria for reporting, then we will review the data submission and score the Promoting Interoperability performance category in accordance with our applicable scoring policies. We refer readers to section IV.A.4.d.(2)(d) of this proposed rule for additional background and details on this proposal. We are not proposing any changes to the existing scoring or reweighting policies described under § 414.1380 for the MIPS performance categories in this section IV.A.4.d. Our current estimates assume that PI submissions include all requirements for scoring; therefore, we are not adjusting our established per response time estimate.

In section IV.A.4.d.(3)(c). of this proposed rule, we are also proposing to modify our policy governing our treatment of multiple data submissions received for the Promoting Interoperability performance category, which we propose to codify at § 414.1325(f)(2). Specifically, we are proposing that, in cases where CMS receives multiple submissions for the Promoting Interoperability performance category, CMS would calculate a score for each data submission received and assign the highest of the scores.

In our analysis of the information collection and reporting burden, we are not adjusting our estimated number of respondents submitting Promoting Interoperability data. These proposals intend to significantly reduce certain issues with the scoring of unintended data submissions affecting MIPS payment adjustments for individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities. These two proposals may limit the unintentional overriding of an approved reweighting or an existing scoreable submission. Our currently approved per response estimates incorporate the required measures and attestations and other required data elements identified in sections IV.A.4.d.(2)(d). and IV.A.4.d.(3)(c). of this proposed rule.

In the CY 2022 PFS final rule, we finalized at § 414.1365(c)(4)(i) that an MVP Participant is required to meet the Promoting Interoperability reporting requirements. We also finalized at § 414.1365(c)(4)(i)(A) the requirements for a subgroup participating in MVP reporting (86 FR 65413 and 65414). Specifically, we stated that for the CY 2023 and 2024 MIPS performance periods/2025 and 2026 MIPS payment years, an MVP Participant that is a subgroup is required to submit its affiliated group's data for the Promoting Interoperability performance category. The submission of the affiliated group's data will be on the subgroup's behalf. If the affiliated group chooses to report as a group for the Promoting Interoperability performance category, the group will still be required to submit its own data separately and in accordance with the reporting rules for groups. In section IV.A.4.b.(4). of this rulemaking, we are proposing to modify § 414.1365(c)(4)(i)(A) by removing the references to the specific MIPS performance periods/payment years to state that an MVP Participant that is a subgroup is required to submit its affiliated group's data for the Promoting Interoperability performance category. The proposed change would allow a subgroup to submit the affiliated group's data for the MVP Promoting Interoperability performance category for the CY 2025 performance period/2027 MIPS payment year and beyond. As this proposal would not create new reporting requirements, there are no burden implications for this proposal.

The Department of Health and Human Services (HHS) final rule, 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking (hereafter referred to as the Disincentives final rule) was released on June 24, 2024 (*https://www.healthit.gov/topic/information-blocking#Disincentives*). Section IV.A.4.e.(4)(d). of this proposed rule summarizes several policies in the Disincentives final rule under which a MIPS eligible clinician that the Office of Inspector General determines has committed information blocking would not be a meaningful EHR user, and therefore would be unable to earn a score (instead earning a score of zero) for the Promoting Interoperability performance category. We note the Disincentives final rule described in section IV.A.4.e.(4)(d). of this proposed rule would not create any additional reporting, recordkeeping, or third party disclosure requirements. Consequently, we are not proposing any updates in this proposed rule.

In sections IV.A.4.e (4)(e)(iii) of this proposed rule, we note that we recently released the CMS Interoperability and Prior Authorization final rule which appeared in the **Federal Register** on February 8, 2024 (89 FR 8758). In the CMS Interoperability and Prior Authorization final rule final rule, we finalized the addition of a new measure, the ''Electronic Prior Authorization'' measure, under the Health Information Exchange (HIE) objective for the MIPS Promoting Interoperability performance category beginning with the CY 2027 performance period/2029 MIPS payment year (89 FR 8909 through 8927). The burden estimate for MIPS clinicians to report the ''Electronic Prior Authorization measure'' was provided in the CMS Interoperability and Prior Authorization final rule (89 FR 8953 through 8956). In the CMS Interoperability and Prior Authorization final rule final rule, we identified that this measure will be included in a PRA package related to the CMS Interoperability and Prior Authorization final rule (89 FR 8946). Consequently, we are not proposing any updates in this proposed rule.

Due to the availability of updated data on the Promoting Interoperability submissions during the CY 2022 performance period/2024 MIPS payment year, we are adjusting our currently approved estimated burden for the submission of data in Promoting Interoperability performance category (88 FR 79451 and 79452). In Table 111, we estimate that a total number of 18,609 respondents, consisting of 14,500 individual MIPS eligible clinicians, 4,089 groups and virtual groups, and 20 subgroups will submit data for the Promoting Interoperability performance category in the CY 2025 performance period/2027 MIPS payment year.

As noted in section V.B.8.a.(1)(a) of this proposed rule, we have not updated our Quality Payment Program burden estimates to reflect MIPS Promoting Interoperability reporting requirements of non-MIPS eligible clinicians due to requirements for the Shared Savings Program. For MIPS eligible clinicians participating in an APM, we continue our assumption from the CY 2023 PFS final rule (87 FR 70163) and CY 2024 PFS final rule (88 FR 79451) that each MIPS eligible clinician in an APM Entity reports data for the Promoting Interoperability performance category through either their group TIN or individual reporting in the CY 2019 PFS final rule, we established that MIPS

eligible clinicians who participate in the Shared Savings Program are no longer limited to reporting for the Promoting Interoperability performance category through their ACO participant TIN (83 FR 59822 and 59823). Burden estimates for this proposed rule assume group TIN-level reporting as we believe this is the most reasonable assumption for MIPS eligible clinicians in the Shared Savings Program, which requires that ACOs include full TINs as ACO participants. Accordingly, we assume that any Promoting Interoperability data submitted at the APM-Entity level adheres to APM or Shared Savings Program requirements. Sections 1899 and 1115A of the Act (42 U.S.C. 1395jjj and 42 U.S.C. 1315a, respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models are not subject to the PRA.

TABLE 111: Estimated Number of Respondents to Submit Promoting Interoperability Performance Data

Burden and Respondent Descriptions	# of Respondents
# of Individual Clinicians to Submit Promoting Interoperability in CY 2025 Performance Period (a)	14,500
# of Groups to Submit Promoting Interoperability in CY 2025 Performance Period (b)	4,089
# of Subgroups to Submit Promoting Interoperability in MVPs during the CY 2025 Performance Period (c)	20
Total Respondents in CY 2025 Performance Period (d) = (a) + (b) + (c)	**18,609**
Currently Approved Respondents (2024 PFS Final Rule) (e)	25,990
Difference in # of Respondents (f) = (d) – (e)	**-7,381**

As shown in Table 112, we are continuing our currently approved estimated time of 2.70 hours per response. Therefore, we estimate that it will result in a total burden of 50,244 hours (18,609 respondents × 2.70 incremental hours for a computer analyst's time above and beyond the physician, medical and health services manager, and computer system's analyst time required to submit quality data) and $5,353,065 (18,609 responses × $287.66/response) to submit data for the Promoting Interoperability performance category in the CY 2025 performance period/2027 MIPS payment year.

TABLE 112: Estimated Burden for Promoting Interoperability Performance Category Data Submission

Burden and Respondent Description	Burden Estimate
Number of Individual Clinicians to Submit Promoting Interoperability (a)	14,500
Number of Groups to Submit Promoting Interoperability (b)	4,089
Number of Subgroups to Submit Promoting Interoperability (c)	20
Total Respondents (d) = (a) + (b) + (c)	**18,609**
Annual Hours Per Respondent (e)	2.70
Total Annual Hours (f) = (d) × (e)	**50,244**
Cost per Respondent to Submit Promoting Interoperability Data at Computer System Analyst's Labor Rate $106.54 (g) = (e) × $106.54/hr (g)	$287.66
Total Annual Cost (h) = (d) × (g)	**$5,353,065**

In Table 113, we illustrate the change in burden for clinicians to submit data in the Promoting Interoperability performance category for the CY 2025 performance period/2027 MIPS payment year. In aggregate, we estimate that the decrease in the number of respondents from 25,990 to 18,609 will result in an adjustment of −19,929 hours (−7,381 respondents × 2.70 hr/response) and −$2,123,218.

TABLE 113: Change in Estimated Burden for Promoting Interoperability Performance Category Data Submission

Burden and Respondent Description	Burden Estimate
Total Currently Approved Annual Hours (a)	70,173
Total Annual Hours for Respondents in CY 2025 PFS Proposed Rule (b) (see Table 112, row (f))	50,244
Difference in Annual Hours (c) = (b) − (a)	**-19,929**
Total Currently Approved Annual Cost (d)	$7,476,283
Total Annual Cost for Respondents in CY 2025 PFS Proposed Rule (e) (see Table 112, row (h))	$5,353,065
Difference in Annual Cost (f) = (e) − (d)	**-$2,123,218**

h. ICRs Regarding Improvement Activities Submission (§§ 414.1305, 414.1355, 414.1360, and 414.1365)

The following proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621)

We are not proposing changes due to the improvement activities proposals discussed in section IV.A. of this proposed rule. In the following paragraphs, we discuss these proposed policies and our reasons for not changing the currently approved per response burden for improvement activities submission.

In section IV.A.4.e.(3)(b)(iv) of this proposed rule, we are proposing two scoring and reporting policy changes for the improvement activities performance category effective for the CY 2025 performance period/2027 MIPS payment year and subsequent years. First, we are proposing to eliminate the weighting of improvement activities. In the CY 2017 Quality Payment Program final rule, we established a differentially weighted model for the improvement activities performance category with two categories, medium and high, to provide flexible scoring (81 FR 28210). In that rule (81 FR 77177 and 77178), we codified at § 414.1380(b)(3) that clinicians (except for non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic health professional shortage areas (HPSAs)) receive 10 points for each medium-weighted improvement activity and 20 points for each high-weighted improvement activity. Non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs receive 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity.

Second, we are proposing to further simplify improvement activity reporting requirements by reducing the number of activities to which clinicians are required to attest to achieve a score in the improvement activities performance category, beginning in the CY 2025 performance period/2027 MIPS payment year. Currently, MIPS eligible clinicians are required to report two high-weighted activities, four medium-weighted activities, or one high-weighted and two medium-weighted activities while MVP participants are currently required to report one high-weighted activity or two medium-weighted activities. We are proposing that MIPS eligible clinicians who participate in traditional MIPS would be required to report two activities and MVP participants would be required to report one activity to achieve 40 points, or full credit. In addition, we are proposing that MIPS eligible clinicians who are categorized as small practice, rural, in a provider-shortage area, or non-patient facing would now be required to report one activity (for either traditional MIPS or MVPs).

We established our currently approved estimate that it will take a computer analyst 5 minutes to log in and manually attest that improvement activities were completed in the CY 2019 PFS final rule (83 FR 60016). We believe the proposed removal of weighting for improvement activities will decrease burden for MIPS eligible clinicians who previously reported medium-weighted activities. As MIPS eligible clinicians who previously only reported high-weighted activities will have the same attestation requirements under this proposal, we are not proposing a change to our currently estimated per response burden. We refer readers to section VII.E.17.e.(2)(c). of this proposed rule where we discuss our impact analysis for this proposal.

In section IV.A.4.e.(3)(b)(iii) of this rulemaking, we are also proposing changes to the improvement activities inventory for the CY 2025 performance period/2027 MIPS payment year and future years as follows: adding two new improvement activities; modifying two existing improvement activities; and removing eight previously adopted improvement activities. In the CY 2023 PFS final rule (87 FR 70211) and the 2024 PFS final rule (88 FR 79519), we anticipated that most clinicians performing improvement activities, to comply with existing MIPS policies, will continue to perform the same activities because previously finalized improvement activities continue to apply for the current and future years unless otherwise modified per rulemaking (82 FR 54175). We believe this proposal will not significantly affect burden because the majority of activities are not revised. We refer readers to section VII.E.17.e.(2)(b) of this proposed rule where we discuss our impact analysis for this proposal, and section VII.E.17.e.(2)(c) where we discuss the impact analysis for modifications to modifications to improvement activities scoring and reporting policies. As discussed in section IV.A.4.d.(2)(c) in this proposed rule, we previously finalized at § 414.1360(a)(2) that MIPS eligible clinicians, groups, virtual groups, or subgroups must submit a yes response for each improvement activity that is performed for at least a continuous 90-day period during the applicable performance period to receive points in the improvement activities performance category described under § 414.1360(b)(3). We currently assign a score for any submission or attestation received in the improvement activities performance category via the submission types described under § 414.1325(a)(1) regardless of whether the submission or

attestation included a yes response or not. Several MIPS eligible clinicians have notified us that there have been instances where they unintentionally submitted non-scorable data for a MIPS performance category, which overrode an approved reweighting or a previously scorable data submission for a performance categories. In the event of a submission without yes responses, we currently assign a score of zero. In section IV.A.4.d.(2)(c). of this proposed rule, we are proposing to adopt minimum criteria for a qualifying data submission for a performance period for the improvement activities performance category. We are proposing to specify what we consider to be a data submission at § 414.1325(a)(1)(ii) to state that for the improvement activities performance category, a data submission must include a response of ''yes'' for at least one activity in the MIPS improvement activities inventory. We anticipate the proposed change would potentially avoid unintentional overriding of an approved reweighting or a prior data submission for the improvement activities performance category due to submissions or attestations without a response of ''yes'' for any of the improvement activities. We note that we are not proposing any changes to the data submission criteria and scoring for the improvement activities performance category described under §§ 414.1360 and 414.1380(b)(3) respectively.

Additionally, we are proposing to codify our existing policies governing multiple data submissions received for the improvement activities performance category at § 414.1325(f)(1). We refer readers to section IV.A.4.d.(3)(b) of this proposed rule for details. These proposals, if finalized, would not affect the requirements for MIPS eligible clinicians and groups that submit data for the improvement activities performance category. We assume these proposals would not affect the number improvement activities submissions, as the intent is to eliminate certain issues with the scoring of an unintended data submission affecting payment adjustments for individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities. Therefore, we are not proposing any adjustments to our currently approved estimated burden due to these policy proposals.

As shown in Table 114, we are adjusting the currently approved burden estimates (88 FR 79454 and 79455) due to available updated submission data for the CY 2022 performance period/2024 MIPS payment year, as discussed in section V.B.8.e.(3). of this proposed rule. As identified in Table 79, the proposed change in burden reflects adjustments for updated data, rather than proposed requirements or statues in this proposed rule. We estimate that a total of 38,433 respondents consisting of 29,017 individual clinicians, 9,396 groups and 20 subgroups will submit improvement activities during the CY 2025 performance period/2027 MIPS payment year. This adjustment represents a decrease of 11,856 respondents from the currently approved estimate of 50,289 respondents in the CY 2024 PFS final rule (88 FR 79454 and 79455). We did not include in our estimates clinicians who participated in an APM Entity and are determined to be QPs for the CY 2022 performance period/2024 MIPS payment year as we assume they are not required to submit improvement activities data.

TABLE 114: Estimated Number of Respondents to Submit Improvement Activities Data

Burden and Respondent Descriptions	Count
# of Clinicians to Participate in Improvement Activities Data Submission as During the CY 2025 Performance Period (a)	29,017
# of Groups to Submit Improvement Activities on Behalf of During the CY 2025 Performance Period (b)	9,396
# of Subgroups to Submit Improvement Activities in MVPs During the CY 2025 Performance Period (c)	20
Total # of Respondents (Groups, Subgroups, Virtual Groups, and Individual Clinicians) to Submit Improvement Activities Data During the CY 2025 Performance Period (d) = (a) + (b) + (c)	**38,433**
Total # of Currently Approved Respondents (Groups, Virtual Groups, and Individual Clinicians) to Submit Improvement Activities Data (CY 2024 PFS Final Rule) (e)	50,289
Difference in # of Respondents (f) = (d) − (e)	**-11,856**

In Table 115, we continue to estimate that the time required per response per individual or group is 5 minutes or 0.083 hours for a computer system analyst at a labor rate of $106.54/hr to submit by logging in and manually attesting that certain activities were performed in the form and manner specified by CMS with a set of authenticated credentials. Therefore, we estimate an annual burden of 3,190 hours (38,433 respondents × 0.083 hr/response) at a cost of $339,748 (38,433 respondents × $8.84/response) for the CY 2025 performance period/2027 MIPS payment year.

TABLE 115: Estimated Burden for Improvement Activities Data Submission

Burden and Respondent Descriptions	Burden Estimate
Total # of Respondents (Groups, Subgroups, Virtual Groups, and Individual Clinicians) to Submit Improvement Activities Data on Behalf of Clinicians During the CY 2025 Performance Period (a)	38,433
Total Annual Hours Per Respondent (b)	0.083
Total Annual Hours (c) = (a) × (b)	**3,190**
Cost per Respondent to Submit Improvement Activities Data at Computer System Analyst's Labor Rate of $106.54/hr (d) = (b) × $106.54/hr	$8.84
Total Annual Cost (e) = (a) × (d)	**$339,748**

As shown in Table 116, using our unchanged currently approved per respondent burden estimate, the decrease in the number of respondents results in an adjustment of −984 hours and −$104,807 for the CY 2025 performance period/2027 MIPS payment year.

TABLE 116: Change in Estimated Burden for Improvement Activities Submission

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	4,174
Total Annual Hours for Respondents in CY 2025 PFS Proposed Rule (b) (See Table 115, row (c))	3,190
Difference in Annual Hours (c) = (b) − (a)	**-984**
Total Currently Approved Annual Cost (d)	$444,555
Total Annual Cost for Respondents in CY 2025 PFS Proposed Rule (e) (See Table 115, row (e))	$339,748
Difference in Annual Cost (f) = (e) − (d)	**-$104,807**

i. ICRs Regarding the Nomination of Improvement Activities (§ 414.1360)

In this rulemaking, we are not proposing any new or revised collection of information requirements or burden related to the Nomination of Improvement Activities for the CY 2025 performance period/2027 MIPS payment year. The requirements and burden associated with this information collection are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes to the Nomination of Improvement Activities under that control number.

j. ICRs Regarding the Nomination of MVPs

In section IV.A.4.a.(2) of this proposed rule, we are proposing a modification to the MVP maintenance webinar process previously finalized in the CY 2022 PFS final rule (86 FR 65410) and modified in the CY 2023 PFS final rule (87 FR 70037). Specifically, we are proposing to modify the MVP maintenance webinar process to provide us more flexibility in how we communicate submitted maintenance recommendations prior to proposing them formally in rulemaking. We believe this flexibility in communicating recommendations through alternative webinar formats or other public communication channels would offer similar opportunities for public review and feedback as a live public webinar. As this proposal would not require additional steps to the MVP nomination process described in the CY 2021 PFS final rule (85 FR 84990 and 84991), we are continuing our currently approved 12 hours per response burden estimate for the CY 2025 performance period/2027 MIPS payment year. We refer readers to section VII.E.17.e.(2)(d). of this proposed rule where we discuss our impact analysis for this proposal.

The requirements and burden for the nomination of MVPs are currently approved by OMB under control number 0938–1314 (CMS–10621). Since the proposed change does not set out any new or revised requirements or burden outside of providing CMS with flexibility in how we communicate, we are not proposing any changes to the nomination of MVPs under that control number.

k. ICRs Regarding the Cost Performance Category (§ 414.1350)

The cost performance category relies on administrative claims data. The Medicare Parts A and B claims submission process (OMB control number 0938–1197; CMS–1500 and CMS–1490S) is used to collect data on cost measures from MIPS eligible clinicians. MIPS eligible clinicians are not required to provide any documentation by CD or hardcopy. Moreover, the following proposals in section IV.A.4.e.(2). of this proposed rule would not result in the need to add or revise or delete any claims data fields: (1) add 6 new episode-based cost measures; (2) modify 2 existing episode-based measures; (3) update the operational list of care episode and

patient condition groups and codes to reflect new and modified measures we are proposing; (4) and adopt criteria to specify objective bases for the removal of any cost measures from the MIPS cost performance category. Consequently, we are not proposing any changes under the aforementioned control number. We refer readers to section IV.A.4.e.(2).for details on these proposals.

l. ICRs Regarding Partial QP Elections (§§ 414.1310(b) and 414.1430)

We are not proposing any new or revised collection of information requirements or related to the Partial QP Elections to participate in MIPS as a MIPS eligible clinician in the CY 2025 performance period/2027 MIPS payment year. In this section of this proposed rule, we identify proposed adjustments to the estimated burden for partial QP elections that will be submitted to OMB for review under control number 0938–1314 (CMS–10621), as summarized in Tables 78 and 79. These proposed adjustments to estimated burden for the CY 2025 performance period/2027 MIPS payment year are due to the availability of updated data, rather than proposed policies or statute changes in section IV.A.4. of this proposed rule.

Based on the number of QP elections submitted for the CY 2023 performance period/2025 MIPS payment year, we estimate in this proposed rule that we will receive a total of 18 partial QP elections from 18 APM respondents (representing 333 distinct national provider identifiers (NPIs) and 363 distinct TIN/NPIs). We do not estimate any partial QP elections at the eligible clinician level, as no individual eligible clinicians elected to report as partial QPs for the CY 2023 performance period/2025 MIPS payment year. This estimate is a decrease of 269 submissions from the currently approved estimate of 287 (87 FR 70167 and 70168). We continue to estimate it will take 0.25 hours for a computer system analyst or equivalent to complete and submit the election process.

In Table 117, we estimate an annual burden of 5 hours (18 responses × 0.25 hr/response) at a cost of $480 (18 responses × $26.64/response) for the CY 2025 performance period/2027 MIPS payment year.

TABLE 117: Estimated Burden for Partial QP Elections

Burden and Respondent Descriptions	Burden Estimate
Total # of Respondents Making Partial QP Election (18 APM Entities, 0 Eligible Clinicians) (a)	18
Total Annual Hours per Other Payer Arrangement (b)	0.25
Total Annual Hours (c) = (a) × (b)	**5**
Cost per Respondent at Computer System Analyst's Labor Rate of $106.54/hr (d) = (b) × $106.54/hr	$26.64
Total Annual Cost (e) = (a) × (d)	**$480**

In Table 118, we illustrate the net change in estimated burden for the Partial QP Election Process using the currently approved burden in the CY 2023 PFS final rule (87 FR 70167 and 70168). In aggregate, the estimated change in responses will result in an adjustment of −67 hours and −$7,166 for the CY 2025 performance period/2027 MIPS payment year.

TABLE 118: Change in Estimated Burden for Partial QP Elections

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours for Respondents (a)	72
Total Annual Hours for Respondents in CY 2025 PFS Proposed Rule (b) (See Table 117, row (c))	5
Difference in Annual Hours (c) = (b) − (a)	**-67**
Total Currently Approved Annual Cost for Respondents (d)	$7,646
Total Annual Cost for Respondents in CY 2025 PFS Proposed Rule (e) (See Table 117, row (e))	$480
Difference in Annual Cost (f) = (e) − (d)	-$7,166

m. ICRs Regarding Other Payer Advanced APM Determinations: Payer-Initiated Process (§ 414.1445) and Eligible Clinician-Initiated Process (§ 414.1445)

In this section, we identify proposed adjustments to the estimate burden for ICRs regarding other payer advanced APM determinations. These proposed adjustments, summarized in Tables 78 and 79, reflect the availability of updated data rather than proposed policies or statutory requirements, and will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

(1) Payer-Initiated Process (§ 414.1445)

We are not proposing any new or revised collection of information requirements related to the Payer-Initiated Process for the CY 2025 performance period/2027 MIPS payment year. Due to declining requests in recent years, we are adjusting our burden estimates for the CY 2025 performance period/2027 MIPS payment year. In this proposed rule, we estimate that we will receive 10 submissions for the Payer-Initiated Process for the CY 2025 performance period/2027 MIPS payment year, a decrease of 5 submissions from the currently approved estimate of 15 responses (86 FR 65607 and 65608). We continue to estimate it will take 10 hours for a computer system analyst per arrangement.

In Table 119, we estimate an annual burden of 100 hours (10 responses × 10 hr/response) at a cost of $10,654 (10 responses × $1,065.40/response) for the CY 2025 performance period/2027 MIPS payment year.

TABLE 119: Estimated Burden for Other Payer Advanced APM Identification Determinations: Payer-Initiated Process

Burden and Respondent Descriptions	Burden Estimate
Total # of Other Payer Arrangements (2 Medicaid, 6 Medicare Advantage Organizations, 2 Remaining Other Payers) (a)	10
Total Annual Hours per Other Payer Arrangement (b)	10
Total Annual Hours (c) = (a) × (b)	**100**
Cost per Respondent at Computer System Analyst's Labor Rate of $106.54/hr (d) = (b) × $106.54/hr	$1,065.40
Total Annual Cost (e) = (a) × (d)	**$10,654**

In Table 120, we illustrate the net change in estimated burden for the Payer-Initiated Process using the currently approved responses in the CY 2022 PFS final rule (86 FR 65606 and 65607). In aggregate, the estimated change in the number of responses will result in an adjustment of −50 hours and −$5,327 for the CY 2025 performance period/2027 MIPS payment year.

TABLE 120: Change in Estimated Burden for Other Payer Advanced APM Identification Determinations: Payer-Initiated Process

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours for Respondents (a)	150
Total Annual Hours for Respondents in CY 2025 PFS Proposed Rule (b) (See Table 119, row (c))	100
Difference in Annual Hours (c) = (b) − (a)	**-50**
Total Currently Approved Annual Cost for Respondents (d)	$15,981
Total Annual Cost for Respondents in CY 2025 PFS Proposed Rule (e) (See Table 119, row (e))	$10,654
Difference in Annual Cost (f) = (e) − (d)	**-$5,327**

(2) Eligible Clinician-Initiated Process (§ 414.1445)

We are not proposing any new or revised collection of information requirements related to the Eligible Clinician-Initiated Process for the CY 2025 performance period/2027 MIPS payment year. Due to declining requests in recent years, we are adjusting our burden estimates for the CY 2025 performance period/2027 MIPS payment year. In this proposed rule, we estimate that we will receive 10 submissions for the Eligible Clinician-Initiated Process for the CY 2025 performance period/2027 MIPS payment year, a decrease of 5 submissions from the currently approved estimate of 15 (86 FR 65607 and 65608). We continue to estimate it will take 10 hours for a computer system analyst to complete and submit the payment arrangement.

In Table 121, we estimate an annual burden of 100 hours (10 responses × 10 hr/response) at a cost of $10,654 (10 responses × $1,065.40/response) for the CY 2025 performance period/2027 MIPS payment year.

TABLE 121: Estimated Burden for Other Payer Advanced APM Identification Determinations: Eligible Clinician-Initiated Process

Burden and Respondent Descriptions	Burden Estimate
Total # of Other Eligible Clinician-Initiated Arrangements (a)	10
Total Annual Hours per Other Payer Arrangement (b)	10
Total Annual Hours (c) = (a) × (b)	**100**
Cost per Respondent at Computer System Analyst's Labor Rate of $106.54/hr (d) = **(b)** × $106.54/hr	$1,065.40
Total Annual Cost (e) = (a) × (d)	**$10,654**

In Table 122, we illustrate the net change in estimated burden for the Eligible Clinician-Initiated Process using the currently approved responses in the CY 2022 PFS final rule (86 FR 65607 and 65608). In aggregate, the estimated change in the number of responses will result in an adjustment of −50 hours and −$5,327 for the CY 2025 performance period/2027 MIPS payment year.

TABLE 122: Change in Estimated Burden for Other Payer Advanced APM Identification Determinations: Clinician-Initiated Process

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours for Respondents (a)	150
Total Annual Hours for Respondents in CY 2025 PFS Proposed Rule (b) (See Table 121, row (c))	100
Difference in Annual Hours (c) = (b) − (a)	**-50**
Total Currently Approved Annual Cost for Respondents (d)	$15,981
Total Annual Cost for Respondents in CY 2025 PFS Proposed Rule (e) (See Table 121, row (e))	$10,654
Difference in Annual Cost (f) = (e) − (d)	**-$5,327**

(3) Submission of Data for QP Determinations Under the All-Payer Combination Option (§ 414.1440)

We are not proposing any new or revised collection of information requirements related to the Submission of Data for QP Determinations under the All-Payer Combination Option for the CY 2025 performance period/2027 MIPS payment year. In the past few years, we have observed a significant drop in the number of submissions from payment arrangements from outside parties. Therefore, we are adjusting our estimates downward for the CY 2025 performance period/2027 MIPS payment year. In this proposed rule, we estimate that 10 APM Entities, 100 TINs, and 10 eligible clinicians will submit data for QP determinations under the All-Payer Combination Option in CY 2025 performance period/2027 MIPS payment year. Our aggregated estimate of 120 submissions is a decrease of 431 submissions from our currently approved estimate of 551 in the CY 2020 PFS final rule (84 FR 63113 and 63114). We continue to estimate it will take 5 hours for a medical or health systems to prepare and submit an arrangement.

In Table 123, we estimate an annual burden of 600 hours (120 responses × 5 hr/response) at a cost of $77,568 (120 responses × $646.40/response) for the CY 2025 performance period/2027 MIPS payment year.

TABLE 123: Estimated Burden for the Submission of Data for All-Payer QP Determinations

Burden and Respondent Descriptions	Burden Estimate
Total # of APM Entities Submitting Data for All-Payer QP Determinations (a)	10
Total # of TINs Submitting Data for All-Payer QP Determinations (b)	100
Total # of Eligible Clinicians Submitting Data for All-Payer QP Determinations (c)	10
Total # of Respondents (d) = (a) + (b) + (c)	**120**
Hours Per respondent QP Determinations (e)	5
Total Annual Hours (f) = (d) × (e)	**600**
Cost per Respondent at Medical and Health Services Manager Labor Rate of $129.28/hr (g) = (e) × $129.28/hr	$646.40
Total Annual Cost (h) = (d) × (g)	**$77,568**

In Table 124, we illustrate the net change in estimated burden for the submission of data for all-payer QP determinations using the currently approved responses in the CY 2020 PFS final rule (84 FR 63113 and 63114). In aggregate, the estimated change in the number of responses will result in an adjustment of −2,155 hours and −$278,598 for the CY 2025 performance period/2027 MIPS payment year.

TABLE 124: Change in Estimated Burden for the Submission of Data for All-Payer QP Determinations

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours for Respondents (a)	2,755
Total Annual Hours for Respondents in CY 2025 PFS Proposed Rule (b) (See Table 123, row (f))	600
Difference in Annual Hours (c) = (b) − (a)	**-2,155**
Total Currently Approved Annual Cost for Respondents (d)	$356,166
Total Annual Cost for Respondents in CY 2025 PFS Proposed Rule (e) (See Table 123, row (h))	$77,568
Difference in Annual Cost (f) = (e) − (d)	**-$278,598**

n. ICRs Regarding Voluntary Participants Election to Opt-Out of Performance Data Display on Compare Tools (§ 414.1395)

This rulemaking is not proposing any new or revised collection of information requirements or burden related to the election by voluntary participants to opt-out of public reporting on Compare Tools for the CY 2025 performance period/2027 MIPS payment year. The requirements and burden associated with this information collection are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes to the election of voluntary participants to opt-out of performance data display on Compare Tools under that control number.

C. Summary of Proposed Annual Burden Estimates

Table 125 sets out the burden for this rulemaking's proposed provisions that are subject to the PRA. It does not score burden adjustments that are strictly based on updated data and are unrelated to any of the proposed provisions.

TABLE 125: Annual Requirements and Burden Estimates

Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID No.)	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§§ 414.1318, 414.1325, 414.1335, 414.1360, 414.1365, 414.1375, 414.1380, 414.1400, 414.1430, 414.1440, and 414.1445 Quality Payment Program	0938-1314 (CMS-10621)	57,247 (56,981 clinicians and groups-level TINs;218 APMs, 10 payers, 218 third part intermediaries or entities responding to calls for nomination)	(35,357)	Varies	(78,366)	Varies	(9,000,834)
§§ 427.402(c)(4) and (5), 428.302(c)(4) and (5), and 428.303(c)(4) and (5) (Regarding Rebate Reduction Requests Submitted Under Sections 11101 and 11102 of the Inflation Reduction Act)	0938-NEW (CMS-10858)	20	20	31	620	Varies	74,756
TOTAL		**57,267**	**(35,337)**	**Varies**	**(77,746)**	**Varies**	**(8,926,078)**

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed previously, please visit the CMS website at *https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing*, or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** sections of this proposed rule and identify the rule (CMS–1807–P), the ICR's CFR citation, and OMB control number.

VI. Response to Comments

Because of the large number of public comments, we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VII. Regulatory Impact Analysis

A. Statement of Need

In this proposed rule, we are proposing payment and policy changes under the Medicare PFS and changes to implement amendments made under the section 502 of the Further Continuing Appropriations and Other Extensions Act, 2024 (Pub. L. 118–22) (FCAOEA, 2024). Our proposed policies in this rulemaking specifically address: changes to the PFS; and other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, the relative value of services, and changes in the statute; updates and refinements to Medicare Shared Savings Program (Shared Savings Program) requirements; updates to the Quality Payment Program (MIPS and Advanced APMs); changes to payment policies for drugs and biologicals products paid under Medicare Part B, changes to the Clinical Laboratory Fee Schedule requirements, other changes to Medicare Part B payment policies for Rural Health Clinics and Federally Qualified Health Centers, the Medicare coverage of opioid use disorder services furnished by opioid treatment programs and coverage and payment for certain preventive services; updates to electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan (section 2003 of the SUPPORT Act); and proposed change to the regulations associated with the Ambulance Fee Schedule. The policies reflect CMS' stewardship of the Medicare program and overarching policy objectives for ensuring equitable beneficiary access to appropriate and quality medical care.

1. Statutory Provisions

a. Clinical Laboratory Fee Schedule (CLFS)—Proposed Revisions Consistent With Recent Statutory Changes

In section III.F. of this proposed rule, we propose the conforming regulations text changes for CLFS data reporting requirements due to the enactment of section 502 of the Further Continuing Appropriations and Other Extensions Act, 2024 (Pub. L. 118–22) (FCAOEA, 2024). For clinical diagnostic laboratory tests (CDLTs) that are not advanced diagnostic laboratory tests (ADLTs), section 502(b) of the FCAOEA, 2024 delayed the next data reporting period by one year. Instead of taking place from January 1, 2024, through March 31, 2024, data reporting will now take place from January 1, 2025, through March 31, 2025, based on the original data collection period of January 1, 2019, through June 30, 2019. Data reporting for these tests then resumes on a 3-year cycle. Additionally, section 502(a) of the

FCAOEA, 2024 amended the statutory provisions for the phase-in of payment reductions resulting from private payor rate implementation to specify that the applicable percent for CY 2024 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2024 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2023. Section 502(a) of the FCAOEA, 2024 further amended the statutory phase-in provisions to provide that for CYs 2025 through 2027, the payment amount for a CDLT may not be reduced by more than 15 percent as compared to the payment amount for that test established in the preceding year.

b. Medicare Prescription Drug Inflation Rebate Program

Section III.I. of this proposed rule proposes regulations to implement provisions of the Inflation Reduction Act (IRA) that establish the Medicare Prescription Drug Inflation Rebate Program. Section 11101 of the IRA adds new section 1847A(i) to the Act, which establishes a requirement for manufacturers to pay Medicare Part B rebates for certain single source drugs and biological products with prices that increase faster than the rate of inflation, beginning on January 1, 2023. Section 11102 of the IRA adds new section 1860D–14B to the Act, which established a requirement for manufacturers to pay Medicare Part D rebates for certain Part D drugs and biological products with prices that increase faster than the rate of inflation, beginning on October 1, 2022.

c. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan

In section III.L. of this rulemaking, we propose a change to the electronic prescribing for controlled substances (EPCS) requirement specified in § 423.160(a)(5) (referred to as the CMS EPCS Program). The provision in section III.L. of this proposed rule proposes to revise § 423.160(a)(5) to specify that prescriptions written for a beneficiary in a long-term care (LTC) facility would not be included in determining CMS EPCS Program compliance until January 1, 2028, and that compliance actions against prescribers who do not meet the compliance threshold based on prescriptions written for a beneficiary in a LTC facility would commence on or after January 1, 2028.

d. Quality Payment Program

This proposed rule is also necessary to make changes to the Quality Payment Program to move the program forward to focus more on measurement efforts, refine how clinicians would be able to participate in a more meaningful way through the Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs), and highlight the value of participating in Advanced Alternative Payment Models (APMs). Authorized by MACRA, the Quality Payment Program is an incentive program that includes two participation tracks, MIPS and Advanced APMs. MIPS eligible clinicians are subject to a MIPS payment adjustment based on their performance in four performance categories: cost, quality, improvement activities, and Promoting Interoperability. Currently, reporting for traditional MIPS is seen as siloed across the performance categories. These policy proposals are intended to promote better quality reporting to improve patient health outcomes by coordinating reporting for MIPS across performance categories and make changes to scoring that would provide a better picture of clinicians' performance.

2. Discretionary Provisions

a. Drugs and Biological Products Paid Under Medicare Part B

In Section III.A.1. of this proposed rule, as part of our continued implementation of section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58, November 15, 2021) (IIJA), which amended section 1847A of the Act to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug (hereinafter, refundable drug), we are proposing a change in how we would identify certain drugs that are excluded from the definition of refundable drug for those which payment has been made under Part B for fewer than 18 months; how we identify drugs from a single-dose container; to require the JW modifier if a billing supplier is not administering a drug, but there are discarded amounts during the preparation process before supplying the drug to the patient; and we discuss an application received for increased applicable percentage.

In section III.A.2 of this proposed rule, we are proposing how payment limits would be calculated when manufacturers report negative or zero ASP data to CMS. Generally, we are proposing that negative and zero ASP data be considered ''not available'' under section 1847A(c)(5)(B) of the Act and that positive ASP data be considered available. In circumstances in which negative or zero ASP data is reported for some, but not all National Drug Codes (NDCs) associated with a billing and payment code for a drug, we are proposing to calculate the payment limit using only NDCs with positive ASP data. In certain circumstances, we are proposing to carryover the most recent positive ASP data for the drug to calculate a payment limit when the manufacturer's ASP is negative or zero. For biosimilars with negative or zero ASP data for all NDCs, we are proposing to use positive ASP data from other biosimilars with the same reference product, when available, to calculate the payment limit.

In section III.A.3. of this proposed rule, we are proposing to clarify how Medicare Administrative Contractors (MACs) pay for radiopharmaceuticals that are furnished in the physician's office. We are proposing to codify in regulations at § 414.904(e)(6) that, for radiopharmaceuticals furnished in a setting other than the hospital outpatient department, MACs shall determine payment limits for radiopharmaceuticals based on any methodology used to determine payment limits for radiopharmaceuticals in place on or prior to November 2003. Such methodology may include, but is not limited to, the use of invoice-based pricing.

In section III.A.4. of this proposed rule, we are proposing policies to reduce barriers faced by beneficiaries receiving immunosuppressive drugs under the Medicare Part B immunosuppressive drug benefit. That is, we are proposing at § 410.30 to include orally and enterally administered compounded formulations with active ingredients derived only from FDA-approved drugs that have approved immunosuppressive indications or FDA-approved drugs that have been determined by a MAC to be reasonable and necessary for specific purposes in immunosuppressive treatment in the immunosuppressive drug benefit. In addition, we are proposing changes regarding supplying fees and refills for immunosuppressive drugs. These proposals include allowing payment of a supply fee for a prescription of a supply of up to 90 days and allowing prescriptions for immunosuppressive drugs to be refillable.

In section III.A.5. of this proposed rule, we are proposing to update § 410.63(b) to clarify existing CMS policy that blood clotting factors must be self-administered to be considered

clotting factors for which the furnishing fee applies. Additionally, we are proposing to clarify at § 410.63(c) that the furnishing fee is only available to entities that furnish blood clotting factors, unless the costs associated with furnishing the clotting factor are paid though another payment system, including the PFS. That is, we are proposing to clarify through revisions to § 410.63 that clotting factors (as specified in section 1861(s)(2)(I) of the Act) and those eligible to receive the clotting factor furnishing fee (as specified in section 1842(o)(5) of the Act) are the same subset of products.

b. RHCs and FQHCs

In section III.B.2. of this proposed rule, we are proposing several changes to the furnishing of care coordination services in RHCs and FQHCs. We are proposing to require RHCs and FQHCs to report the individual HCPCS codes that make up the general care management HCPCS code G0511 and to utilize the same codes as those billing under the PFS. RHCs and FQHCs would no longer be required to report the general care management HCPCS code (G0511). We are also proposing to permit billing of the add-on codes associated with these services. In addition, beginning in CY 2025, we are proposing to adopt the coding and policies regarding Advanced Primary Care Management (APCM) services, as discussed in section II.G of this proposed rule.

For all of the care coordination services, we are proposing to allow separate payment at the national non-facility PFS payment rate when the individual code is on an RHC or FQHC claim, either alone or with other payable services. Payment rates would be updated annually based on the PFS amounts for these codes. We are also seeking comment on how we can improve the transparency and predictability regarding which HCPCS codes are considered care coordination services to automate processes downstream for RHCs and FQHCs.

In section III.B.3. of this proposed rule, we are proposing the policy to continue to adopt the definition ''immediate availability'' as including real-time audio and visual interactive telecommunications for the direct supervision of services and supplies furnished incident to a physician's service through December 31, 2025, for RHCs and FQHCs. We are also proposing, on a temporary basis, to allow payment for non-behavioral health visits furnished via telecommunication technology in a manner that would closely align with the payment mechanisms mandated by statute through December 31, 2024, that is, RHCs and FQHCs would continue to bill for RHC and FQHC services furnished using telecommunication technology services by reporting HCPCS code G2025 on the claim through December 31, 2025. In addition, we are proposing to continue to delay the in-person visit requirement for mental health services furnished via communication technology by RHCs and FQHCs to beneficiaries in their homes until January 1, 2026.

In section III.B.4. of this proposed rule, we discuss the implementation of section 4124 of the CAA, 2023. Section 4124 of the CAA, 2023 established Medicare coverage for intensive outpatient program (IOP) services furnished by a hospital to its outpatients, or by a community mental health center, a RHC or a FQHC, as a distinct and organized intensive ambulatory treatment service offering less than 24-hour daily care in a location other than an individual's home or inpatient or residential setting, effective January 1, 2024 (88 FR 81838). We are proposing to provide a payment rate for 4 or more services per day in the RHC and FQHC setting.

In section III.B.5. of this rulemaking, we are proposing to allow RHCs and FQHCs to bill for Part B preventive vaccines and the administration at the time of service. We propose that payments for these claims will be made according to Part B preventive vaccine payment rates in other settings, to be annually reconciled with the facilities' actual vaccine costs on their cost reports. Due to the operational systems changes needed to facilitate payment through claims, we propose that RHCs and FQHCs begin billing for preventive vaccines and their administration at the time of service, for dates of service on or after July 1, 2025.

In section III.B.6. of this proposed rule, we discuss our proposal relating to RHC productivity standards. We are proposing to remove productivity standards for RHCs.

In section III.B.7. of this proposed rule, we discuss proposals relating to the FQHC market basket. We are proposing to rebase and revise the FQHC PPS market basket to reflect a 2022 base year.

In section III.B.8. of this proposed rule, we are clarifying that when RHCs and FQHCs furnish dental services that align with the inextricably linked policies and operational requirements in the physician setting, we would consider those services to be a qualifying visit and the RHC would be paid at the RHC AIR and the FQHC would be paid under the FQHC PPS.

c. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

In section III.F.2 of this proposed rule, we are proposing telecommunication flexibilities related to periodic assessments and initiation of treatment with methadone. We are proposing to allow periodic assessments to be furnished via audio-only communications when two-way audio-video communications technology is not available to the beneficiary on a permanent basis, to the extent that this flexibility is authorized by SAMHSA and DEA at the time the service is furnished, and all other applicable requirements are met. We believe that making this current flexibility permanent is appropriate, as it would allow a beneficiary to decide with their provider the best modality for receiving care, and evidence has shown that audio-only visits produce many of the same benefits as video-based visits.[790] Additionally, permanently extending the flexibility to allow periodic assessments to be furnished via audio-only communications would further contribute towards health equity, especially among Medicare beneficiaries who are from underserved populations.[791] We are also proposing to allow OTPs to use audio-visual telecommunications for initiation of treatment with methadone for any new patient who will be treated by the OTP with methadone if the OTP determines that an adequate evaluation of the patient can be accomplished via an audio-visual telehealth platform. We would allow the OTP intake add-on code (HCPCS code G2076) to be paid for two-way audio-video communications technology when it is billed for the initiation of treatment with methadone to the extent that the use of audio-video telecommunications technology to initiate treatment with methadone is authorized by DEA and SAMHSA at the time the service is furnished, and all other applicable requirements are met. We believe this flexibility is needed to align with new policy amendments finalized by SAMHSA for initiation of treatment with methadone at § 8.12(f)(2)(v)(A), and it would help reduce barriers for many individuals

[790] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9446840.*

[791] *https://pubmed.ncbi.nlm.nih.gov/33471458/; https://www.kff.org/medicare/issue-brief/medicare-and-telehealth-coverage-and-use-during-the-covid-19-pandemic-and-options-for-the-future/;https://pubmed.ncbi.nlm.nih.gov/34534186/.*

beginning treatment with methadone who often experience at least one barrier to accessing treatment (for example, reliable transportation, work schedule conflicts, distance to treatment, etc.).[792]

In section III.F.3 of this proposed rule, we are proposing payment updates to intake activities (HCPCS code G2076) furnished by OTPs in response to recent regulatory reforms finalized by SAMHSA at 42 CFR part 8 that aim to recognize more patient-centered and evidence-based paradigms of care for OUD treatment (for example, harm reduction interventions, recovery support services, etc.). Specifically, we are proposing to update the payment for intake activities (HCPCS code G2076) to include payment for social determinants of health risk assessments (HCPCS code G0136) in order to adequately reflect additional effort for OTPs to identify a patient's unmet health-related social needs (HRSNs), or the need and interest for harm reduction interventions and recovery support services that are critical to the treatment of an OUD. These would be consistent with new revisions to standards for initial assessment service activities required by SAMHSA under § 8.12(f)(4)(i). CMS is further requesting information to understand how OTPs currently coordinate care and make referrals to community-based organizations (CBOs) that address unmet HRSNs, provide harm reduction services, and/or offer recovery support services. Altogether, we believe these proposals are necessary to help OTPs address key issues during initial assessments that may increase the risk of a patient leaving OUD treatment prematurely or that pose as barriers to treatment engagement. For example, patients with an OUD are more likely to have lower educational attainment, be food insecure, encounter financial hardship, and housing instability, and they often report financial and logistical barriers (for example, lack of access to transportation) as reasons for not receiving treatment.[793] However, providers (including SUD treatment facilities) who coordinate care with CBOs, including peer support organizations, housing agencies, and educational and employment agencies, to address unmet HRSNs (for example, housing, transportation, etc.) identified during assessments can positively influence health outcomes and better support a patient's engagement in SUD treatment.[794]

Furthermore, in section III.F.4 of this proposed rule, we are proposing to establish payment for new opioid agonist and antagonist medications that were recently approved by the FDA. We would create a new add-on code to the bundled payment to reflect take-home supplies for nalmefene hydrochloride (nalmefene) nasal spray (Opvee®), which is indicated for the emergency treatment of known or suspected opioid overdose induced by natural or synthetic opioids. The add-on code would include payment for a carton of two 2.7 mg nasal sprays of nalmefene and overdose education furnished in conjunction with distributing nalmefene. We are also proposing payment for a new extended-release injectable buprenorphine product (Brixadi®), indicated to treat moderate to severe OUD and that comes in a weekly (8 mg, 16 mg, 24 mg, 32 mg) and monthly formulation (64 mg, 96 mg, and 128 mg). We would create a new weekly bundled payment code (including both a non-drug and drug component) for weekly injectable buprenorphine to reflect the weekly formulation of Brixadi®. In addition, we are proposing to update payment for the drug component of the existing bundled payment under the Medicare OTP benefit for monthly injectable buprenorphine (HCPCS G2069) in order to reflect payment for the monthly formulation of Brixadi®. We believe these proposals are consistent with our statutory authority under sections 1861(jjj)(1)(A) and 1834(w) of the Act, which allow the Secretary to establish Medicare bundled payment for opioid agonist and antagonist treatment medications that are approved by the FDA. These proposals would expand access to new opioid agonist and antagonist medications that are important to help prevent additional opioid overdose deaths, reduce illicit opioid use, and retain more individuals with an OUD in treatment.[795]

Lastly, in section III.F.5 of this proposed rule, we are clarifying a billing requirement that an OUD diagnosis code is required on claims submitted under the Medicare OTP benefit for OUD treatment services. This clarification is needed to ensure payments made to OTPs are in alignment with statutory requirements under sections 1861(s)(2)(HH), 1861(jjj)(1), and 1834(w) of the Act, which all specify that services paid to OTPs under Medicare Part B must be for the treatment of opioid use disorder.

d. Medicare Shared Savings Program

In section III.G. of this proposed rule, we are proposing modifications to the Shared Savings Program to further advance Medicare's value-based care strategy of growth, alignment, and equity, and to make changes that would allow for timely improvements to program policies and operations.

The proposed changes to the Shared Savings Program include the following:

Proposed changes to the quality performance standard and other quality reporting requirements, including to (1) require Shared Savings Program ACOs to report the APP Plus quality measure set that would incrementally grow to comprise of 11 measures, consisting of the 6 measures in the existing APP quality measure set and 5 newly proposed measures from the Adult Universal Foundation measure set that would be incrementally incorporated into the APP Plus quality measure set over performance years 2025 through 2028, (2) focus the collection types available to Shared Savings Program ACOs for reporting the APP Plus quality measure set to all payer/all patient eCQMs and Medicare CQMs, (3) require Shared Savings Program ACOs that report the APP Plus quality measure set, to report on all measures in the APP Plus quality measure set, as applicable, (4) establish a Complex Organization Adjustment for Virtual Groups and APM Entities, including Shared Savings Program ACOs, when reporting eCQMs, (5) score Medicare CQMs using flat benchmarks in their first 2 performance periods in MIPS, and (6) extend the eCQM reporting incentive in order to promote the adoption of eCQMs.

Proposed changes to establish a new ''prepaid shared savings'' option to assist eligible ACOs, with a history of earning shared savings, with cash flow and encourage investments that would provide additional services for beneficiaries, and proposed refinements to recently-established advance investment payment policies.

Proposed modifications to the Shared Savings Program's financial methodology including to (1) ensure the benchmarking methodology includes sufficient incentive for ACOs providing care to underserved communities to enter and remain in the program through the application of a proposed health equity benchmark adjustment, (2) specify a calculation methodology to

[792] *https://ascpjournal.biomedcentral.com/articles/10.1186/s13722-022-00316-3.*

[793] *https://www.sciencedirect.com/science/article/pii/S1544319123000560?via%3Dihub. https://www.sciencedirect.com/science/article/pii/S0749379722001040?via%3Dihub.*

[794] *https://www.commonwealthfund.org/sites/default/files/202209/ROI_calculator_evidence_review_2022_update_Sept_2022.pdf; https://aspe.hhs.gov/sites/default/files/private/pdf/260791/BestSUD.pdf.*

[795] *https://www.cdc.gov/drugoverdose/pdf/pubs/2018-evidence-based-strategies.pdf; https://pubmed.ncbi.nlm.nih.gov/24247147/.*

account for the impact of improper payments in recalculating expenditures and payment amounts used in Shared Savings Program financial calculations, upon reopening a payment determination pursuant to § 425.315(a), (3) establish a methodology for excluding payment amounts for HCPCS and CPT codes exhibiting significant, anomalous, and highly suspect (SAHS) billing activity during CY 2024 or subsequent calendar years that warrant adjustment, and (4) technical changes for consistency and clarity in provisions of the Shared Savings Program regulations on financial calculations, to align and clarify the language we used to describe weights applied to the growth in ACO and regional risk scores for each Medicare enrollment type, as part of the calculation for capping ACO and regional risk score growth, respectively.

Proposed changes to other programmatic areas, including: a proposal in connection with the Shared Savings Program compliance requirements to permit continued participation by ACOs whose number of assigned beneficiaries falls below 5,000 during their agreement period; proposed updates to provisions of the Shared Savings Program regulations on application procedures to reflect the latest approach Antitrust Agencies use to evaluate ACOs and enforce antitrust measures; proposed updates to the beneficiary assignment methodology including to (1) revise the definition of primary care services to align with payment policy proposals and include, among other services for the purposes of beneficiary assignment, Safety Planning Interventions, Post-Discharge Telephonic Follow-up Contacts Intervention, Virtual Check-in Services, Advanced Primary Care Management Services, Cardiovascular Risk Assessment and Risk Management Services, Interprofessional Consultation Services, Direct Care Caregiver Training Services, and Individual Behavior Management/Modification Caregiver Training Services, and (2) broaden the existing exception to the program's voluntary alignment policy to allow for additional beneficiaries to be claims-based assigned to entities participating in certain disease- or condition-specific Innovation Center ACO models; and proposed modifications to the beneficiary notification requirements.

e. Medicare Part B Payment for Preventive Services

Section III.H.1 of this proposed rule outlines the implementation of policies that impact the payment amount for administration of preventive vaccines paid under the Part B vaccine benefit, as well COVID–19 monoclonal antibodies and the in-home additional payment for Part B vaccine administration. These provisions are necessary to provide stable payment for preventive vaccine administration and related policies, and to allow predictability for providers and suppliers to rely on for building and sustaining robust vaccination programs.

Section III.H.2 of this proposed rule addresses two items related to payment for hepatitis B vaccine administration under Part B. In section III.M. of this proposed rule, we propose to expand coverage of hepatitis B vaccinations by revising existing regulations. If that coverage expansion of hepatitis B vaccines under Part B is finalized, we would clarify that a physician's order is no longer required for the administration of a hepatitis B vaccine in Part B, which will facilitate roster billing by mass immunizers for hepatitis B vaccine administration. We are also proposing that payment for hepatitis B vaccines and their administration be made at 100 percent of reasonable cost in RHCs and FQHCs, separate from the FQHC PPS or the RHC All-Inclusive Rate (AIR) methodology, to streamline payment for all Part B vaccines in those settings.

In section III.H.3. of this proposed rule, we are proposing a fee schedule for Drugs Covered as Additional Preventive Services (DCAPS), per section 1833(a)(1)(W)(ii) of the Act. We propose to determine payment limits for DCAPS drugs based on the ASP payment methodology set forth under section 1847A of the Act if possible, and we propose alternative payment mechanism for calculating payment limits for DCAPS drugs if ASP data is not available. We also propose payment limits for supplying and administration fees for DCAPS drugs that are similar to those fees for drugs paid under the ASP payment methodology set forth under section 1847A of the Act. Finally, we propose to determine payment limits for DCAPS drugs in RHCs and FQHCs, and any supply and administration fee, using this same fee schedule, and to pay for DCAPS drugs and their administration on a claim-by-claim basis.

f. Expand Colorectal Cancer Screening

In section III.K. of this rulemaking, we propose to update and expand coverage for CRC screening by (1) removing coverage for the barium enema procedure in regulations at § 410.37, (2) adding coverage for the CTC procedure in regulations at § 410.37, and (3) expanding a ''complete colorectal cancer screening'' in § 410.37(k) to include a follow-on screening colonoscopy after a Medicare covered blood-based biomarker CRC screening test (described and authorized in NCD 210.3) returns a positive result. The Center for Disease Control and Prevention (CDC) describes CRC as ''a disease in which cells in the colon or rectum grow out of control . . . Sometimes abnormal growths, called polyps, form in the colon or rectum. Over time, some polyps may turn into cancer. Screening tests can find polyps so they can be removed before turning into cancer. Screening also helps find colorectal cancer at an early stage, when treatment works best.'' [796] The National Cancer Institute reports that CRC is the fourth most common type of cancer and estimates that the United States experienced 153,020 new cases and 52,550 new deaths from CRC in 2023. In addition, the rate of new cases and new deaths from CRC is more common in men than women and significantly greater for those of African American and Non-Hispanic American Indian/Alaska Native descent compared to all races.[797]

g. Expand Hepatitis B Vaccine Coverage

In section III.M. of this rulemaking, we propose to expand Hepatitis B vaccine coverage by revising our regulatory definition for intermediate risk groups by adding a new paragraph to include individuals who have not previously received a completed hepatitis B vaccination series or whose vaccination history is unknown (§ 410.63(a)(2)). Hepatitis B is a vaccine-preventable liver disease caused by the hepatitis B virus.[798] The vaccine consists of a series of typically 3 doses delivered at various intervals.[799] Hepatitis B virus is transmitted when body fluid (blood, semen, or other) from a person infected with the virus enters the body of someone who is uninfected.[800] This can happen through sexual contact; sharing needles, syringes, or other drug-injection equipment; transmission from the gestational parent to baby during pregnancy or at birth; direct contact with blood or open sores; or sharing

[796] CDC website: *https://www.cdc.gov/cancer/colorectal/basic_info/what-is-colorectal-cancer.htm.*

[797] NCI Website: *https://seer.cancer.gov/statfacts/html/colorect.html.*

[798] CDC, 2023. Hepatitis B surveillance 2021. Retrieved from *https://www.cdc.gov/hepatitis/statistics/2021surveillance/hepatitis-b.htm.*

[799] CDC. Viral hepatitis. FAQ for health professionals. Atlanta, GA: U.S. HHS, CDC; 2022. Retrieved from *https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm.*

[800] CDC, 2023. Hepatitis B surveillance 2021. Retrieved from *https://www.cdc.gov/hepatitis/statistics/2021surveillance/hepatitis-b.htm.*

contaminated items such as toothbrushes, razors or medical equipment (such as a glucose monitor) of a person who has hepatitis B.[801] Hepatitis B can be an acute, short-term illness and it can develop into a long-term, chronic infection. Chronic hepatitis B can lead to serious health problems, including cirrhosis, liver cancer, and death. Treatments for hepatitis B are available but no cure exists. There are currently an estimated 2.4 million individuals in the U.S. living with hepatitis B virus and an estimated 20,000 new infections every year.[802] We believe our proposal will help protect Medicare beneficiaries from acquiring hepatitis B infection, contribute to eliminating viral hepatitis as a public health threat in the United States and is in the best interest of the Medicare program and its beneficiaries.

h. Medicare Parts A and B Overpayment Provisions of the Affordable Care Act (§ 401.305(b)(1) Through (3))

Section III.O. of this proposed rule discusses existing § 401.305(b)(1), which specifies when a person who has received an overpayment must report and return an overpayment. We propose to amend this regulation to reference revised § 401.305(b)(2) and new § 401.305(b)(3). We are proposing a technical modification to the introductory language in § 401.305(b)(2) to acknowledge that this paragraph might be applicable after the suspension described in new § 401.305(b)(3) is complete. New proposed § 401.305(b)(3) would identify the circumstances under which the deadline for reporting and returning overpayments would be suspended to allow time for providers to investigate and calculate overpayments. We do not have a basis for estimating the impact associated with this amendment. We solicit comment on the analysis and conclusions provided in the RIA.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 entitled ''Modernizing Regulatory Review'' (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates reform Act of 1995 (March 22, 1995; Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 14094, entitled ''Modernizing Regulatory Review'' (hereinafter, the Modernizing E.O.), amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) ($200 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1)) as measured by the $200 million or more in any 1 year. Accordingly, we have prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners, and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details, see the SBA's website at *https://www.sba.gov/document/support-table-size-standards* (refer to the 620000 series).) Individuals and States are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other suppliers, and providers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this proposed rule is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. Medicare does not pay rural hospitals for their services under the PFS; rather, Medicare payment is made under the PFS for physicians' services, which can be furnished by physicians and NPPs in a variety of settings, including rural hospitals. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this rulemaking will not have a significant

[801] CDC. 2024. Viral Hepatitis FAQs for the public. Retrieved from *https://www.cdc.gov/hepatitis/hbv/bfaq.htm.*

[802] Conners EE, Panagiotakopoulos L, Hofmeister MG, et al. Screening and testing for hepatitis B virus infection: CDC recommendations—United States, 2023. *MMWR Recomm Rep.* 2023;72(1):1–25. Retrieved from *https://www.cdc.gov/mmwr/volumes/72/rr/rr7201a1.htm.*

impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on State, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2024, that threshold is approximately $183 million. This proposed rule will impose no mandates on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this rulemaking does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

We prepared the following analysis, which, together with the information provided in the rest of this proposed rule, meets all assessment requirements. The analysis explains the rationale for and purposes of this proposed rule; details the costs and benefits of this rulemaking; analyzes alternatives; and presents the measures we will use to minimize the burden on small entities. As indicated elsewhere in this proposed rule, we discussed various changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services and to implement provisions of the statute. We provide information for each policy change in the relevant sections of this proposed rule. We are unaware of any relevant Federal rules that duplicate, overlap, or conflict with this proposed rule. The relevant sections of this rulemaking describe significant alternatives we considered, if applicable.

C. Changes in Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of Medicare Part B expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare expenditures for PFS services compared payment rates for CY 2024 with payment rates for CY 2025 using CY 2023 Medicare utilization. The payment impacts described in this proposed rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual practitioner could vary from the average and will depend on the mix of services they furnish. The average percentage change in total revenues will be less than the impact displayed here because practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical diagnostic laboratory tests that are paid under the Clinical Laboratory Fee Schedule (CLFS). The PFS update adjustment factor for CY 2025, as specified in section 1848(d)(19) of the Act, is 0.00 percent before applying other adjustments.

To calculate the estimated CY 2025 PFS conversion factor (CF), we took the CY 2024 conversion factor without the payment increase of 1.25 percent provided by the CAA, 2023 that applied to services furnished from January 1, 2024 through March 8, 2024, and the 2.93 percent payment increase provided by the CAA, 2024 that replaced the previous 1.25 percent increase and applies to services furnished from March 9, 2024 through December 31, 2024 and multiplied it by the budget neutrality adjustment required as described in the preceding paragraphs. We estimate the CY 2025 PFS CF to be 32.3562 which reflects a 0.05 percent positive budget neutrality adjustment required under section 1848(c)(2)(B)(ii)(II) of the Act, the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act, and the removal of the temporary 2.93 percent payment increase for services furnished from March 9, 2024 through December 31, 2024, as provided in the CAA, 2024. We estimate the CY 2025 anesthesia CF to be 20.3340, reflecting the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

TABLE 126: Calculation of the CY 2025 PFS Conversion Factor

CY 2024 Conversion Factor		33.2875
Conversion Factor without the CAA, 2024 (2.93 Percent Increase for CY 2024)		32.3400
CY 2025 Statutory Update Factor	0.00 percent (1.0000)	
CY 2025 RVU Budget Neutrality Adjustment	0.05 percent (1.0005)	
CY 2025 Conversion Factor		**32.3562**

TABLE 127: Calculation of the CY 2025 Anesthesia Conversion Factor

CY 2024 National Average Anesthesia Conversion Factor		20.7739
Conversion Factor without the CAA, 2024 (2.93 Percent Increase for CY 2024)		20.1826
CY 2025 Statutory Update Factor	0.00 percent (1.0000)	
CY 2025 RVU Budget Neutrality Adjustment	0.05 percent (1.0005)	
CY 2025 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	0.70 percent (1.0070)	
CY 2025 Conversion Factor		**20.3340**

Table 128 shows the impact on PFS payment for physicians' services based on the proposed policies included this proposed rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues will be different from those shown in Table 128 (CY 2025 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 128.

- Column A (Specialty): Identifies the specialty for which data are shown.
- Column B (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on CY 2023 utilization and CY 2024 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- Column C (Impact of Work RVU Changes): This column shows the estimated CY 2025 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- Column D (Impact of PE RVU Changes): This column shows the estimated CY 2025 impact on total allowed charges of the changes in the PE RVUs.
- Column E (Impact of MP RVU Changes): This column shows the estimated CY 2025 impact on total allowed charges of the changes in the MP RVUs.
- Column F (Combined Impact): This column shows the estimated CY 2025 combined impact on total allowed charges of all the changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

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TABLE 128: CY 2025 PFS Estimated Impact on Total Allowed Charges by Specialty

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$207	0%	0%	0%	0%
Anesthesiology	$1,488	1%	1%	0%	2%
Audiologist	$70	0%	0%	0%	0%
Cardiac Surgery	$155	0%	0%	0%	0%
Cardiology	$5,748	0%	0%	0%	0%
Chiropractic	$616	0%	1%	0%	1%
Clinical Psychologist	$680	3%	1%	0%	3%
Clinical Social Worker	$794	3%	1%	0%	4%
Colon And Rectal Surgery	$143	0%	1%	0%	0%
Critical Care	$309	0%	0%	0%	1%
Dermatology	$3,717	0%	0%	0%	0%
Diagnostic Testing Facility	$875	0%	-2%	0%	-2%
Emergency Medicine	$2,240	0%	0%	0%	0%
Endocrinology	$491	0%	1%	0%	1%
Family Practice	$5,133	0%	0%	0%	1%
Gastroenterology	$1,372	0%	0%	0%	0%
General Practice	$341	0%	0%	0%	0%
General Surgery	$1,484	0%	0%	0%	0%
Geriatrics	$193	0%	1%	0%	1%
Hand Surgery	$251	-1%	0%	0%	-1%
Hematology/Oncology	$1,501	0%	0%	0%	0%
Independent Laboratory	$512	0%	0%	0%	0%
Infectious Disease	$513	0%	0%	0%	0%
Internal Medicine	$8,771	0%	0%	0%	1%
Interventional Pain Mgmt	$792	0%	0%	0%	0%
Interventional Radiology	$418	0%	-2%	0%	-2%
Multispecialty Clinic/Other Phys	$142	0%	0%	0%	0%
Nephrology	$1,571	0%	1%	0%	1%
Neurology	$1,252	0%	0%	0%	0%
Neurosurgery	$658	0%	0%	0%	0%
Nuclear Medicine	$47	0%	0%	0%	0%
Nurse Anes / Anes Asst	$987	0%	1%	0%	1%
Nurse Practitioner	$6,531	0%	0%	0%	0%
Obstetrics/Gynecology	$531	0%	0%	0%	-1%
Ophthalmology	$4,469	-1%	-1%	0%	-1%
Optometry	$1,280	0%	0%	0%	-1%
Oral/Maxillofacial Surgery	$57	0%	0%	0%	0%
Orthopedic Surgery	$3,239	-1%	0%	0%	-1%
Other	$54	0%	0%	0%	0%
Otolaryngology	$1,095	0%	0%	0%	0%
Pathology	$1,090	0%	0%	0%	0%
Pediatrics	$51	0%	0%	0%	1%
Physical Medicine	$1,054	0%	0%	0%	0%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Physical/Occupational Therapy	$5,607	0%	0%	0%	0%
Physician Assistant	$3,472	0%	0%	0%	0%
Plastic Surgery	$280	0%	0%	0%	-1%
Podiatry	$1,780	0%	0%	0%	0%
Portable X-Ray Supplier	$69	0%	1%	0%	1%
Psychiatry	$795	1%	0%	0%	1%
Pulmonary Disease	$1,188	0%	0%	0%	1%
Radiation Oncology and Radiation Therapy Centers	$1,458	0%	0%	0%	0%
Radiology	$4,273	0%	0%	0%	0%
Rheumatology	$496	0%	0%	0%	0%
Thoracic Surgery	$277	0%	0%	0%	0%
Urology	$1,532	0%	-1%	0%	-1%
Vascular Surgery	$937	0%	-2%	0%	-2%
Total	$106,413	0%	0%	0%	0%

* Column F may not equal the sum of columns C, D, and E due to rounding.

In recent years, we have received requests from interested parties to provide more granular information that separates the specialty-specific impacts by site of service. These interested parties have presented us with high-level information suggesting that Medicare payment policies are directly responsible for consolidating privately owned physician practices and freestanding supplier facilities into larger health systems. Their concerns highlight a need to update the information under the PFS to account for current trends in healthcare delivery, especially concerning independent versus facility-based practices. We published an RFI in the CY 2023 PFS proposed rule to gather feedback on this issue and refer readers to the discussion in the CY 2023 PFS final rule (87 FR 69429 through 69438). As part of our holistic review of how best to update our data and offer interested parties additional information that addresses some of the concerns raised, we have recently improved our current suite of public use files (PUFs) by including a new file that shows estimated specialty payment impacts at a more granular level, specifically by showing ranges of impact for practitioners within a specialty. This file is available on the CMS website under downloads for the CY 2025 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

We provided an additional impact table for this rulemaking cycle that includes a facility/non-facility breakout of payment changes. The following is an explanation of the information represented in Table 129.

- Column A (Specialty): Identifies the specialty for which data are shown.
- Column B (Setting): Identifies the facility or nonfacility setting for which data are shown.
- Column C (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on CY 2023 utilization and CY 2024 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- Column D (Combined Impact): This column shows the estimated CY 2025 combined impact on total allowed charges.

TABLE 129: CY 2025 PFS Estimated Impact on Total Allowed Charges by Setting

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
Allergy/Immunology	*TOTAL*	$207	0%
	Non-Facility	$200	0%
	Facility	$7	0%
Anesthesiology	*TOTAL*	$1,488	2%
	Non-Facility	$297	0%
	Facility	$1,191	2%
Audiologist	*TOTAL*	$70	0%
	Non-Facility	$68	0%
	Facility	$3	1%
Cardiac Surgery	*TOTAL*	$155	0%
	Non-Facility	$28	-1%
	Facility	$126	0%
Cardiology	*TOTAL*	$5,748	0%
	Non-Facility	$3,622	0%
	Facility	$2,126	0%
Chiropractic	*TOTAL*	$616	1%
	Non-Facility	$615	1%
	Facility	$1	1%
Clinical Psychologist	*TOTAL*	$680	3%
	Non-Facility	$549	3%
	Facility	$131	3%
Clinical Social Worker	*TOTAL*	$794	4%
	Non-Facility	$670	4%
	Facility	$124	4%
Colon And Rectal Surgery	*TOTAL*	$143	0%
	Non-Facility	$53	1%
	Facility	$90	0%
Critical Care	*TOTAL*	$309	1%
	Non-Facility	$50	1%
	Facility	$259	1%
Dermatology	*TOTAL*	$3,717	0%
	Non-Facility	$3,580	0%
	Facility	$137	0%
Diagnostic Testing Facility	*TOTAL*	$875	-2%
	Non-Facility	$874	-2%
	Facility	$1	0%
Emergency Medicine	*TOTAL*	$2,240	0%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Non-Facility	$186	0%
	Facility	$2,054	0%
Endocrinology	*TOTAL*	$491	1%
	Non-Facility	$395	1%
	Facility	$96	0%
Family Practice	*TOTAL*	$5,133	1%
	Non-Facility	$4,131	1%
	Facility	$1,002	0%
Gastroenterology	*TOTAL*	$1,372	0%
	Non-Facility	$505	1%
	Facility	$868	0%
General Practice	*TOTAL*	$341	0%
	Non-Facility	$273	0%
	Facility	$68	0%
General Surgery	*TOTAL*	$1,484	0%
	Non-Facility	$438	0%
	Facility	$1,045	0%
Geriatrics	*TOTAL*	$193	1%
	Non-Facility	$125	1%
	Facility	$68	0%
Hand Surgery	*TOTAL*	$251	-1%
	Non-Facility	$134	0%
	Facility	$116	-3%
Hematology/Oncology	*TOTAL*	$1,501	0%
	Non-Facility	$976	-1%
	Facility	$525	0%
Independent Laboratory	*TOTAL*	$512	0%
	Non-Facility	$499	0%
	Facility	$13	0%
Infectious Disease	*TOTAL*	$513	0%
	Non-Facility	$81	0%
	Facility	$432	0%
Internal Medicine	*TOTAL*	$8,771	1%
	Non-Facility	$4,373	1%
	Facility	$4,397	0%
Interventional Pain Mgmt	*TOTAL*	$792	0%
	Non-Facility	$624	0%
	Facility	$168	1%
Interventional Radiology	*TOTAL*	$418	-2%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Non-Facility	$259	-3%
	Facility	$159	1%
Multispecialty Clinic/Other Phys	*TOTAL*	$142	0%
	Non-Facility	$71	0%
	Facility	$71	0%
Nephrology	*TOTAL*	$1,571	1%
	Non-Facility	$934	1%
	Facility	$636	0%
Neurology	*TOTAL*	$1,252	0%
	Non-Facility	$808	0%
	Facility	$444	0%
Neurosurgery	*TOTAL*	$658	0%
	Non-Facility	$115	0%
	Facility	$543	0%
Nuclear Medicine	*TOTAL*	$47	0%
	Non-Facility	$22	-1%
	Facility	$24	1%
Nurse Anes / Anes Asst	*TOTAL*	$987	1%
	Non-Facility	$20	1%
	Facility	$968	1%
Nurse Practitioner	*TOTAL*	$6,531	0%
	Non-Facility	$4,295	0%
	Facility	$2,236	0%
Obstetrics/Gynecology	*TOTAL*	$531	-1%
	Non-Facility	$364	-1%
	Facility	$167	0%
Ophthalmology	*TOTAL*	$4,469	-1%
	Non-Facility	$3,153	-2%
	Facility	$1,315	-1%
Optometry	*TOTAL*	$1,280	-1%
	Non-Facility	$1,223	-1%
	Facility	$56	0%
Oral/Maxillofacial Surgery	*TOTAL*	$57	0%
	Non-Facility	$46	0%
	Facility	$11	1%
Orthopedic Surgery	*TOTAL*	$3,239	-1%
	Non-Facility	$1,424	0%
	Facility	$1,815	-2%
Other	*TOTAL*	$54	0%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Non-Facility	$43	0%
	Facility	$11	1%
Otolaryngology	*TOTAL*	$1,095	0%
	Non-Facility	$874	1%
	Facility	$221	0%
Pathology	*TOTAL*	$1,090	0%
	Non-Facility	$583	0%
	Facility	$507	0%
Pediatrics	*TOTAL*	$51	1%
	Non-Facility	$32	0%
	Facility	$18	1%
Physical Medicine	*TOTAL*	$1,054	0%
	Non-Facility	$520	0%
	Facility	$534	0%
Physical/Occupational Therapy	*TOTAL*	$5,607	0%
	Non-Facility	$5,607	0%
	Facility	$	4%
Physician Assistant	*TOTAL*	$3,472	0%
	Non-Facility	$2,389	0%
	Facility	$1,083	0%
Plastic Surgery	*TOTAL*	$280	-1%
	Non-Facility	$127	-1%
	Facility	$153	-1%
Podiatry	*TOTAL*	$1,780	0%
	Non-Facility	$1,586	0%
	Facility	$195	0%
Portable X-Ray Supplier	*TOTAL*	$69	1%
	Non-Facility	$67	1%
	Facility	$3	1%
Psychiatry	*TOTAL*	$795	1%
	Non-Facility	$466	1%
	Facility	$329	1%
Pulmonary Disease	*TOTAL*	$1,188	1%
	Non-Facility	$523	1%
	Facility	$665	0%
Radiation Oncology and Radiation Therapy Centers	*TOTAL*	$1,458	0%
	Non-Facility	$1,002	-1%
	Facility	$457	2%
Radiology	*TOTAL*	$4,273	0%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Non-Facility	$1,894	-1%
	Facility	$2,379	1%
Rheumatology	*TOTAL*	$496	0%
	Non-Facility	$446	0%
	Facility	$50	0%
Thoracic Surgery	*TOTAL*	$277	0%
	Non-Facility	$57	-2%
	Facility	$220	0%
Urology	*TOTAL*	$1,532	-1%
	Non-Facility	$1,081	-1%
	Facility	$451	1%
Vascular Surgery	*TOTAL*	$937	-2%
	Non-Facility	$676	-2%
	Facility	$261	0%
TOTAL	***TOTAL***	$***85,081***	0%
	Non-Facility	$54,049	0%
	Facility	$31,033	0%

BILLING CODE C

2. CY 2025 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty-level impacts of the RVU changes are generally related to the changes to RVUs for specific services resulting from the misvalued code initiative, including RVUs for new and revised codes. The estimated impacts for some specialties, including clinical social workers and clinical psychologists, geriatrics, anesthesiology, and nurse anesthetists, psychiatry, and family practice, reflect increases relative to other specialties. These increases can largely be attributed to the Year 4 update to clinical labor pricing and/or the proposed adjustments to transfer of postoperative care for global surgical procedures. These increases are also due to increases in values for particular services after considering the recommendations from the American Medical Association's (AMA) Relative Value Scale Update Committee (RUC) and CMS review, and increased payments resulting from supply and equipment pricing updates.

The estimated impacts for several specialties, including diagnostic testing facilities, vascular surgery, interventional radiology, ophthalmology, and orthopedic surgery, reflect decreases in payments relative to payment to other specialties, largely resulting from the redistributive effects of the implementation of the Year 4 update to clinical labor pricing and/or the proposed adjustments to transfer of postoperative care for global surgical procedures. The services furnished by these specialties were negatively affected by the redistributive effects of increases in work RVUs for other codes, and/or rely primarily on supply/equipment items for their practice expense costs and, therefore, were affected negatively by the updated Year 4 clinical labor pricing under budget neutrality. These decreases are also due to the revaluation of individual procedures based on reviews, including consideration of AMA RUC review and recommendations, as well as decreases resulting from the continued phase-in implementation of the previously finalized supply and equipment pricing updates. The estimated impacts also reflect decreases due to the continued implementation of previously finalized code-level reductions that are being phased in over several years. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the CLFS.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table (Table 128), including comments received in response to the valuations. We remind interested parties that although the estimated impacts are displayed at the specialty level, typically, the changes are driven by the valuation of a relatively small number of new and/or potentially misvalued codes. The percentage changes in Table 128 are based upon aggregate estimated PFS allowed charges summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty, and compared to the same summed total from the previous calendar year. Therefore, they are averages and may not necessarily represent what is happening to the particular services furnished by a single practitioner within any given specialty.

As discussed previously, we have reviewed our suite of public use files and have worked on new ways to offer interested parties additional information that addresses concerns about the lack of granularity in our impact tables. To illustrate how impacts can vary within

specialties, we created a public use file that models the expected percentage change in total RVUs per practitioner. Using CY 2023 utilization data, Total RVUs change between −1 percent and 1 percent for more than 80 percent of practitioners, representing approximately 75 percent of the changes in Total RVUs for all practitioners, with variation by specialty. Specialties, such as gastroenterology, exhibit little variation in changes in total RVUs per practitioner. Table 128 (CY 2025 PFS Estimated Impact on Total Allowed Charges by Specialty) indicates an overall change of 0 percent for this specialty, and the practitioner-level distribution shows that 98 percent of these practitioners will experience a change in Total RVUs between −1 percent and 1 percent. The specific service mix within a specialty may vary by practitioner, so individual practitioners may experience different changes in total RVUs. For example, Table 128 indicates a 1 percent increase in RVUs for the physical/occupational therapy specialty as a whole; however, 24 percent of physical/occupational therapy specialty practitioners—representing over 21 percent of Total RVUs for the specialty—will experience a 1 percent or more increase in Total RVUs. Meanwhile, 13 percent of physical/occupational therapy specialty practitioners will experience 1 percent or more decreases in Total RVUs, and these practitioners account for 14 percent of Total RVUs for this specialty. We also note the code level RVU changes are available in the Addendum B public use file that we make available with each rule (see *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates*).

The specialty impacts displayed in Table 128 reflect changes within the pool of total RVUs. The specialty impacts table, therefore, includes any changes in spending that result from finalized policies that are subject to the statutory budget neutrality requirement at section 1848(c)(2)(B)(ii)(II) (such as the updated proposals associated with the transfer of postoperative care for global surgical procedures in CY 2025 or the clinical labor pricing update phase-in that began in CY 2022) but does not include any changes in spending which result from finalized policies that are not subject to the statutory budget neutrality adjustment, and therefore, have a neutral impact across all specialties. The 2.50 and 2.93 percent temporary payment increases for CY 2023 and CY 2024, respectively, are statutory changes that take place outside of BN, and therefore, are not captured in the specialty impacts displayed in Table 128. Section 1848(t)(2)(C) specifies that these temporary payment increases are not to be taken into account in determining fee schedules for physicians' services furnished in years after the respective increases end. As such, these temporary increases are not subject to the PFS budget neutrality adjustment.

b. Impact

Column F of Table 128 displays the estimated CY 2025 impact on total allowed charges, by specialty, of all the RVU changes. A table showing the estimated impact of all of the changes on total payments for selected high volume procedures is available under ''downloads'' on the CY 2025 PFS proposed rule website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*. We selected these procedures for the sake of illustration from among the procedures most commonly furnished by a broad spectrum of specialties. The change in both facility rates and nonfacility rates are shown. For an explanation of facility and nonfacility PE, we refer readers to Addendum A on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*.

D. Impact of Changes Related to Telehealth Services

We are proposing to add several codes to the Medicare Telehealth Services List on a provisional basis, including HCPCS codes G0011, G0013, G0248, GCTD1–3, and GCTB1–2, and CPT Codes 97550, 97551, 97552, 96202, and 96203. We are proposing to maintain certain Telecommunications technology-related flexibilities through 2025, including that we will continue to use a definition of direct supervision that allows ''immediate availability'' of the supervising practitioner using real-time audio and video interactive telecommunications. We are also proposing to delay implementation of the telehealth frequency limitations for subsequent nursing facility and inpatient hospital visits for an additional year, to include two-way, real-time audio-only communication technology for any telehealth service furnished to a beneficiary in their home, and to continue to permit the distant site practitioner to use their currently enrolled practice location instead of their home address when providing telehealth services from their home. While we note that certain other Medicare telehealth flexibilities related to the PHE for COVID–19 are expiring, including the removal of statutory geographic and location limitations for most Medicare telehealth services, the beneficiary's home continues to be a permissible originating site for certain types of services including those furnished for the diagnosis, evaluation, or treatment of a mental health disorder, including a Substance Use Disorder (SUD), and for monthly End Stage Renal Disease (ESRD) related clinical assessments described in section 1881(b)(3)(B). However, expiration of certain flexibilities for Medicare telehealth services is not expected to impact broader utilization of these services because reasonable and necessary services for the diagnosis or treatment of an illness or injury continue to be covered. Please see our request for comment in section II.E. of this proposed rule with regard to what impact, if any, the expiration of the current flexibilities would be expected to have on overall service utilization for CY 2025. Despite the fact that some services will no longer be furnished under telehealth, we expect that they will continue to be furnished in-person. We therefore anticipate that our proposed provisions will result in continued utilization of services that can be furnished as Medicare telehealth services during CY 2025 at levels comparable to observed utilization of these services during CY 2024.

E. Other Provisions of the Regulation

1. Impact of Proposals for Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Medical Services

In section II.J.2. of this proposed rule, we are proposing to add to the list in § 411.15(i)(3)(i) of clinical scenarios under which FFS Medicare payment may be made for dental services inextricably linked to covered services to now include certain dental services associated with dialysis services for beneficiaries with end-stage renal disease (ESRD). Specifically, we are proposing that Medicare Parts A and B payment may be made for dental or oral examination performed as part of a comprehensive workup prior to Medicare-covered dialysis services when used in the treatment of ESRD; and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with covered dialysis services in the treatment of ESRD. By proposing to provide payment for these dental services, we would respond to the interested parties' request that we focus on the ESRD

patient population. We are also soliciting comment on the potential connection between dental services and covered services used in the treatment of diabetes as well as covered services for individuals with sickle cell disease, hemophilia, or autoimmune diseases receiving immunosuppressive therapies. We do not anticipate any significant increase in utilization or payment impact for additional dental services given the historically low utilization of these therapies.

Based on the Renal Management Information System (REMIS) and Enrollment Data Base (EDB) gathered from the Integrated Data Repository (IDR) we estimate Fee-For-Service (FFS) Part B ESRD enrollment to have averaged roughly 240 thousand enrollees during CY 2023. Based on United States Renal Data System (USRDS) from the NIH, we estimate that roughly 40,000 of these enrollees are on the kidney transplant waitlist in any given year and that roughly 10,000 of these patients on the waitlist would typically receive a transplant. Since we already include dental services associated with kidney transplant patients in § 411.15(i)(3)(i)(A) as an example of services for which payment can be made for certain dental services, we removed these patients from the estimate, which left roughly 30,000 FFS beneficiaries.

For a variety of reasons outlined previously, we have historically observed low FFS dental utilization in instances when coverage could apply (<1 percent of potential users). FFS dental billing patterns have shown a cost per covered utilizer of about $525 in recent years. To illustrate the potential cost of the proposed payment for dental services inextricably linked to dialysis services for beneficiaries with ESRD we applied three scenarios of utilization (0.1 percent, 1 percent, 3 percent) and cost per patient of approximately $525 to the 30,000 patients. Under all of these scenarios the policy is projected to represent a negligible cost to the Medicare program (<$1,000,000) in any given year.

Therefore, we do not anticipate a significant payment impact for these provisions. It is important to note that there is some uncertainty in these take-up rate assumptions, but they are consistent with the current utilization of dental services, including after the regulation changes made in the CYs 2023 and 2024 PFS final rules. Additionally, given that our proposed addition to the list of clinical scenarios under which payment may be made for dental services inextricably linked to covered services is not a change in coverage or payment policy, the cost impact of this proposal is negligible and therefore it is not necessary to adjust the conversion factor under the PFS budget neutrality requirement.

2. Impact of Proposed Changes Related to Supervision of Outpatient Therapy Services in Private Practices

As discussed in section II.H. of this proposed rule, we are proposing to change our regulatory requirements for OTs and PTs who are enrolled as suppliers in Medicare as OTs and PTs in private practice (OTPPs and PTPPs, respectively) to allow for general supervision of their occupational therapy assistants (OTAs) and physical therapist assistants (PTAs) to the extent permitted under State law. The requirement for OTPPs and PTPPs to provide direct supervision of OTAs and PTAs, which has been in place since 2005, requires the OTPP/PTPP to be present in the office suite or in the patient's home, and immediately available to furnish assistance and direction throughout the performance of the procedure performed by the OTA/PTA (or by an OT or PT they are supervising who is not enrolled in Medicare as a supplier). In contrast, the proposal to allow for general supervision would mean that the procedure is furnished under the OTPP's/PTPP's overall direction and control, but the OTPP/PTPP need not be present in the treatment location or immediately available.

Should we finalize this proposal, we believe that the change to allow for general supervision of OTAs/PTAs by OTPPs and PTPPs will have a positive impact on patient access to outpatient therapy services; and will align with the currently required general supervision of PTAs/OTAs by PTs and OTs who work for Medicare institutional providers, such as rehabilitation agencies, outpatient hospitals, and SNFs. It would also reflect the supervision level specified in 44 State physical therapy practice acts [803] and all but one State occupational therapy practice act.

3. Impacts of Proposed Changes Related to Advanced Primary Care Management Services

In section II.G.2 of this proposed rule, ''Advanced Primary Care Management (APCM) Services,'' we are proposing to create three HCPCS codes to use for reporting the proposed APCM services (HCPCS codes GPCM1, GPCM2, and GPCM3) to recognize the resources involved in furnishing services using an advanced primary care delivery model under the PFS. As described in sections II.G.2.b and II.G.2.c of this proposed rule, the proposed APCM services incorporate elements of existing services with the understanding that some patients will require more resources and some fewer based on variability in patient complexity and needs. As we ordinarily do, we are proposing to base the PFS valuation for APCM codes on the resources involved in furnishing the typical case of the service which may not necessarily reflect the actual resources involved in furnishing every individual service. To value APCM, we compared the service elements described by the proposed APCM codes to the values we have established for the specific care management services and communication technology-based services (CTBS) codes on which we modeled the proposed service elements of the APCM codes and which we built into the service descriptors for GPCM1, GPCM2, and GPCM3 (see also Table 129 and sections II.G.2.b. through II.G.2.d. of this proposed rule). Specifically, the proposed APCM services incorporate elements of chronic care management (CPT codes 99487, 99489, 99490, 99491, 99439, 99437), principal care management (CPT codes 99424, 99425, 99426, 99427)), transitional care management (CPT codes 99495 and 99496), interprofessional internet consultation furnished by treating/requesting practitioner (CPT code 99452), remote evaluation of patient videos/images (HCPCS code G2250), virtual check-ins (HCPCS code G2251 and G2252), and online digital E/M or e-visits (CPT codes 98970, 98971, 98972, 99421, 99422, 99423) into this new bundled PFS payment beginning for CY 2025.

As discussed throughout section II.G.2 of this proposed rule, we believe that the proposed elements of APCM services reflect the comprehensive approach to care management involved in care delivery using the advanced primary care model. This is a model of primary care that is being integrated into current medical practice. As such, we believe that it would be appropriate to use the current valuation and uptake of the codes on which we modeled the APCM codes to inform our valuation of APCM services. Using Medicare FFS claims data and evidence from the CMS Innovation Center's testing of a series of advanced primary care models (see discussion in section II.G.2.a.(1) of this proposed rule), we sought to understand how these different services have been

[803] Federation of State Boards of Physical Therapy Jurisdiction Licensure Reference Guide, *https://www.fsbpt.net/lrg/Home/SupervisionRequirementLevelsBySetting.*

used historically and relate that information to the way we are thinking about the service elements for APCM and the valuation of the three APCM code levels. As discussed in section II.G.2.e. of this proposed rule, for Medicare beneficiaries who receive care management services during a year, the non-complex CCM base code is billed on average for five months and with three add-on codes during those five months. However, this does not account for the care management services that are provided beyond one time-based billing interval and without reaching the next; nor does it account for the resources involved in maintaining certain advanced primary care practice capabilities and readiness, including patient population monitoring and care needs assessment, to fully furnish and bill APCM services as is medically reasonable and necessary for any individual patient during any calendar month. Finally, this does not account for changes to utilization of APCM that may occur as a result of the billing and documentation requirements for APCM services when compared to the current coding and payment for care management and CTBS services.

We are estimating a utilization of approximately 300,000 claims for the proposed HCPCS code GPCM1, 1.3 million claims for the proposed HCPCS code GPCM2, and 400,000 claims for the proposed HCPCS code GPCM3, and are seeking comment on our assumptions. To estimate utilization for GPCM1, we first calculated an eligible GPCM1 population by estimating the number of Medicare beneficiaries without multiple chronic conditions who have an established relationship with a primary care provider using Welcome to Medicare and Annual Wellness Visit claims and estimating the uptake of APCM Level 1 based on average uptake of CCM/PCM/TCM in CY 2022 claims data; then, we adjusted this estimate to account for increased frequency of billing (multiplied by 12 to account for 12 months of assumed practitioner billing for the proposed APCM service). To estimate utilization for GPCM2, we first calculated estimated ratios to represent the average utilization of CCM/PCM/TCM services in the first year of policy implementation compared to CY 2022 claims; then, we applied a reduced utilization ratio to CY 2022 claims for CPT codes 99490 and 99487 (10.4 percent) and multiplied by the eligible GPCM2 population of Medicare beneficiaries with multiple chronic conditions who are non-QMB; finally, as described for GPCM1, we adjusted this estimate to account for increased frequency of billing (increase from an average of five months of CCM claims per beneficiary to 12 months of assumed practitioner billing for the proposed APCM service, or 237.3 percent). To estimate utilization for GPCM3, we took the estimated number of GPCM2 claims for CPT codes 99490 and 99487 and multiplied by the eligible GPCM3 population of Medicare beneficiaries with multiple chronic conditions who are QMB; again, we adjusted this estimate to account for increased frequency of billing (same percentage applied to GPCM2).

We anticipate that these proposed coding and payment policies for APCM services would result in slight reductions in utilization of existing care management and CTBS services during CY 2025 when compared to observed utilization of these services during CY 2024. Specifically, we are estimating an approximate 11.4 percent reduction in utilization from CY 2024 across the 20 service codes which are incorporated into the APCM services (see previously). The estimated total net increase is approximately 700,000 claims, and we do not anticipate a significant payment impact for these provisions. We believe that the cost impact of this proposal is negligible and therefore it is not necessary to adjust the conversion factor under the PFS budget neutrality requirement.

4. Impact of Proposed Changes Related to Strategies for Improving Global Surgery Payment Accuracy

In section II.G.5 of this proposed rule, ''Strategies for Improving Global Surgery Payment Accuracy,'' we discuss our current policy to require the use of modifiers to help us identify and adjust payment for a global package when there is a formal transfer of care (that is, a written agreement) between the practitioner who furnishes the procedure (proceduralist) and another practitioner. The transfer of care modifiers identify and adjust the global package payment for cases where the pre-operative, operative, and post-operative portions of the global package are furnished by different practitioners. We are proposing to require the use of the appropriate transfer of care modifier (modifier –54, –55, or –56) for all 90-day global surgical packages in any case when a practitioner (or another in the same group practice) expects to furnish only a portion of a global package (including but not limited to when there is a formal, documented transfer of care as under current policy, or an informal, non-documented but expected, transfer of care. This could result in more application of, and therefore more impact on spending from the appropriate usage of the transfer of care modifiers (modifiers –54, –55, and –56).

As noted earlier, we are proposing to require the use of the existing modifier (–54) for all 90-day global surgical packages in any case when a practitioner (or group practice) expects to furnish only the procedure portion of a global package (including when there is a formal, documented transfer of care as under current policy). Since we believe that this will result in expanded use of the transfer of care modifiers, which will have a corresponding effect on the payment for the affected services, we have reflected this in our utilization estimates accordingly (see download file for this proposed rule titled CY 2025 PFS final rule 2023 Utilization Data Crosswalked to 2025 at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices?DLSort=2&DLEntries=10&DLPage=1&DLSortDir=descending*) and anticipate more global surgical packages and post-op care to be billed separately using the modifiers, which could have payment consequences for a selection of high-volume global surgery codes. We assume that the same number of global surgery codes would be billed; however, we anticipate more codes would be billed using the transfer of care modifiers. We do not expect the utilization of separately billable post-operative E/M services would change. Rather than modify our utilization estimates for these codes, our utilization estimate in this proposal includes only 90-day high volume and/or high-cost procedure codes where reporting post-operative visits with CPT code 99024 (*Postoperative follow-up visit, normally included in the surgical package, to indicate that an evaluation and management service was performed during a postoperative period for a reason(s) related to the original procedure*) is required. This is a relatively small set of codes (approximately 180) versus the full range of approximately 4,000 global surgical codes; however, this subset of codes accounts for about 73 percent of total Medicare 90-day procedure volume. The full list of affected codes is available in the file titled ''CY 2024 Analytic Crosswalk to CY 2025'' on the CMS website under downloads for the CY 2025 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

For this select list of global surgical codes, we are estimating that the transfer of care modifier, modifier –54, will be employed 20 percent of the time.

We believe that this is a conservative estimate given the frequency with which these global surgical services involve a transfer of postoperative care. RAND's research has indicated that a post-operative transfer of care is common for 90-day global surgical procedures but that these transfers of care are almost never reported with the appropriate –54 or –55 modifiers. Then, for the 20 percent of cases where we believe the transfer of care modifier will be employed, we are proposing to apply the payment reduction associated with the modifier –54 for postoperative care and apply it to the utilization estimate for the associated procedures billed using the transfer of care modifiers. These percentages can be found in the PFS Relative Value Files under the columns labeled ''pre op, intra op, post op'' at *https://www.cms.gov/medicare/payment/fee-schedules/physician/pfs-relative-value-files*. For example, CPT code 27447 (*Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)*) is a high-volume knee replacement procedure where the postoperative portion of the total payment is 21 percent. We are proposing that there will be a postoperative transfer of care 20 percent of the time for CPT code 27447, and in those 20 percent of cases, there will be a corresponding 21 percent decrease in payment. This is reflected in a utilization crosswalk of 0.958 for CPT code 27447 as a result of this 4.2 percent reduction (20 percent times 21 percent) to capture this estimated reduction in spending associated with our proposal to require the use of these transfer of care modifiers.

We note that for purposes of estimating the utilization of the transfer of care modifiers, our estimates include increased reporting of the transfer of care modifier for codes that are subject to the RAND data collection exercise, with the exception of cases where the modifier is already used 5% of the time or more. We recognize that this policy will apply more broadly and seek comment on this.

We note that the impact of the conversion factor on this proposed reduction in spending associated with this policy is redistributed across the PFS via an increase in the budget neutrality adjustment to the conversion factor. We are soliciting comments from interested parties on our proposed implementation of this postoperative transfer of care policy.

We are also proposing a new HCPCS code, GPOC1, to capture the additional practitioner time and resources spent in providing follow up post-operative care by a practitioner who did not perform the surgical procedure. Additionally, we expect the proposed global surgical add-on code, HCPCS code GPOC1, will be billed during the post-operative period of 90 days following the procedure. We expect that this code will be billed once during the global period when the patient is seen for an office/outpatient (O/O) evaluation and management (E/M) visit that is related to the recent surgical procedure. We believe that this code will be billed by a physician or other practitioner (other than the proceduralist or another practitioner in the same practice) who is seeing the patient for a visit during the post-operative period and did not furnish the surgical procedure. We believe that there is additional time, resources, and complexity involved in the first O/O E/M visit following a procedure that should be captured during the post-operative period and may be billed in certain instances when a transfer of care modifier was not appended to the claim.

We are estimating a utilization of approximately 40,000 total claims in the first year for the proposed add-on code, HCPCS code GPOC1. We calculated this utilization estimate based on claims data for procedure codes with a post-operative diagnosis code and an observed to expected ratio (that is the ratio of visits that are included in the global surgical package compared to the number of visits actually furnished) of less than 25 percent. We anticipate that uptake of HCPCS code GPOC1 would be low initially, consistent with initial uptake of other new services we have finalized under the PFS. We are seeking comment on these assumptions and welcome input from the public.

5. Drugs and Biological Products Paid Under Medicare Part B

a. Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58, November 15, 2021) amended section 1847A of the Act to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The refund amount is either as noted in section 1847A(b)(1)(B) of the Act in the case of a single source drug or biological or as noted in section 1847A(b)(1)(C) of the Act in the case of a biosimilar biological product, multiplied by the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges (subject to certain exclusions) for the drug in a given calendar quarter. In the CY 2023 and 2024 final rules, we finalized several policies to implement the provision. These policies are described in section III.A.1 of this proposed rule.

In section III.A.1 of this proposed rule, we are proposing additional policies for implementing the provision including: a change in how we would identify certain drugs that are excluded from the definition of refundable drug for those which payment has been made under Part B for fewer than 18 months; how we identify drugs from a single-dose container; to require the JW modifier if a billing supplier is not administering a drug, but there are discarded amounts during the preparation process before supplying the drug to the patient; and we discuss an application for increased applicable percentage (CMS 10835, OMB 0938–1435).

In the CY 2024 PFS final rule (88 FR 79485 through 79490), we analyzed JW modifier data from 2021 as if the data represented dates of service on or after the effective date of section 90004 of the Infrastructure Act (that is, January 1, 2023).[804] Similar to our regulatory impact analysis in the CY 2023 PFS final rule (87 FR 70187 through 70188), we used the 2021 JW modifier data to estimate refund amounts as described in section 1847A(h)(3) of the Act. In this proposed rule, we performed the same analysis on the 2022 JW modifier data. First, we subtracted the percent units discarded by 10 percent (the applicable percentage for most refundable drugs), except for drugs with an increased applicable percentage as described in § 414.940(d). We note that since the data indicating which drugs will have an increased applicable percentage of 26 percent for the unique circumstances of rarely utilized orphan drugs (§ 414.940(d)(5)) will not be available until the data is analyzed for the initial report, we entered 26 percent for orphan drugs furnished to fewer than 100 beneficiaries in CY 2022 based on data on the CMS website.[805] Therefore, the drugs with increased applicable percentage under § 414.940(d)(5) may change each year based on claims data; it is applied in this analysis for estimation purposes only. Then, we multiplied that percentage by the CY 2022 total allowed amount to estimate the annual refund for a given billing and

[804] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units.*

[805] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-spending-by-drug.*

payment code. The quarterly refund was estimated by dividing the annual estimate by 4. This analysis remains appropriate for this proposed rule because we are applying the finalized policies from the CY 2023 and 2024 PFS final rules to the most recent publicly available data for the JW modifier data from 2022.

Overall, according to data on the CMS website [806] for Medicare Part B discarded drug units in the 2022 calendar year, Medicare paid over $800 million for discarded amounts of drugs from a single-dose container or single-use package paid under Part B. In that year, there were 55 billing and payment codes with 10 percent or more discarded units based on JW modifier data. Of these, 10 did not meet the definition of refundable single-dose container or single-use package drug in section 1847A(h)(8) of the Act because they are not single source drugs or biologicals; 5 were excluded from the definition of refundable single-dose container or single-use package drug (as specified in section 1847A(h)(8)(B) of the Act) because they are identified as radiopharmaceuticals or imaging agents in FDA-approved labeling; and 3 are products referred to as skin substitutes, which were removed because we anticipate making changes to coding and payment policies regarding those products in future rulemaking. After these exclusions, there were 35 billing and payment codes that met the definition of refundable single-dose container or single-use package drug. Of these, 29 codes have discarded units above the relevant finalized applicable percentage, and 6 codes have discarded units that would fall below increased applicable percentages finalized in this proposed rule.

We estimated refund amounts as described in section 1847A(h)(3) of the Act were calculated based on this data by subtracting the percent units discarded by 10 percent (the applicable percentage), except for drugs with higher applicable percentages finalized in the CY 2023 or 2024 final rules. Then, we multiplied the appropriate percentage by the CY 2022 total allowed amount to estimate the annual refund for a given billing and payment code. The quarterly refund was estimated by dividing the annual estimate by 4. Based on this data, there would be approximately $98.7 million in refunds due from manufacturers for the calendar year of 2022 ($24.7 million each calendar quarter).

There are several limitations to this analysis that could substantially affect the total quarterly refund. Since new drugs are continually being approved, this estimate does not consider newer drugs that will meet the definition of refundable single-dose container or single-use package drug on or after the effective date of January 1, 2023. Since section 1847A(h)(8)(B)(iii) of the Act excludes drugs approved by FDA on or after November 15, 2021, and for which payment has been made under Part B for fewer than 18 months from this definition, we expect an impact on refund amounts after the 18-month exclusion has ended if the drug otherwise meets the definition. We also noted that this estimate is based on CY 2022 data for discarded drug amounts, which, for reasons discussed in the CY 2023 PFS final rule (87 FR 69716), we believe to be an underestimate due to the frequent omission of the JW modifier Claims edits for both the JW and JZ modifiers will likely increase accurate reporting of discarded drug amounts. Other substantial changes to this estimate may occur if a billing and payment code no longer meets this definition. For example, if a generic version of one of these drugs is marketed, the billing and payment code will become a multiple source drug code and will no longer meet the definition of refundable single-dose container or single-use package drug. Subsequently, the manufacturers will not be responsible for refunds under this provision. There may be changes in the percent discarded units for a given refundable single-dose container or single-use package drug if the manufacturer introduces additional vial sizes or modifies the vial size to reduce the amount discarded. Lastly, since data from the CMS website only includes billing and payment codes on the ASP drug pricing file [807] and implementation of section 90004 of the Infrastructure Act is not restricted to billing and payment codes included on the file, there may be other applicable data that was not assessed as part of this estimate.

b. Impacts Related to the Payment Limit Calculation When Manufacturers Report Negative or Zero Average Sales

In section III.A.2 of this proposed rule, CMS is proposing how payment limits would be calculated when manufacturers report negative or zero ASP data to CMS. We are proposing to amend § 414.904(i) to reflect CMS' approach to setting a payment limit for circumstances in which negative or zero ASP data is reported by a manufacturer for a single source drug.

Specifically, we are proposing to codify that in cases where negative or zero ASP data is reported for some, but not all, NDCs of a multiple source drug, we would calculate the payment limit using the positive ASP data reported for the drug, except for the existing carryover policy for multiple source drugs that we would apply when missing data results in a significant change in the ASP payment limit. We are proposing to move this carryover policy for multiple source drugs within § 414.904(i) to fit within the structure of the proposed new set of payment limit methodologies. We are also proposing to codify that in the case of a multiple source drug for which negative or zero ASP data is reported for all NDCs, we would set the payment limit using the most recent available positive ASP data from a previous quarter until at least one NDC for the drug has positive ASP data for a quarter.

We are proposing to codify that in cases where negative or zero ASP data is reported for some, but not all, NDCs of a single source drug that is not a biosimilar, we would calculate the payment limit using the positive ASP data reported for the drug. We are proposing to codify that for single source drugs that are not biosimilars with all negative or zero ASP data for a given quarter, the payment limit would be, until at least one NDC for the drug has positive manufacturer ASP data for a quarter, the lesser of 106 percent of the volume-weighted average of the most recent available positive manufacturer ASP data for at least one NDC from a previous quarter and 106 percent of the wholesale acquisition cost, and we would use 106 percent of the lowest wholesale acquisition cost per billing unit if there is more than one wholesale acquisition cost per billing unit.

We are also proposing to codify that in cases where negative or zero ASP data is reported for some, but not all, NDCs of a biosimilar, we would calculate the payment limit using the positive ASP data reported for the biosimilar. Lastly, we are proposing to codify two scenarios when the manufacturer reports negative or zero ASP for all NDCs for a biosimilar for a given quarter: (1) when positive ASP data is available for another biosimilar(s) with the same reference product for the given quarter, we are proposing to set the payment limit equal to the sum of the volume-weighted average of the positive ASP data from all other biosimilars referencing the same

[806] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units.*

[807] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice.*

reference product plus 6 percent (or 8 percent for a qualifying biosimilar biological) of the amount determined under section 1847A(b)(4) of the Act for the reference biological product for the given quarter; and (2) when either no other biosimilars have been approved for the same reference product or no other biosimilars with the same reference product report positive ASP data for the given quarter, we are proposing to set the payment limit equal to the sum of the volume-weighted average of the most recent available positive ASP data from a previous quarter plus 6 percent (or 8 percent for a qualifying biosimilar biological) of the amount determined under section 1847A(b)(4) of the Act for the reference biological product for the given quarter.

With regard to estimating changes in expenditures for CY 2025, because drugs and biologicals that report negative or zero ASP data vary by quarter and we cannot predict those that will report such data, we used historic claims data to perform an illustrative analysis of how program spending would have changed had the proposed policies been in place in CY 2023. In the analysis, we identified single source and multiple source billing and payment codes associated with negative or zero ASP data for which we published payment limits based on other applicable pricing data (that is, the manufacturer or published wholesale acquisition cost) in the four calendar quarters of 2023. For each such billing and payment code, we used claims data to identify: (1) the number of allowed billing units in a calendar quarter (that is, the number of billing units of a drug or biological paid for by Medicare); (2) the payment limit per billing unit we applied to that drug or biological under our current policies; and (3) the payment limit per billing unit our proposal would apply to the billing and payment code. We then subtracted the product of the allowed billing units for the payment limit under current policies by the product of the allowed billing units and the payment limit under our proposal, and the difference between the two is what the difference between what Medicare spending on the billing and payment codes would have been if our proposed payment limit methodologies were used in that calendar quarter of 2023 and what Medicare actually spent. These data and net reductions (or increases) in program spending are illustrated in Table 130.

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TABLE 130: Theoretical Changes in Medicare Spending on Drugs and Biologicals with Negative or Zero ASP Data Based on CY 2023 Claims Data

1Q2023	Allowed Billing Units	Current Policy (WAC+6)	Proposal	Δ Between Current and Proposal
J2770	15	$493.9695	$337.4653	$2,347.56
J1020	47,111	$4.6110	$1.4914	$146,966.53
J0600	406	$5,708.5940	$5,592.5623	$47,108.84
J0641	741,697	$0.3456	$0.2660	$58,985.13
J0720	116	S41.2552	$40.4146	$97.51
J1000	1,445	S29.6991	$26.4542	$4,688.84
J3300	360,762	$4.1851	$3.9035	$101,596.03
J9214	62	S32.5738	$31.8462	$45.11
J9302	601	S63.9572	$62.2336	$1,035.92
J9320	0	$370.1838	$332.9778	$0.00
Total				$362,871.47
2Q2023	**Allowed Billing Units**	**Current Policy (WAC+6)**	**Proposal**	**Δ Between Current and Proposal**
J1952	83,802	S98.4290	$88.7509	$811,044.34
J0285	79	S46.3220	$41.8181	$355.81
J0287	408	S11.1300	$10.2985	$339.24
J0600	435	$5,708.5940	$5,592.5623	$50,473.78
J1020	51,393	$4.6110	$3.1920	$72,927.54
J3300	381,643	$4.1850	$3.9035	$107,421.25
J9071	69,165	$3.8690	$3.5744	$20,374.38
J9214	31	S32.5740	$31.8462	$22.56
J9268	114	$2,585.4140	$2,320.1163	$30,243.93
J9320	0	$370.1840	$332.9778	$0.00
Total				
3Q2023	**Allowed Billing Units**	**Current Policy (WAC+6)**	**Proposal**	**Δ Between Current and Proposal**
J0216	67	2.565	$2.23	$22.12
J0636	74,355	0.795	$0.76	$2,503.99
J9214	21	32.574	$31.85	$15.28
J0287	154	11.13	$10.30	$128.05
J1572	1,991	56.1164	$44.54	$23,049.18
J1738	242	3.321333333	$3.13	$46.94
J2360	13,633	16.536	$5.38	$152,117.66
J3300	342,992	4.268885	$3.90	$125,314.01
J7342	23	30.0192	$30.01	$0.25
J9046	42,252	48.54739429	$8.65	$1,685,649.00
J9198	406	40.28	$24.67	$6,330.93
J9296	3,417	9.655727059	$9.74	-$273.00
J9393	27,650	21.2	$3.07	$501,318.72
Total				$2,496,223.13

4Q2023	Allowed Billing Units	Current Policy (WAC+6)	Proposal	Δ Between Current and Proposal
J9071	140,721	3.869	$1.19	$377,386.29
J1000	1,003	32.6692	$30.68	$1,993.04
J1980	1,085	35.46442	$33.23	$2,421.54
J0595	272	2.54347	$5.05	-$681.42
J0893	12,457	2.12	$2.24	-$1,495.80
J9198	237	40.28	$24.67	$3,700.20
J9394	56,602	53	$1.65	$2,906,338.93
Total				$3,289,662.78

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As illustrated in Table 131, the application of the proposed payment limit calculation approaches would have reduced program spending for all but three drugs that reported negative or zero ASP data in calendar quarters in 2023 and reduced spending by a total of $7,241,960.21 over the year.

We separately analyzed theoretical changes in program spending for one biosimilar product (ZIEXTENZO®, Q5120) that has reported negative ASP data for all NDCs for three consecutive quarters beginning with the second calendar quarter of 2022, and calculated the payment limit under our proposed method for biosimilars with negative or zero ASP data and changes in program spending for the three impacted quarters had our proposed payment approach been applied. We also analyzed payment limits and theoretical changes in program spending under two alternatives considered under the proposed rule. Under the first alternative, we would include the ASP data and billing units sold of the reference biological for a given quarter along with those of the other biosimilars in the volume-weighted average calculation. Under the second alternative, we would set the payment limit for a given quarter using the biosimilar's most recent available positive ASP data and either 6 percent (or 8 percent for qualifying biosimilar biologicals) of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in § 414.902) for the given quarter. The calculated payment limits under the proposal and the two alternatives, as well as the estimate reductions in program expenditures, are illustrated in Table 131.

TABLE 131: Theoretical Changes in Medicare Spending on Q5120 for 4Q 2023 through 2Q 2024

Ziextenzo (Q5120)	Allowed Billing Units	Current Policy (WAC+6)	Payment limit: Proposal	Payment limit: First Alternative	Payment limit: Second Alternative
4Q2023	2,299	$346.755	$118.369	$95.267	$29.24
1Q2024	1179	$346.755	$117.313	$86.053	$27.40
2Q2024	132	$346.755	$149.574	$127.623	$31.86
			Spending Δ: Proposal	Spending Δ: First Alternative	Spending Δ: Second Alternative
4Q2023			$525,058.988	$578,171.42	$729,975.52
1Q2024			$270,512.618	$307,367.11	$376,513.91
2Q2024			$26,027.867	$28,925.38	$41,565.72
Total Savings			**$821,599.473**	**$914,463.917**	**$1,148,055.145**

We note that the spending change estimates reflect preliminary claims data. Providers and suppliers have a 12-month period to submit Medicare Part B claims, including claims for drugs payable under Part B, so a lag exists between the date of service when a drug is administered and when the claim is submitted and adjudicated. Because of this lag in finalized claims, there may also be a lag in available JW modifier data for any given date of service quarter. An evaluation of July 2010 Medicare Part B claims in the Physician/Supplier-Carrier setting showed that 91.68, 96.84, and 98.32, and 99.13 percent of claims were final at 3, 6, 9, and 12 months, respectively, following the date of service. At 24 and 48 months, 99.83 and 100 percent of the claims, respectively, were considered to be final. Therefore, for the allowed billing units and estimated program expenditure reduction for the first 2 calendar quarters of CY 2024 are significantly lower than we would expect after claims mature for a full

year. Over the 3 calendar quarters (4Q2023, 1Q2024, and 2Q2024), our proposed approach for calculating the payment limit for biosimilars with only negative or zero ASP and the two alternative approaches would have reduced program expenditures by at least $821,599.473, $914,463.917, and $1,148,055.145, respectively.

After assessing the effect of applying the proposed alternative payment limit calculation approaches to recent Medicare FFS claims experience over 2023 and 2024, we estimate an average annual gross Part B effect of $10 million dollars in reduced program spending for 2025 and approximately $100 million over 2025 to 2034, as shown in Table 134. Historically we have observed that negative or zero ASP pricing data may occasionally occur for a drug when it is discontinued or substituted away for another product and assume this to occur in the future. Moreover, given the infrequency of negative or zero ASP data, we do not expect in all years that alternative pricing approaches will be necessary or to affect drugs with material levels of utilization. Therefore, for a low estimate we project the policy to have a negligible effect on program spending for the projection window. To illustrate a potential high impact estimate scenario, the affected utilization from 2023 was doubled relative to the observed data. Please note that the actual effect of the policy will be specific to the affected drugs in any given year and considerations that affect their utilization and pricing, therefore actual experience may deviate considerably from these projections.

c. Impacts Related to the Payment of Radiopharmaceuticals in the Physician Office

In section III.A.3. of this proposed rule, while we evaluate our broader policies in this space for future rulemaking, we are proposing to codify in regulations at § 414.904(e)(6) that, for radiopharmaceuticals furnished in a setting other than the hospital outpatient department, MACs shall determine payment limits for radiopharmaceuticals based on any methodology used to determine payment limits for radiopharmaceuticals in place on or prior to November 2003. Such methodology may include, but is not limited to, the use of invoice-based pricing. The proposal does not necessarily change the payment methodology in place for a MAC but rather clarifies that any payment methodology that was being used by any MAC prior to the enactment of the MMA can continue to be used by any MAC. Therefore, we believe that this proposal will have no impact on Medicare spending.

d. Impacts Related to Immunosuppressive Therapy

In section III.A.4 of this proposed rule, we are proposing to modify regulations to include orally or enterally administered compounded formulations of FDA-approved drugs that have approved immunosuppressive indications, or that have been determined by a Medicare Administrative Contractor (MAC) to be reasonable and necessary for specific purposes in immunosuppressive treatment in the immunosuppressive drug benefit. In addition, we are proposing two changes regarding supplies of immunosuppressive drugs to align with current standards of practice and reduce barriers to medication adherence: to allow payment of a supply fee for a prescription of a supply of up to 90 days and to allow prescriptions for these immunosuppressive drugs to be refillable.

CMS has limited insight into how many patients who are currently prescribed compounded immunosuppressive drugs would have their immunosuppressive medication paid for under Part B if the proposed changes to the immunosuppressive drug benefit are finalized. Medicare Part D claims data for CY 2023 indicates there were 2,662 prescriptions filled that year for compounded immunosuppressive drugs that could have been administered through oral or enteral routes (that is, that would likely be paid under Part B if the immunosuppressive drug benefit revision is finalized as proposed). We estimate that this number of prescriptions correlates to up to 2,000 Part D enrollees that were prescribed compounded immunosuppressive drugs that would be covered if the proposal is finalized. However, we do not know how many Part B beneficiaries currently have their compounded immunosuppressive drugs paid for by means other than a Part D policy. And finally, and perhaps most importantly, compounded drugs are priced by each A/B and DME MAC and have no estimable payment limit. Thus, we are unable to estimate the cost shift from Part D and other plans to Part B that would result from a finalization of the immunosuppressive drug benefit proposed policies, including allowing payment of supply fees for prescriptions fills for supplies of up to 90 days and for immunosuppressive drugs to be refillable.

e. Impacts Related to Clotting Factors

In section III.A.5. of this proposed rule, we are proposing to update § 410.63(b) to clarify existing CMS policy that blood clotting factors must be self-administered to be considered clotting factors for which the furnishing fee applies. Additionally, we are proposing to clarify at § 410.63(c) that the furnishing fee is only available to entities that furnish blood clotting factors, unless the costs associated with furnishing the clotting factor are paid though another payment system, including the PFS. That is, we are proposing to clarify through revisions to § 410.63 that clotting factors (as specified in section 1861(s)(2)(I) of the Act) and those eligible to receive the clotting factor furnishing fee (as specified in section 1842(o)(5) of the Act) are the same subset of products. Accordingly, the clarification will not be adding a furnishing fee to any new products. Therefore, we believe that this clarification will have no impact on Medicare spending.

6. Impacts Related to Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

In section III.B.2. of this proposed rule, we are proposing to require RHCs and FQHCs to bill the individual codes that make up the general care management HCPCS code, G0511. Payment amounts for some services that comprise HCPCS code G0511 are less than the payment amount for G0511 and if an RHC or FQHC mostly furnishes these services, they could see a potential decline in payment. We are also proposing to allow RHCs and FQHCs to bill the add-on codes for additional time spent once the minimum threshold of time was met to account for a complete encounter. This could potentially offset any decrease in payments. In addition, beginning in CY 2025, we are proposing to adopt the coding and policies regarding Advanced Primary Care Management (APCM) services proposed under the PFS, as discussed in section II.G of this proposed rule. In terms of estimated impacts to the Medicare program, we believe that the proposals discussed in section III.B.2 of this proposed rule would have no impact on Medicare spending.

In section III.B.3. of this proposed rule, we are proposing the policy to continue to adopt the definition ''immediate availability'' as including real-time audio and visual interactive telecommunications for the direct supervision of services and supplies furnished incident to a physician's service through December 31, 2025, for

RHCs and FQHCs. We are also proposing, on a temporary basis, to allow payment for non-behavioral health visits furnished via telecommunication technology in a manner that would closely align with the payment mechanisms mandated by statute through December 31, 2024, that is, RHCs and FQHCs would continue to bill for RHC and FQHC services furnished using telecommunication technology services by reporting HCPCS code G2025 on the claim through December 31, 2025. In addition, we are proposing to continue to delay the in-person visit requirement for mental health services furnished via communication technology by RHCs and FQHCs to beneficiaries in their homes until January 1, 2026. We believe these RHC/FQHC proposals related to telecommunication technology would have a negligible impact on Medicare spending.

In section III.B.4. of this proposed rule, we discuss the implementation of section 4124 of the CAA, 2023. Section 4124 of the CAA, 2023 established Medicare coverage for intensive outpatient (IOP) services furnished by a hospital to its outpatients, or by a community mental health center, a RHC or a FQHC, as a distinct and organized intensive ambulatory treatment service offering less than 24-hour daily care in a location other than an individual's home or inpatient or residential setting, effective January 1, 2024 (88 FR 81838). We are proposing to provide a payment rate for 4 or more services per day in the RHC and FQHC setting. In terms of impact, we believe that this proposal would have negligible impact on Medicare spending.

In section III.B.5. of this rulemaking, we are proposing to allow RHCs and FQHCs to bill for Part B preventive vaccines and the administration at the time of service. We propose that payments for these claims will initially be made according to Part B preventive vaccine payment rates in other settings, but that they will be annually reconciled with the facilities' actual vaccine costs on their cost reports, which is current practice and statutorily mandated. Therefore, we believe that this proposal would have no impact on Medicare spending.

In section III.B.6. of this proposed rule, we discuss our proposal relating to RHC productivity standards. We are proposing to remove productivity standards for RHCs and therefore believe that the proposal discussed in this section III.B.6. of this proposed rule would have no impact on Medicare spending.

In section III.B.8. of this proposed rule, we are clarifying that when RHCs and FQHCs furnish dental services that align with the inextricably linked policies and operational requirements in the physician setting, we would consider those services to be a qualifying visit and the RHC would be paid at the RHC AIR and the FQHC would be paid under the FQHC PPS. We believe this clarification related to dental services furnished in RHCs and FQHCs would have a negligible impact on Medicare spending. Even though this is a new benefit, it would only cover dental services inextricably linked to specific medical services as described in section II.J. of this proposed rule.

7. Changes in the RHC and FQHC CfCs: Provision of Services (§ 491.9(a)(2) and (c)(2)(ii) and (vi))

Provision of Services (§ 491.9)

At § 491.9(a)(2), we are proposing to explicitly state that an RHC and FQHC must provide primary care services and an RHC cannot be a rehabilitation agency or a facility that is primarily for the care and treatment of mental diseases. We believe this proposal would result in real, but difficult to estimate, long-term benefits to patients receiving services at RHCs and FQHCs, as well as economic benefits to the clinic or center. Regarding the estimated impacts on the Medicare program, the proposals discussed in section III.C.2 of this proposed rule would have no impact on Medicare spending.

This proposed change would provide RHCs with additional flexibility to provide outpatient specialty services on-site or hire additional providers with specialized expertise to meet the needs of their community, including internal medicine, pediatrics, geriatrics, obstetrics and gynecology, dermatology, cardiology, neurology, endocrinology, and ear, nose and throat. As a result, RHCs would be able to improve access to care by serving more patients in communities served by RHCs and FQHCs, including rural communities, and not requiring patients to travel longer distances to receive specialty services. Patients could have access to specialists within their own communities, improving overall access for Medicare beneficiaries. Moreover, if this policy were to be finalized, CMS would no longer determine or enforce the standard of RHCs ''being primarily engaged in furnishing primary care services.'' [808] which has been enforced via the sub-regulatory guidance contained in the *State Operations Manual Appendix G—Guidance for Surveyors: Rural Health Clinics (RHCs).* Resources that clinics are currently using to evaluate if they are meeting this requirement could be devoted to other administrative tasks. Therefore, we believe that there would be no burden imposed on RHCs or FQHCs related to this proposal.

We are also proposing to remove hemoglobin and hematocrit (H&H) lab tests from the list of specific tests RHCs must provide, as well as update the language regarding the primary culturing requirement to reflect current standards of practice at § 491.9(c)(2)(ii) and (vi), respectively. As discussed in section III.C.2.b of this proposed rule, RHCs report the H&H lab requirement is particularly burdensome and costly for clinics due to purchasing and maintaining the equipment, even if it is seldom or never used.

This proposed change would reduce the overall burden for RHCs by reducing the number of diagnostic tests they must provide. RHCs would no longer be required to purchase or maintain H&H lab test equipment or supplies, freeing up resources for other essential services. H&H lab tests are most often ordered as part of a larger panel of labs that is not provided at the RHC. When this is the case, patients will receive the H&H as part of that larger panel at an outside lab that offers the larger panel of labs. These patients may be inconvenienced by having to travel to another laboratory, but this limits the number of specimens they must provide for the laboratory tests, reducing the number of times a patient's veins must be accessed for blood draws. RHCs report that when laboratory tests are ordered that are not provided by the RHC, such as a comprehensive blood count (CBC), their patients are often sent to the nearest hospital that would have a full-service laboratory available to perform the test. A CBC test looks at a patient's overall health and can detect a wide range of conditions that the hemoglobin and hematocrit tests cannot. This ensures comprehensive patient care and may result in a decreased need for follow-up testing and decreased patient turnaround time.[809]

Currently, there are approximately 5,462 Medicare-certified RHCs. Applying the most recent data from

[808] Centers for Medicare & Medicaid Services. (2020, February 21). State Operations Manual Appendix G—Guidance for Surveyors: Rural Health Clinics (RHCs) (pp. 63–64). *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_g_rhc.pdf.*

[809] Mayo Foundation for Medical Education and Research. (2023, January 14). *Complete blood count (CBC).* Mayo Clinic. *https://www.mayoclinic.org/tests-procedures/complete-blood-count/about/pac-20384919.*

2021, 66 percent (3,605) of RHCs are designated as ''provider-based,'' which are owned and operated as an integral part of a hospital, nursing home, or home health agency.[810] The remaining 34 percent (1,857) of RHCs are ''independent clinics'' and, though uncommon, may be owned and/or operated by a healthcare system. Therefore, we assume that at most, half of the independent clinics, for a total of 929 RHCs, would continue to provide H&H tests because it is less likely that they are a part of a healthcare system. As a result, we assume that 4,534 (3,605 provider-based RHCs + 929 independent clinics) RHCs will continue to refer patients to a fully certified laboratory rather than directly provide the H&H test. Because the regulatory requirements at § 491.9 States that RHCs must provide H&H lab tests on-site, RHCs must have and maintain the appropriate equipment to perform these tests, even if the equipment is not utilized. There are variations in the H&H testing equipment RHCs may use; however, we note that the average cost of an H&H meter or analyzer costs approximately $1,200 for the system and is replaced on average every 3 years. The systems also have an approximate $100 annual maintenance fee. We estimate that over the next 3 years, 4,534 RHCs will each save approximately $1,500. This would result in a total annual savings of $2,267,000 ((4,534 RHCs that typically refer patients to a fully certified laboratory × $1,500)/3). After 3 years, the RHC program would save a total of $6,801,000 (4,534 × $1,500).

8. Clinical Laboratory Fee Schedule

In section III.D. of this proposed rule, we outline statutory revisions to the data reporting period and phase-in of payment reductions under the CLFS. In accordance with section 502 of the FCAOEA, 2024, we are proposing certain conforming changes to the data reporting and payment requirements in our regulations at 42 CFR part 414, subpart G. Specifically, for CDLTs that are not ADLTs, we are proposing to update certain definitions and revise § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017, and is required every 3 years beginning January 2025. Section 502(b) of the FCAOEA, 2024 delays the next data reporting period under the CLFS for CDLTs that are not ADLTs by 1 year, that is, it requires the next data reporting period for these tests to take place during the period of January 1, 2025, through March 31, 2025. Subsequently, the next private payor rate-based CLFS update for these tests will be effective January 1, 2026, instead of January 1, 2025. In addition, we are proposing conforming changes to our requirements for the phase-in of payment reductions to reflect section 502(a) of the FCAOEA, 2024. Specifically, we are proposing to revise § 414.507(d) to indicate that for CY 2024, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2023, and for CYs 2025 through 2027, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

We recognize that private payor rates for CDLTs paid on the CLFS and the volumes paid at each rate for each test, which are used to determine the weighted medians of private payor rates for the CLFS payment rates, have changed since the first data collection period (January 1, 2016, through June 30, 2016) and data reporting period (January 1, 2017, through March 31, 2017). In addition, as outlined in section III.D. of this proposed rule, in the CY 2019 PFS final rule (83 FR 59671 through 59676), we amended the definition of applicable laboratory to include hospital outreach laboratories that bill Medicare Part B using the CMS–1450 14x Type of Bill. As such, the FCAOEA, 2024 amendments to the data reporting period will delay using updated private payor rate data to set revised CLFS payment rates for CDLTs that are not ADLTs.

Due to unforeseen changes in private payor rates due to shifts in market-based pricing for laboratory tests and the unpredictable nature of test volumes and their impact on calculating updated CLFS payment rates based on the weighted median of private payor rates, it is uncertain whether the delay in data reporting will result in a measurable budgetary impact. In other words, to assess the impact of delayed reporting and subsequent implementation of updated CLFS rates, we will need to calculate weighted medians of private payor rates based on new data and compare the revised rates to the current rates. As such, we believe that we will only know the impact of the delay in data reporting after collecting actual updated applicable information from applicable laboratories and calculating the updated CLFS rates.

Regarding the proposed conforming changes to our requirements for the phase-in of payment reductions, we note that for CYs 2025 through 2027, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year. Based on data reported in the 2017 data collection period, we estimate 14.8 percent (191) of tests on the CLFS may be subject to the full 15 percent phase-in reduction in CY 2025.

9. Effects of Proposals Relating to the Medicare Diabetes Prevention Program Expanded Model

a. Effects on Beneficiaries

We are proposing to modify certain Medicare Diabetes Prevention Program (MDPP) expanded model policies to: (1) align MDPP terminology and definitions with the proposed 2024 Centers for Disease Control and Prevention (CDC) Diabetes Prevention Recognition Program (DPRP) Standard[811] definitions for ''in-person with a distance learning component,'' ''combination with an online component,'' and ''online''; (2) remove the MDPP bridge payment; (3) provide a more effective option for a beneficiary to self-report their weight in an MDPP distance learning session, by submitting 2 photos; (4) facilitate Medicare Administrative Contractors (MACs) in processing claims for a MDPP make-up session held on the same day as a regularly scheduled session by requiring use of an existing HCPCS modifier; and (5) align current rule language with previous rulemaking.

MDPP is a non-pharmacological behavioral intervention consisting of up to 22 sessions using a CDC approved National Diabetes Prevention Program (National DPP) curriculum.[812] CDC administers a national quality assurance program recognizing eligible organizations that furnish the National DPP through its evidence based DPRP Standards, which are updated every three years. The 2024 CDC DPRP Standards replace the 2021 CDC DPRP Standards in June 2024.[813]

The Calendar Year (CY) 2021 PFS final rule allowed virtual delivery of MDPP during the COVID–19 Public

[810] Gale, J.A., Croll, Z., Croom, J., Munk, L., & Jonk, Y. (2022). Community Characteristics and Financial and Operational Performance of Rural Health Clinics in the United States: A Chartbook. University of Southern Maine, Muskie School of Public Service, Maine Rural Health Research Center. *https://digitalcommons.usm.maine.edu/cgi/viewcontent.cgi?article=1016&context=clinics.*

[811] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

[812] *https://www.cdc.gov/diabetes/prevention/resources/curriculum.html.*

[813] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

Health Emergency (PHE) (85 FR 84830). Improvements to MDPP in the Calendar Year 2024 final rule included a simplified payment structure to allow for fee-for-service (FFS) payments for beneficiary attendance, while retaining the performance-based payments for diabetes risk reduction (that is, weight loss) (88 FR 79241). This policy also extended certain PHE flexibilities including the option to deliver some or all MDPP sessions via distance learning, until December 31, 2027 (88 FR 79241). Another PHE flexibility extended through December 31, 2027, at 42 CFR 410.79(e)(3)(iii), is for MDPP suppliers to obtain weight measurements for beneficiaries using one of the following options: (1) via digital technology, such as scales that transmit weights securely via wireless or cellular transmission; or (2) via self-reported weight measurements from the at-home digital scale of the MDPP beneficiary.

The 2024 CDC DPRP Standards were proposed after the CY 2024 PFS was finalized. To align with 2024 CDC DPRP Standards, we are proposing to update the MDPP definition for ''online'' delivery to align with the proposed 2024 CDC DPRP definition. We are also proposing to add terms and definitions for CDC's new modalities including ''in-person with a distance learning component'' and ''combination with an online component'' and to remove the existing ''combination'' term and definition. Lastly, we are specifying that MDPP make-up sessions must be provided in-person or via distance learning delivery, as required by the CY 2024 PFS final rule.[4]

Furthermore, the MDPP bridge payment (G9880), which is a payment made to the subsequent supplier for the first session when a beneficiary switches MDPP suppliers, is no longer necessary in MDPP's CY 2024 FFS payment structure and may increase risk for fraud, waste, or abuse. We are proposing to remove the bridge payment from the MDPP CY 2025 Fee Schedule. In addition, we have identified a more effective option for a beneficiary to self-report their weight in an MDPP distance learning session. We have also identified the need to require suppliers to use Current Procedural Terminology (CPT) Modifier 79 to allow Medicare Administrative Contractors (MACs) to identify a claim for an MDPP make-up session held on the same day as a regularly scheduled session. Finally, we are proposing to align current rule language with previous rulemaking pertaining to MDPP terminology, requirements, and payment structure.

All the proposed changes for MDPP in CY 2025 are conforming or administrative and expected to have a modest impact on beneficiaries' access to MDPP services. Aligning with 2024 CDC DPRP Standards for MDPP delivery modes may help expand beneficiary access by streamlining data submission for MDPP suppliers and increasing the number of MDPP eligible organizations that enroll in Medicare as MDPP suppliers. Additionally, allowing for MDPP make-up sessions to be scheduled on the same day as regularly scheduled sessions would increase flexibility for both MDPP suppliers and beneficiaries and may help expand access for beneficiaries with transportation and other scheduling issues that prevent scheduling sessions more than one day a week or month. Increased flexibility in scheduling MDPP sessions may help to address a lack of MDPP suppliers in certain communities and challenges related to beneficiary logistics concerning course attendance.

Additionally, we are proposing to provide a more effective option to beneficiaries to self-report weight for a MDPP distance learning session, by allowing beneficiaries to submit 2 (two) photos to capture both the beneficiary weight on the digital scale and the beneficiary visible in their home. Current MDPP supplier standards at § 424.205 require beneficiary weight to be reported at each MDPP session attended. This proposed change would help to address concerns voiced by MDPP suppliers who have reported that many of their beneficiaries are unable to take a picture while standing on their home scales due to risk of injury and physical health limitations. This new flexibility may promote more consistent collection of weight for MDPP sessions.

Lastly, we do not expect removing the MDPP bridge payment to have an impact on beneficiary access. This payment for the first session attended with a new supplier when a beneficiary switches MDPP suppliers is not necessary in MDPP's CY 2024 FFS payment structure that includes payment for every session attended and historically has been submitted by few MDPP suppliers.

Overall, these modifications address MDPP supplier and beneficiary needs based upon available monitoring and evaluation data received to date, feedback from Medicare Advantage plans and existing MDPP suppliers, and feedback from beneficiary focus groups. The changes are also in response to comments from interested parties made through public comments in response to prior rulemaking.

b. Effects on the Market

We anticipate that the conforming and administrative changes proposed in this rulemaking are likely to result in modest increases of MDPP suppliers and beneficiary access to the set of MDPP services. We anticipate that this would assist in contributing to a reduction of the incidence of diabetes among eligible Medicare beneficiaries. As of April 2024, there are approximately 810 in-person organizations nationally that are eligible to become MDPP suppliers based on their preliminary or full CDC Diabetes DPRP status. However, only 36 percent of these eligible in-person organizations are participating in MDPP.[814] Aligning with CDC DPRP delivery modes, particularly adding the new ''in-person with a distance learning component'' mode, is expected to help increase recruitment of new DPRP organization as MDPP suppliers, who currently would need to obtain both in-person and distance learning CDC DPRP recognition to deliver sessions via both modalities. Furthermore, only about one-third of MDPP suppliers have submitted MDPP-related claims.[815] Our proposed change to remove the MDPP bridge payment would help to further simplify the payment structure, which is expected to have a positive impact on supplier claim submissions. While requiring MDPP suppliers to add a modifier to indicate that a claim is for a MDPP same day make-up session does add complexity because we have proposed to use an existing CPT modifier in use and recognized by the MACs, we expect this addition to require minimal changes in claim processing systems. Additionally, this modifier is only to be used for same day make-up sessions, which are only allowed once per week, and, while an important tool to increase access for beneficiaries with barriers to participation in MDPP, are not expected to be used for most session attendance claims. In summary, we believe that having more flexibility in how the set of MDPP services are delivered would make MDPP more accessible to beneficiaries, particularly those who live in rural areas or in communities with gaps in MDPP supplier locations.

c. Payment for MDPP Services

Regulations at § 414.84 specify that MDPP suppliers may be eligible to receive payments for furnishing MDPP services and meeting performance

[814] Centers for Disease Control and Prevention. Diabetes Prevention Recognition Program Application. Registry of All Recognized Organizations. *https://dprp.cdc.gov/Registry.*

[815] Unpublished MDPP monitoring data. 2023.

targets related to beneficiary weight loss and attendance. We anticipate that the proposed change to the MDPP payment structure would have minimal impact on total payment for MDPP services. A smaller proportion of MDPP suppliers, only 9.8 percent since the start of the program through April 2024, have submitted claims for the MDPP bridge payment, with an even smaller proportion of 2.7 percent having received payment for a bridge payment claim. According to CDC DPRP data, less than 1 percent of MDPP sessions are same day make-up sessions.[816] The total maximum payment per beneficiary for MDPP of $768 would remain unchanged by our proposals.

d. Effects on the Medicare Program

(a) Estimated 10-Year Impact of MDPP

The changes proposed this year for implementation in the CY PFS 2025 are expected to have no impact on Medicare spending.

10. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

As outlined in section III.F.2 of this proposed rule, we are proposing to permanently allow periodic assessments to be furnished via audio-only communication when two-way audio-video communications technology is not available to the beneficiary, to the extent that it is authorized by SAMHSA and DEA at the time the service is furnished and all other applicable requirements are met. We are also proposing to allow the OTP intake add-on code to be furnished via two-way audio-video communications technology when billed for the initiation of treatment with methadone to the extent that the use of audio-video telecommunications technology to initiate treatment with methadone is authorized by DEA and SAMHSA at the time the service is furnished, an OTP determines that an adequate evaluation of the patient can be accomplished via a via an audio-visual telehealth platform, and all other applicable requirements are met. We believe the Part B cost impact of these flexibilities for the use of telecommunications will be minimal because we do not expect that these flexibilities will significantly increase the frequency with which medically necessary intake activities and periodic assessments are furnished, and since the payment rate for these services will be the same regardless of if an OTP furnishes these services via telecommunications or in-person.

In section III.F.3 of this proposed rule, CMS is proposing to update the payment rate for intake activities (HCPCS code G2076) by adding in the value of the non-facility rate for SDOH risk assessments described by HCPCS code G0136 (*Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5–15 minutes, not more often than every 6 months*). We believe updating the payment amount for intake activities with an addition of HCPCS code G0136 would serve as a reasonable proxy to reflect the value and resources required by new SAMHSA standards for initial assessment service activities at § 8.12(f)(4)(i) that OTPs are required to provide, including an assessment to identify a patient's unmet HRSNs or the need for harm reduction intervention and recovery support services that are critical to the treatment of an OUD. Currently, the CY 2024 payment rate for the intake add-on code (G0276) is $201.73 and adding the value of a crosswalk to the CY 2024 non-facility rate of $18.66 would result in a payment rate of approximately $220.39. The payment rate would also continue to be updated annually by the percentage increase in the Medicare Economic Index (MEI) and the Geographic Adjustment Factor (GAF) as codified in § 410.67(d)(4)(ii) through (iii). According to historical claims data for intake activities (HCPCS code G2076) furnished by OTPs from the beginning of CY 2020 through the end of CY 2023, the number of claims for intake activities is low. Due to low utilization of the intake activities add-on code (HCPCS code G2076), CMS estimates that an increase in the add-on payment amount to HCPCS code G2076 by $18.66 per claim would still result in a negligible cost to the Medicare program. Lastly, in section III.F.4 of this proposed rule, we are proposing to establish payment for new opioid agonist and antagonist medications that were recently approved by the FDA. We proposed to include a new add-on code to the bundled payment for a new opioid overdose reversal product, nalmefene hydrochloride nasal spray product (Opvee®), which includes one carton of two, 2.7 mg nasal sprays of nalmefene. We proposed to price the drug component of this add-on code for nalmefene according to the ASP payment methodology set forth in section 1847A, except that the payment amount shall be ASP + 0. The non-drug component of this add-on code would also include overdose education furnished in conjunction with nalmefene, and it would be updated annually by the percentage increase in the MEI and GAFs consistent with other opioid antagonist medications in § 410.67(d)(4)(ii) through (iii). We are limiting Medicare payment to OTPs for nalmefene to one add-on code every 30 days, however, we will allow exceptions to this limit in the case where the beneficiary overdoses and uses the initial supply of nalmefene dispensed by the OTP, to the extent that it is medically reasonable and necessary to furnish additional doses of nalmefene. We are also proposing payment for the weekly formulation of the new extended-release injectable buprenorphine product Brixadi®, via a new weekly bundled payment code that includes a drug and non-drug component. We proposed to price the drug component consistent with our payment methodology for implantable and injectable medications codified § 410.67(d)(2)(i)(A), and we proposed to limit the payment amount to 100-percent of ASP and to use a crosswalk to the weekly Brixadi® formulation described by HCPCS code J0577 (*Injection, buprenorphine extended release (brixadi), less than or equal to 7 days of therapy*). The non-drug component (individual and group therapy, SUD counseling, toxicology testing) would also include administration of an injection based on CPT code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*); updated annually by the percentage increase in MEI and GAFs. CMS is further proposing to update the drug-component of the existing HCPCS code (G2069) for monthly injectable buprenorphine to include the monthly formulation of Brixadi® based on a crosswalk to HCPCS code J0578 *(Injection, buprenorphine extended release (brixadi), greater than 7 days and up to 28 days of therapy*). We proposed to continue to use the existing payment methodology for both the drug and non-drug component of G2069 after averaging in payment for the monthly formulation of Brixadi®. Since the proposed payment methodology for the new add-on code for Opvee® (GOTP1), the weekly bundled payment for weekly Brixadi® (GOTP2), and the update to the monthly bundled payment for injectable buprenorphine (HCPCS code G2069) is based on comparable and existing drugs billed under the Medicare OTP benefit, and assuming an OTP may provide these new drugs to a Medicare beneficiary in lieu of the comparable

[816] Diabetes Prevention Recognition Program. Unpublished data. April 2024.

and existing drugs under the Medicare OTP benefit (*e.g.,* Opvee® instead of Narcan® or Kloxxado®, or the weekly or monthly formulation of Brixadi® instead of Sublocade®), then CMS estimates the financial impacts of these new drugs would be negligible.

11. Medicare Shared Savings Program

a. General Impacts

As of January 1, 2024, 10.8 million Medicare beneficiaries receive care from a health care provider in one of the 480 ACOs participating in the Shared Savings Program, one of the largest value-based care programs in the country. The Shared Savings Program proposed policies in this proposed rule would advance Medicare's value-based care strategy of growth, alignment, and equity, with many proposals supporting more than one of these goals. The proposed policies in this proposed rule are designed, in part, to further improve the quality of care furnished by ACOs by revising the quality performance standard and reporting requirements, broaden program participation particularly in underserved communities, and promote the continued integrity and fairness of Shared Savings Program financial calculations.

As described in section III.G.7.b of this proposed rule, under the benchmarking methodology for agreement periods beginning on January 1, 2024, and in subsequent years, CMS calculates two adjustments in establishing the historical benchmark, a regional adjustment (refer to § 425.656) and a prior savings adjustment (refer to § 425.658). We determine which adjustment is applied to the benchmark, either the regional adjustment, prior savings adjustment, or no adjustment (refer to § 425.652(a)(8) and (c)). One of the changes to the Shared Savings Program financial methodology finalized with the CY 2024 PFS final rule (see 88 FR 79185 through 79195, see also 88 FR 79494 and 79495) was to mitigate the impact of the negative regional adjustment on the benchmark for ACOs in agreement periods beginning on January 1, 2024, and in subsequent years. We explained our belief that this change would further encourage continued participation among high-cost ACOs that serve medically complex beneficiaries by eliminating the potential of a lower benchmark due to an overall negative regional adjustment, and may also encourage ACOs serving such populations that may have otherwise been discouraged from participating in the Shared Savings Program by the prospect of a lower benchmark to join (see 88 FR 79188, see also 88 FR 79494 and 79495). Under this approach, an ACO with an overall negative regional adjustment that was not eligible for a prior savings adjustment would ultimately receive no adjustment, upward or downward, to its benchmark (see § 425.652(a)(8)(iii) and see also 88 FR 79190). The proposed Health Equity Benchmark Adjustment (HEBA) described in section III.G.7.b of this proposed rule would add a third avenue for ACOs to receive a positive adjustment to their historical benchmark, and would be most impactful for new ACOs serving medically complex, high-cost populations in underserved communities.

We combined an analysis of the impact of the HEBA on currently participating ACOs with the projected impact of HEBA on new ACOs not yet participating in the Shared Savings Program, to generate an overall impact estimate of the HEBA. The HEBA would likely have a limited impact on currently participating ACOs. Only about 20 percent of the 456 ACOs participating in performance year 2023 were estimated to have a proportion of assigned beneficiaries who were enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid equal to or greater than 20 percent. That 20 percent threshold would have to be met for an ACO to be eligible for the HEBA under the HEBA proposal (as discussed in section III.G.7.b. of this proposed rule, and specified in proposed § 425.662(b)(3)). Of that 20 percent of ACOs participating in performance year 2023 that were estimated to have a proportion of assigned beneficiaries who were enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid equal to or greater than 20 percent, only about one quarter of such ACOs were estimated to not already be eligible for a higher benchmark adjustment from either a positive regional adjustment or a prior savings adjustment. That is, about 5 percent of ACOs participating in performance year 2023 were estimated to benefit from the proposed HEBA policy at rebasing (median effect about 1 percent increase to the benchmark), because an ACO would receive the proposed HEBA only if the HEBA adjustment were higher than the existing ''higher of'' adjustment method (see discussion in section III.G.7.b of this proposed rule, and proposed §§ 425.652(a)(8)(ii)(B)(*1*) and 425.662(c)). The proposed HEBA is projected to increase program spending for existing ACOs by about $140 million over 10 years.

The number of ACOs that would be incentivized to participate in the Shared Savings Program by the HEBA is uncertain. Changes to the Shared Savings Program finalized in the CY 2023 CY 2024 PFS final rules were already projected to increase program participation among ACOs with higher spending and provide more opportunities for improving care and reducing spending (see 87 FR 70191 through 70196, and 88 FR 79494 and 79495). Therefore, we can reasonably estimate that at least some new ACOs may join and succeed in the Shared Savings Program regardless of the benefit afforded to them by the proposed HEBA (if finalized). Savings to the Shared Savings Program are expected to grow to the extent that the HEBA were to cause new, high-spending ACOs to participate—that is, ACOs serving populations with risk-adjusted spending that is significantly higher than corresponding regional benchmark spending at baseline. We project in the 2034 performance year, the proposed HEBA would likely increase program participation by 25 additional ACOs (but our estimates of increased program participation range from 0 to 100 additional ACOs), as compared to program participation today, and on net increase Federal Medicare program savings by $460 million over the 2025–2034 period because of this new participation.

The estimated impact of the proposed HEBA, accounting for both its impact on currently participating ACOs that are assumed to renew their participation in the Shared Savings Program over the next 5 years and new ACOs that are expected to participate in the program for the first time over the next 10 years, is shown in Table 132. Mean Shared Savings Program spending is expected to be reduced by $320 million over the next ten years as a result of the HEBA, if finalized. However, uncertainty regarding the number of high spending ACOs that would participate in response to a HEBA, combined with uncertainty regarding high spending ACOs' savings potential, results in a wide range of potential impacts in total over that 10 year period, from $2.3 billion in net savings at the 10th percentile (that is, only 10 percent of stochastic trials reduced Federal spending by a greater magnitude than $2.3 billion) to $1.2 billion in net spending at the 90th percentile.

TABLE 132: Projected Impact of Proposed Health Equity Benchmark Adjustment ($ Millions; Negative Values Represent Savings to the Program)

	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	Total
Impact Estimate	20	20	30	20	10	-20	-60	-100	-120	-120	**-320**
Estimate Range:											
Low Estimate (10th Percentile)	0	-20	-40	-90	-140	-240	-340	-420	-490	-540	**-2,320**
High Estimate (90th Percentile)	50	70	90	110	130	140	140	140	150	180	**1,200**

For the proposed calculation methodology to account for the impact of improper payments in recalculating expenditures and payment amounts used in Shared Savings Program financial calculations, upon reopening a payment determination pursuant to § 425.315(a) (described in section III.G.7.c of this proposed rule), some ACOs would selectively elect to request reopening for a prior performance year. As a result, we project at least some degree of higher program spending for increased shared savings payments (or reduced loss recoupments) in cases for which CMS decides to reopen the payment determination and issue a revised initial determination to account for the impact of improper payments. However, because reopening would not be limited to adjusting performance year and benchmark year expenditures for ACO assigned beneficiaries but would also impact other potentially offsetting calculations including regional and national expenditure trends used to update ACO benchmarks, and because, in addition to the reopening, CMS would also adjust the historical benchmark calculated for a potential subsequent agreement period, the frequency of requests, and the net impact of any given request, are likely to be limited. The proposed reopening policy is projected to increase program spending by $60 million in total over the 2025 to 2034 period, ranging from $30 million at the 10th percentile to $90 million at the 90th percentile, as shown in Table 133.

TABLE 133: Projected Impact for Modifications to Specify the Calculation Methodology to Account for Improper Payments in Recalculating Expenditures and Payment Amounts used in Financial Calculations, Upon Reopening a Payment Determination ($ Millions; Negative Values Represent Savings to the Program)

	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	Total
Impact Estimate	10	0	0	0	0	10	10	10	10	10	**60**
Estimate Range:											
Low Estimate (10th Percentile)											**30**
High Estimate (90th Percentile)											**90**

Note: Projections at the 10th and 90th percentile are shown in aggregate but not at the annual level because scenarios contributing to the high estimate projection generally involve elevated spending in a limited number of years rather than consistently higher spending across the projection period.

The proposed methodology for excluding payment amounts for HCPCS and CPT codes exhibiting SAHS billing activity, as described in section III.G.7.d of this proposed rule, is anticipated to be utilized only in rare and extreme cases where a number of criteria are satisfied, including that the level of billing represents a significant claims increase representing a deviation from historical utilization trends that is unexpected and not clearly attributable

to reasonably explained changes in policy or the supply or demand for covered items or services during a limited time period. Even in cases where CMS may apply the adjustment to Shared Savings Program calculations for SAHS billing activity (if finalized), for CY 2024 or subsequent calendar years, there is no expectation that it would necessarily increase or decrease overall shared savings or shared losses because the policy would be applied systematically across all ACOs in the Shared Savings Program in a method that adjusts both performance year and benchmark year expenditures for ACO assigned beneficiaries and regional and national expenditures used in benchmark calculations. However, this policy would have the benefit of reducing potential costs generated by selective reopening requests under the reopening proposal, because it would prevent extreme cases of SAHS billing activity from injecting variation in the distribution of ACO shared savings and loss calculations which could lead to an elevated number of selective reopening requests from ACOs predicting that reopening would improve their financial outcome. For this reason, without the proposal to adjust Shared Savings Program calculations for SAHS billing activity during CY 2024 or subsequent calendar years, the estimated impact shown in Table 133 would have included between $100 to $300 million in additional projected spending from selective reopening requests.

We estimate that there would be no additional program expenditures stemming from the implementation of the prepaid shared savings payment option, which we proposed to provide eligible ACOs with additional cash flow to encourage their investment in activities that could potentially reduce costs for the Medicare program and beneficiaries and improve the quality of care furnished to their assigned beneficiaries. Any risk of higher program spending as a result of finalization of our prepaid shared savings proposal would be fully mitigated by the fact that eligibility would be limited to ACOs that CMS estimates are most likely to earn shared savings, and any prepaid shared savings payments an ACO receives would have to be repaid to CMS. CMS would be protected by the ACOs' repayment mechanisms in the event that an ACO does not earn shared savings or cannot otherwise repay the amount owed to CMS. On the other hand, there is a high degree of uncertainty regarding whether (a) a meaningful number of ACOs would choose this option given the requirements for how prepayments must be spent, and (b) the potential impact (if any) that participation in this option would have on the cost of care.

As to this uncertainty, our analysis assumed that up to 30 ACOs would opt to receive prepaid shared savings per year (with the probability distribution skewed toward zero participants), with a 33 percent chance that ACOs receiving prepaid shared savings would respond by reducing spending for assigned beneficiaries by between 0 to 2 percentage points (with the probability distribution skewed toward zero impact) as compared to their current spending on assigned beneficiaries.[817] This projection accounts for annual prepaid shared savings (offset by eventual recoupments and/or repayments) of roughly $2 million per ACO participating in the payment option. The associated impact on ACO spending was projected to be nominal. Both at the mean and at the 90th percentile the projected net impacts on Medicare spending round to zero. At the 10th percentile (the optimistic end of the range), we project small net savings of $20 million in total to the Medicare Program over 10 years.

TABLE 134: Projected Impact for the Prepaid Shared Savings Option ($ Millions; Negative Values Represent Savings to the Program)

	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	Total
Impact Estimate	0	0	0	0	0	0	0	0	0	0	**0**
Estimate Range:											
Low Estimate (10th Percentile)											**-20**
High Estimate (90th Percentile)											**0**

Note: Projections at the 10th and 90th percentiles are shown in aggregate but not at the annual level because scenarios contributing to the $20 million savings at the 10th percentile are too small to round above zero in any given year.

The remaining proposed changes to the Shared Savings Program regulations are not estimated to have an impact on program spending at the aggregate level. These proposed changes include requiring Shared Savings Program ACOs to report the APP Plus quality measure set beginning in performance year 2025, that would incrementally grow to comprise of 11 measures, consisting of the 6 measures in the existing APP quality measure set and 5 newly proposed measures from the Adult Universal Foundation measure set that would be incrementally incorporated

[817] The assumptions allow for a limited possibility that performance by ACOs receiving prepaid shared savings could generate shared savings comparable to the savings generated by certain ACOs in the ACO Investment Model. Abt Associates, Evaluation of the Accountable Care Organization Investment Model, Final Report (September 2020), available at *https://www.cms.gov/priorities/innovation/data-and-reports/2020/aim-final-annrpt.*

into the APP Plus quality measure set over performance years 2025 through 2028; focusing the collection types available to Shared Savings Program ACOs for reporting the APP Plus quality measure set to all payer/all patient eCQMs and Medicare CQMs; requiring Shared Savings Program ACOs that report the APP Plus quality measure set to report on all measures in the APP Plus quality measure set, as applicable; establishing a Complex Organization Adjustment for Virtual Groups and APM Entities, including Shared Savings Program ACOs, when reporting eCQMs; scoring Medicare CQMs using flat benchmarks in their first 2 performance periods in MIPS; and promoting the adoption of eCQMs by extending the eCQM reporting incentive. Additional proposed changes include permitting continued participation by ACOs whose number of assigned beneficiaries falls below 5,000 during their agreement period; ensuring clarity of provisions on application procedures; revisions to the definition of primary care services under § 425.400(c) for purposes of beneficiary assignment; refining advance investment payment policies; providing clarity and consistency in provisions of the Shared Savings Program regulations on calculation of the ACO risk score growth cap in risk adjusting the benchmark each performance year and the regional risk score growth cap in calculating the regional component of the three-way blended benchmark update factor; and modifying beneficiary notification requirements.

The combined impacts for all Shared Savings Program proposals are shown in Table 135.

TABLE 135: Projected Impact of Medicare Shared Savings Program Proposals (Individually Shown in Tables 132, 133 and 134) ($ Millions; Negative Values Represent Savings to the Program)

	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	Total
Impact Estimate	30	20	30	20	10	-10	-50	-90	-110	-110	**-260**
Estimate Range:											
Low Estimate (10th Percentile)	10	-20	-40	-90	-140	-230	-330	-410	-480	-530	-2,260
High Estimate (90th Percentile)	60	70	90	110	130	150	150	150	160	190	1,260

b. Compliance With Requirements of Section 1899(i)(3) of the Act

Certain policies, including both existing policies and the proposed new policies described in this proposed rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, and that do not result in program expenditures greater than those that would result under the statutory payment model. The following proposals require the use of our authority under section 1899(i) of the Act: the proposal to allow ACOs to receive prepaid shared savings as described in section III.G.5 of this proposed rule; the proposal to use a calculation methodology to account for the impact of improper payments in recalculating expenditures and payment amounts for certain Shared Savings Program financial calculations, upon reopening an ACO's payment determination and issuing a revised initial determination pursuant to § 425.315(a) as described in section III.G.7.c of this proposed rule; the proposal to use a methodology for certain Shared Savings Program calculations to mitigate the impact of SAHS billing activity occurring in CY 2024 or subsequent calendar years, as described in section III.G.7.d of this proposed rule; and the proposed technical changes to the provision describing how we calculate the weights applied when capping growth in regional risk scores as part of the regional component of the three-way blended benchmark update factor, as described in section III.G.7.f of this proposed rule. When considered together these proposed changes to the Shared Savings Program's payment methodology are expected to improve the quality and efficiency of items and services furnished under the Medicare program by improving the ability for ACOs to sustain effective participation particularly in serving medically complex, high-cost populations in underserved communities, and promoting integrity and fairness and ensuring the accuracy of Shared Savings Program financial calculations. These proposed changes are not expected to result in a situation in which the payment methodology under the Shared Savings Program, including all policies proposed to be adopted under the authority of section 1899(i) of the Act, results in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act.

In the CY 2023 PFS final rule, we estimated that the projected impact of the payment methodology that incorporates all policies finalized by that final rule would result in $4.9 billion in greater program savings compared to a hypothetical baseline payment methodology that excluded the policies that required section 1899(i)(3) of the Act authority (see 87 FR 70195 and 70196). The marginal impact of the proposed changes in the CY 2024 PFS final rule were estimated to lower net spending by $330 million over the subsequent ten-year period for all new policies combined, including the cap an ACO's regional service area risk score growth, the addition of a new third step to the beneficiary assignment methodology, and the revised approach

to identify the assignable beneficiary population (88 FR 79496). The marginal impact of the proposed changes in this proposed rule are estimated to lower net spending by an additional $260 million in total through 2034. Although the provisions in this proposed rule that require section 1899(i) of the Act authority are estimated to increase spending by only $60 million over 10 years, the cumulative impact of all policies (including those in this proposed rule) are estimated to result in more than $4.9 billion in greater program savings compared to a hypothetical baseline payment methodology that excludes the policies that require section 1899(i)(3) of the Act authority. Therefore, we estimate that the implementation of the proposals made in this proposed rule would not be greater than those that would result under the statutory payment model, consistent with the requirements of section 1899(i)(3)(B) of the Act.

We will continue to reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. Additional Shared Savings Program data beginning to accumulate after the end of the COVID–19 public health emergency, along with emerging information on the characteristics of new entrants in the Shared Savings Program for agreement periods beginning on January 1, 2024 and January 1, 2025, are anticipated to gradually improve our ability to reevaluate program impacts in a comprehensive fashion. In the event that we later determine that the payment model that includes policies established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

12. Medicare Part B Payment for Preventive Services

In section III.H.2. of this proposed rule, based on the proposals in section III.M of this proposed rule, we propose to clarify that a physician's order is no longer required for the administration of a hepatitis B vaccine in Part B, which would facilitate roster billing by mass immunizers for hepatitis B vaccine administration. We also propose that payment for hepatitis B vaccines and their administration be made at 100 of reasonable cost in RHCs and FQHCs, separate from the FQHC PPS or the RHC All-Inclusive Rate (AIR) methodology, in order to streamline payment for all Part B vaccines in those settings. We believe that Medicare spending impacts from both of these proposals will be negligible, as hepatitis B vaccines are already available to all Medicare enrollees under either Part B or Part D. While we believe that there will be an uptake of hepatitis B vaccines under Part B as shifted from Part D, we believe that this impact on the Part B program will be negligible for several reasons, including the fact that a portion of current beneficiaries have already received the hepatitis B vaccine through either Part B or Part D, and since a significant number of individuals will likely receive this vaccine by the time they are Medicare age due to current CDC recommendations (please see section III.M of this proposed rule for more information).

In section III.H.3. of this proposed rule, we propose a fee schedule for Drugs Covered as Additional Preventive Services (DCAPS), per section 1833(a)(1)(W)(ii) of the Act. We also propose payment limits for supply and administration fees for DCAPS drugs that are similar to those fees for drugs paid under the ASP payment methodology set forth in section 1847A of the Act, and we propose payment limits for DCAPS drugs and any supply and administration fees in RHCs and FQHCs according to this same fee schedule. We believe impacts from these proposed policies will be minimal as well. While no drugs are currently covered as DCAPS, DCAPS drugs are likely to be covered under Part D before coverage under the Part B additional preventive services benefit would commence.

13. Impact of Provisions for Medicare Prescription Drug Inflation Rebate Program

We are proposing regulations in section III.I. to codify existing policies established in program guidance as well as revised and new policies to implement the Medicare Part B Drug Inflation Rebate Program, including the requirement for manufacturers to pay rebates for certain single source drugs and biological products with prices that increase faster than the rate of inflation; criteria for the identification of Part B rebatable drugs; computation of the beneficiary coinsurance adjustment for Part B rebatable drugs; determination of the rebate amount for Part B rebatable drugs; reduction of the rebate amount for Part B rebatable drugs in shortage and when there is a severe supply chain disruption; provision of reports to each manufacturer of a Part B rebatable drug; and establishment of enforcement provisions via civil money penalties.

Additionally, we are proposing regulations in section III.I. to codify existing policies established in program guidance as well as revised and new policies to implement the Medicare Part D Drug Inflation Rebate Program, including the requirement for manufacturers to pay rebates for certain Part D drugs and biological products; criteria for the identification of Part D rebatable drugs; determination of the rebate amount for Part D rebatable drugs; reduction of the rebate amount for shortages and when there is a severe supply chain disruption or likely shortage; provision of reports to each manufacturer of a Part D rebatable drug; and establishment of enforcement provisions via civil money penalties.

We do not expect these proposals to have a material impact on inflation rebates. The majority of proposals codify existing guidance. Proposed new policies or changes to existing policies in guidance are technical provisions that we do not expect to have a material impact on the calculation of total rebates in aggregate.

As discussed in section III.I. of this proposed rule, for Part D drug inflation rebates, we are proposing to implement section 1860D–14B (b)(1)(B) of the Act which requires the Secretary to exclude 340B units from the total number of units used to calculate the total rebate amount owed by a manufacturer, beginning on January 1, 2026. For the first three quarters of 2026, we are proposing use an estimation policy that would remove a percentage of units from the total number of units used to calculate the total rebate amount to remove 340B units from Part D drug inflation rebate calculations. That percentage would be equal to the total number of units purchased under the 340B Drug Pricing Program for an NDC–9, divided by the number of total units sold of that NDC–9.

CMS does not currently have data on 340B claims for the Part D program or at the drug level in general, which prevents CMS from quantifying the impact of this provision. While we expect that the exclusion of 340B units from Part D inflation rebates will reduce the amount of rebates collected through this program, the magnitude of this reduction is unknown due to the lack of data on 340B claims for the Part D program. The use of a temporary estimation policy will allow CMS to implement the exclusion of 340B units from Part D inflation rebates by January 2026. It also alleviates the burden from interested parties to modify existing

processes to provide 340B claims information.

14. Expand Colorectal Cancer Screening

In section III.K. of this rulemaking we propose to update and expand coverage for CRC screening by (1) removing coverage for the barium enema procedure in regulations at § 410.37, (2) adding coverage for the CT colonography procedure in regulations at § 410.37, and (3) expanding a ''complete colorectal cancer screening'' in § 410.37(k) to include a follow-on screening colonoscopy after a Medicare covered blood-based biomarker CRC screening test (described and authorized in NCD 210.3) returns a positive result.

We do not anticipate our proposal to remove coverage for the barium enema procedure to result in a significant financial impact on the Medicare program. An internal claims analysis found that Medicare Fee for Service only paid 62 claims for the screening barium enema procedure in calendar year 2021 and only 72 claims for the screening barium enema procedure in calendar year 2022.

We do not anticipate our proposal to add coverage for the CTC procedure for CRC screening to result in a significant financial impact on the Medicare program. CTC could be an appropriate option for patients and clinicians who seek a direct visualization procedure as a first step in CRC screening that is less invasive and less burdensome on the patient (including those who are medically fragile or have complex or usual anatomy) compared to Screening Colonoscopy. We expect that patients will most often choose CTC as an alternative to colonoscopy for CRC screening and that future increased utilization of CTC will be balanced, in part, by avoided screening colonoscopies. Our goal is that the patient and their clinician make the most appropriate choice in CRC screening, which includes considerations of the risks, burdens and tradeoffs for each covered test or procedure. We expect that utilization of CTC for CRC screening will be modest, especially considering that CTC requires bowel preparation and travel to an outpatient clinical services site (similar to a colonoscopy) and also considering the availability of non-invasive stool-based tests that can be administered at home and mailed to a lab. A 2015 study titled ''Medicare cost of colorectal cancer screening: CT colonography vs. optical colonoscopy'' concluded that CTC is 29 percent less expensive than colonoscopy (accounting for related procedures) for the Medicare population in the base scenario. Although the CTC cost advantage is increased or reduced under alternative scenarios, it is always positive.[818]

We do not anticipate our proposal for expanding a ''complete colorectal cancer screening'' in § 410.37(k) to include a follow-on screening colonoscopy after a Medicare covered blood-based biomarker CRC screening test returns a positive result to produce a significant financial impact on the Medicare program. We expect that patients will choose either a stool-based test or a blood-based biomarker test for a non-invasive first option in CRC screening and that patients who choose a blood-based biomarker test within the context of a complete colorectal cancer screening under our proposal will be offset, in part, by the avoided utilization of a stool-based test.

In conclusion, we anticipate that our proposal to update and expand coverage for CRC screening will result in some additional utilization, but that additional utilization will be balanced, in part or in whole, by avoided utilization of alternative types of tests as well as benefits and savings resulting from increased prevention and early detection (allowing for less invasive and more effective treatment).

15. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan

In section III.L of this proposed rule, we propose one update to the CMS EPCS Program. We are proposing that prescriptions written for a beneficiary in a LTC facility would not be included in determining compliance under the CMS EPCS Program until January 1, 2028, and that compliance actions against prescribers who do not meet the compliance threshold based on prescriptions written for a beneficiary in a LTC facility would commence on or after January 1, 2028. Without this provision, if we keep the existing date of January 1, 2025, as in the current regulatory text at § 423.160(a)(5) for the CMS EPCS Program, we estimate at least 6,800 prescribers would become non-compliant due to CMS including prescriptions written for beneficiaries in LTC in the CMS EPCS Program compliance threshold calculation. This estimate is based on data from calendar year 2022 and is prior to considering emergency and disaster exceptions and waivers, which could reduce these numbers. This proposal, should we finalize it, would allow prescribers additional time to adopt the new e-prescribing standard, NCPDP SCRIPT standard version 2023011, and utilize EPCS. Additionally, this proposal would prevent an increased number of prescribers from potentially applying for a waiver for circumstances beyond their control due to difficulty of reliably conducting EPCS for beneficiaries in LTC facilities by the current deadline of January 1, 2025.

We do not believe this proposal would cause additional costs as we are only extending the deadline by which we would include prescriptions written for patients in LTC facilities in the CMS EPCS Program compliance threshold calculation and not modifying the requirement to become compliant. We also note that beneficiaries in LTC facilities may not receive the full benefits of EPCS, which we describe in the CY 2022 PFS final (86 FR 65362), until a later date, but we believe the delay is necessary due to the logistical challenges of prescribers electronically prescribing controlled substances prescriptions for beneficiaries in LTC facilities.

We seek public comments on our impact assumptions.

16. Expand Hepatitis B Vaccine Coverage

In section III.M. of this rulemaking, we propose to expand Hepatitis B vaccine coverage by revising our regulatory definition for intermediate risk groups by adding a new paragraph to include individuals who have not previously received a completed hepatitis B vaccination series or whose vaccination history is unknown (§ 410.63(a)(2)).

Hepatitis B vaccine is currently covered under Medicare Part B for enrollees who are at intermediate or high risk of contracting hepatitis B virus, and, for Part D enrollees who do not fall into those categories the vaccine may be covered under Medicare Part D.[819] In 2021, about 51 million of 65 million Medicare beneficiaries were enrolled in Part D and 21,629 received the vaccine. In 2019, Part B covered 300,000 doses of hepatitis B vaccine for beneficiaries who were at high or

[818] Pyenson, B., Pickhardt, P.J., Sawhney, T.G. et al. Medicare cost of colorectal cancer screening: CT colonography vs. optical colonoscopy. Abdom Imaging 40, 2966–2976 (2015). *https://doi.org/10.1007/s00261-015-0538-1.*

[819] Sayed, BA, Finegold, K, Ashok, K, Schutz, S, De Lew, N, Sheingold, S, Sommers, BD. Inflation Reduction Act Research Series: Medicare Part D Enrollee Savings from Elimination of Vaccine Cost-Sharing. (Issue Brief No. HP–2023–05). Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. September 2023. Retrieved from *https://aspe.hhs.gov/sites/default/files/documents/407d41b6534e7af6702eb280b3945d00/aspe-ira-vaccine-part-d.pdf.*

intermediate risk for the disease.[820] Since the vaccine has been available for several decades, we are not able to determine how many Medicare beneficiaries have already received the vaccine.

Overall vaccination rates among adults, including older adults, are generally low.[821] [822] A Centers for Disease Control and Prevention (CDC) analysis of data from the National Health Interview Survey found that fewer than half of all adults (less than 45 percent) received age-appropriate recommended vaccinations in 2019.[823] An estimated 20 percent of adults aged ≥60 years have been vaccinated against hepatitis B; and approximately 34 percent of adults aged ≥19 years have been vaccinated against hepatitis B.[824] We do not anticipate our proposal to result in significant economic impact on the Medicare program.

As of January 1, 2023, the Inflation Reduction Act (IRA) eliminated out-of-pocket costs for vaccines covered under Medicare Part D that are recommended by the Advisory Committee on Immunization Practices (ACIP).[825] Before the Inflation Reduction Act (IRA), beneficiaries incurred out of pocket costs for Part D vaccines. While we would expect that after the IRA, more beneficiaries would receive covered vaccines because of eliminating out of pocket costs, existing research shows that cost-sharing is only one factor among other determinants. Trust in vaccines, access to health care, health literacy, perceived risk, socio-demographic factors and awareness of vaccine recommendations, all shape whether individuals obtain a recommended vaccine.[826] If the number of people receiving the hepatitis B vaccine under Part D is any indication, we assume that even by increasing access, there will not be immediate or significant change in the number of covered hepatitis B vaccines paid under Medicare Part B. For these reasons, we do not anticipate that expanding the definition of intermediate risk for hepatitis B vaccine will result in a significant financial impact to the Medicare Program.

17. Low Titer O+ Whole Blood Transfusion Therapy During Ground Ambulance Transport

As discussed in section III.N of this proposed rule, we propose to modify the definition of ALS2 at § 414.605 by adding the administration of low titer O+ whole blood transfusion therapy (WBT) to the list of ALS2 procedures as a new number 8. We would also reflect this change in the Medicare Benefit Policy Manual, Chapter 10, Ambulance Services, section 30.1.1, Definition of Ground Ambulance Services. Under this proposal, a ground ambulance transport that provides WBT would itself constitute an ALS2-level transport.

We believe that many ground ambulance transports providing WBT already qualify for ALS2 payment, given that patients requiring such transfusions are generally critically injured or ill and often suffering from cardio-respiratory failure and/or shock and are therefore likely to receive one or more procedures currently listed as ALS procedures in the definition of ALS2, such as endotracheal intubation, central venous line, chest decompression, and placement of an intraosseous line. For impact analysis, for ground ambulance transports that provide WBT only and currently do not qualify for ALS2 payment, we are assuming that these transports are reported as ALS1 (advanced life support, level 1) emergencies.

In order to help identify the number of ground ambulance transports that could potentially be affected by this proposal, we analyzed inpatient hospital claims related to multiple-trauma that started with an ALS1 emergency ambulance transport and also included a blood transfusion done in the hospital. The inpatient admissions were identified by DRG code ''813'' and diagnosis code of ''24,'' the ambulance transport is identified by HCPCS ''A0427,'' and the blood transfusion administered to these patients in the hospital setting is identified by the presence of covered charges, patient liability amounts, and replacement units for blood.

Since payments vary for urban, rural, and super-rural ground ambulance transports, we calculated the average Medicare payment amount for ALS2 (HCPCS A0433) and ALS1 (HCPCS A0427) over the last several years. The average payment differential over calendar years 2019 and 2023 is estimated to be roughly $162 per transport. It is difficult to make an assumption for the number of transports that will be impacted by this proposal, but the potential number over the last several years, based on an analysis of actual experience, is very few. Even if all of these ALS1 emergency transports shifted to being ALS2 transports, which is very unlikely, the impact would be negligible.

18. Updates to the Quality Payment Program

In this section of this proposed rule, we estimated the overall and incremental impacts of the Quality Payment Program policies. We estimated participation, final scores, and payment adjustment for eligible clinicians participating through traditional MIPS, MVPs, and the Advanced APMs. We also presented the incremental impacts to the number of expected Qualified Participants (QPs) and associated APM Incentive Payments that result from our policies relative to a baseline model that reflects the status quo in the absence of any modifications to the previously finalized policies.

A. Overall MIPS Modeling Approach and Data Assessment

(1) MIPS Modeling Approach

For this proposed rule, we used a similar modeling approach as the CY 2024 PFS final rule (88 FR 79504 through 79506). We created two MIPS RIA models: a baseline and proposed policy model. Our baseline model includes previously finalized policies that will be in effect for the CY 2024 performance period/2026 MIPS payment year in the absence of any of the newly proposed policies in this proposed rule. Examples of previously finalized policies included in the baseline model include: updated QP

[820] Medpac 2021. Report to the Congress: Medicare and the Health Care Delivery System. Chapter 7. Medicare vaccine coverage and payment. Retrieved from *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/default-document-library/jun21_ch7_medpac_report_to_congress_sec.pdf.*

[821] CDC. (2022, February 17). Vaccination Coverage among Adults in the United States, National Health Interview Survey, 2019–2020. Centers for Disease Control and Prevention. Retrieved February 27, 2023, from *https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/vaccination-coverage-adults-2019-2020.html.*

[822] Gellin, B.G., Shen, A.K., Fish, R., Zettle, M.A., Uscher-Pines, L., & Ringel, J.S. (2016). The National Adult Immunization Plan: Strengthening Adult Immunization Through Coordinated Action. American journal of preventive medicine, 51(6), 1079–1083. *https://doi.org/10.1016/j.amepre.2016.04.014.*

[823] CDC. (2022, February 17). Vaccination Coverage among Adults in the United States, National Health Interview Survey, 2019–2020. Centers for Disease Control and Prevention. Retrieved February 27, 2023, from *https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/vaccination-coverage-adults-2019-2020.html.*

[824] CDC. 2023. Vaccination Coverage among Adults in the United States, National Health Interview Survey, 2021. Retrieved from *https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/vaccination-coverage-adults-2021.html#:~:text=Hepatitis%20B%20vaccination%20coverage%20in,and%20Other%20(40.2%25)%20adults.*

[825] Sayed, BA, et al. 2023. Inflation Reduction Act Research Series.

[826] Sayed, BA, et al. 2023. Inflation Reduction Act Research Series.

and partial QP thresholds, and the previously finalized list of MVPs.

The proposed policies model builds off the baseline model and incorporates the MIPS policies for the CY 2025 performance period/2027 MIPS payment year included in this proposed rule. By comparing the baseline model to the proposed policies model, we are able to estimate the incremental impact of the specific policies in this proposed rule.

Our modeling approach utilizes the same scoring engine that is used to determine MIPS payment adjustments. This modeling approach enables our model to align as much as possible with actual MIPS scoring and minimizes differences between our projections and policy implementation. These limitations of our model are discussed later in this RIA.

(2) Data Used To Estimate Future MIPS Performance

In the CY 2024 PFS final rule (88 FR 79504), we explained our decision to use CY 2022 performance period submissions data. We noted that using CY 2022 performance data presents the most current data and aligns our participation, final scoring, and payment adjustment analysis around the same common data set. CY 2022 performance data were the most recently available data in time for us to construct our simulation model for this proposed rule and for the same reasons discussed in the CY 2024 PFS final rule (88 FR 79504), we are considering it to construct the baseline and proposed policies model in this proposed rule. As more data becomes available, we will assess the feasibility and validity of that data for use in RIA simulations.

b. APM Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs

For payment years from 2019 through 2025, through the Medicare Option, eligible clinicians who have a sufficient percentage of their Medicare Part B payments for covered professional services or Medicare patients through Advanced APMs will be QPs for the applicable QP Performance Period for a year and the corresponding payment year. In payment years 2019 through 2024 these QPs will receive a lump-sum APM Incentive Payment equal to 5 percent of their estimated aggregate paid amounts for covered professional services furnished during the calendar year immediately preceding the payment year. In payment year 2025, QPs will receive a lump-sum APM Incentive Payment equal to 3.5 percent payment of their estimated aggregate paid amounts for covered professional services furnished during CY 2024. Beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the All-Payer Combination Option. The All-Payer Combination Option allows eligible clinicians to become QPs by meeting the QP payment amount or patient count threshold through a pair of calculations that assess a combination of both Medicare Part B covered professional services furnished or patients through Advanced APMs and services furnished or patients through Other Payer Advanced APMs. Eligible clinicians who become QPs for a year are not subject to MIPS reporting requirements and payment adjustments. Eligible clinicians who do not become QPs but meet a lower threshold to become Partial QPs for the year may elect to report to MIPS and, if they elect to report, will then be scored under MIPS and receive a MIPS payment adjustment. Partial QPs are not eligible to receive the APM Incentive Payment.

If an eligible clinician does not attain either QP or Partial QP status, and is not excluded from MIPS on another basis, the eligible clinician will be subject to the MIPS reporting requirements and will receive the corresponding MIPS payment adjustment.

Beginning in payment year 2026, there are two separate PFS CFs—one for eligible clinicians who are QPs for the year (the qualifying APM CF), and the other for all non-QP eligible clinicians and other suppliers paid under the PFS (the non-qualifying APM CF). The update to the qualifying APM CF for a year is 0.75 percent, while the update to the non-qualifying APM CF for a year is 0.25 percent.

In addition, the thresholds to achieve QP status beginning in the 2025 QP Performance Period will increase to 75 percent for the payment amount method, and 50 percent for the patient count method. Overall, we estimated that for the 2025 QP Performance Period between 339,561 and 436,579 eligible clinicians will become QPs, and therefore be excluded from MIPS reporting requirements and payment adjustments.

In section IV.A.4.k.(2) of this proposed rule, we propose to modify the definition of ''attribution-eligible beneficiary'' to include any beneficiary who has received a covered professional service furnished by the eligible clinician (NPI) for whom we are making the QP determination. By no longer specifying evaluation and management (E/M) services as the default attribution basis, we also would eliminate the need to develop customized attribution bases for Advanced APMs that do not use E/M services as the basis for attribution. Therefore, our proposal would standardize the attribution methodology for QP determinations by making covered professional services the basis for attribution across all Advanced APMs.

We projected the number of eligible clinicians who will be QPs, and thus excluded from MIPS, using several sources of information. First, the projections are anchored in the most recently available public information on Advanced APMs. The projections reflect Advanced APMs that will be operating during the 2025 QP Performance Period, as well as some Advanced APMs anticipated to be operational during the 2025 QP Performance Period. The projections also reflect an estimated number of eligible clinicians that will attain QP status through the All-Payer Combination Option. The following APMs are expected to be Advanced APMs for the 2025 QP Performance Period:

- Bundled Payments for Care Improvement Advanced Model;
- ACO REACH Model (formerly Global and Professional Direct Contracting) Model;
- Kidney Care Choices Model (Comprehensive Kidney Care Contracting Options, Professional Option and Global Option);
- Maryland Total Cost of Care Model (Care Redesign Program; Maryland Primary Care Program);
- Medicare Shared Savings Program (Level E of the BASIC Track and the ENHANCED Track); and
- Enhancing Oncology Model (EOM); and
- Primary Care First (PCF) Model.

We used the Participation Lists and Affiliated Practitioner Lists, as applicable, (see § 414.1425(a) for information on the APM Participant Lists and QP determinations) for the 2023 QP performance period third snapshot QP determination date to estimate the number of QPs, total Part B paid amounts for covered professional services, and the aggregate total of APM Incentive Payments for the 2025 QP Performance Period. We examined the extent to which Advanced APM participants will meet the QP Thresholds of having at least 75 percent of their Part B covered professional services or at least 50 percent of their Medicare beneficiaries furnished Part B covered professional services through the APM Entity.

c. Estimated Number of MIPS Eligible Clinicians in the CY 2025 Performance Period/2027 MIPS Payment Year

(1) Initial Population of Clinicians Included in the RIA Baseline and Proposed Policies Models

For this proposed rule, we applied the same assumptions as in the CY 2024 PFS final rule (88 FR 79505) to estimate our initial population of clinicians based on CY 2022 performance period/ 2024 MIPS payment year data.

We used the same CY 2022 final reconciled eligibility determination file described in the CY 2024 PFS final rule (88 FR 79505). This file reconciles eligibility from two determination periods and aligns with the CY 2022 performance period submissions data on which we based this model. Our analysis included 1,820,899 clinicians with PFS claims in this initial population. This initial population of clinicians was used to determine eligibility using the methodology described in the following sections.

(2) Estimated Number of MIPS Eligible Clinicians After Applying Eligibility Assumptions

(a) Methods and Assumptions Used To Estimate Eligibility

After identifying the clinician population with PFS claims we applied the same eligibility assumptions and determination process described in the CY 2024 PFS final rule (88 FR 79505). We are not proposing any modifications to MIPS eligibility requirements and the same eligibility assumptions apply to both the baseline and final policies model.

For our RIA model, we established the ''required eligibility'' category, which means the clinician exceeds the low-volume threshold in all 3 criteria and is subject to a MIPS payment adjustment. We base this estimate on the CY 2022 performance period data described in this section of this proposed rule, which includes the three low volume criteria. Within this category we divide clinicians into two groups- clinicians who report data and clinicians who do not report data.

Our next two eligibility assumptions concern clinicians and groups who may participate in MIPS but are not required to participate. First, we estimate group eligibility. These are the clinicians who have a group submission and their group exceeds the low-volume threshold in all 3 criteria. Next, we apply our opt-in eligibility assumptions. Individuals or groups who exceed the low-volume threshold in 1 criterion but not all 3 may elect to opt-in. Based on the CY 2022 data we determine which individuals opted-in to MIPS and for the purposes of our model estimate that these clinicians will continue to opt-in to MIPS.

After applying the process outlined in this section of this proposed rule, we next estimate the number of ''Potentially MIPS Eligible'' clinicians. These clinicians are not included in our total number of MIPS eligible clinicians. These are clinicians who are not MIPS eligible individually but who may either opt-in because they exceed the low volume threshold in at least one criterion but not all three or who could report as part of a group which exceeds all three low volume criteria.

Finally, we estimate the number of clinicians who are neither MIPS eligible nor potentially MIPS eligible. First, we estimate the number of MIPS eligible clinicians who are below all three low-volume criteria (both as an individual and as a group) again using the CY 2022 performance period data as described in this section of this proposed rule.

Next, we estimate the number of QPs (not MIPS eligible). In section VII.E.17.b. of this proposed rule, we estimated a range of QPs. For the purposes of our RIA population, we estimate a specific number of QPs. This is because it is necessary to establish a specific population of clinicians to use to simulate the impacts of our final policies on participation, final scores, and payment adjustments. Finally, we estimate the number of clinicians who are excluded for other reasons including that they are a non-eligible clinician type or newly enrolled in Medicare.

After applying these assumptions to our initial population, we estimate 686,645 MIPS eligible clinicians with $5.5 billion in allowed charges. However, this number may be as high as 1,270,806 MIPS eligible clinicians and $7 billion allowed charges if *all potentially* MIPS eligible [827] clinicians either opt-in or report as a group. This is an unlikely scenario but it establishes the full range of possible MIPS eligible clinicians in our initial population.

(b) MIPS Eligibility Estimates

Eligibility among many clinicians is contingent on submission to MIPS as a group or election to opt-in: therefore, we would not know the number of MIPS eligible clinicians who submit until the submission period for the CY 2023 performance period is closed. For the remaining analysis, we use the estimated population of 686,645 MIPS eligible clinicians described in previously in this section of this proposed rule. Table 136 summarizes our eligibility estimates for the proposed policies model after applying our assumptions discussed in this section of this proposed rule.

[827] We define potentially MIPS eligible clinicians as those clinicians who are not required to participate in 13MIPS but *may* either opt-in or join a group that exceeds the low-volume threshold in all three criteria.

TABLE 136: Description of MIPS Eligibility Status for CY 2025 Performance Period/2027 MIPS Payment Year Using the CY 2025 PFS Proposed Rule Assumptions**

Eligibility Status	Predicted Participation Status in MIPS Among Clinicians *	Number of Clinicians	PFS allowed charges ($ in mil)**
MIPS Eligible Clinicians			
MIPS eligible (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Reported to MIPS	105,843	$29,530
MIPS eligible	Did not Report to MIPS	40,813	$11,951
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria)	Had a group submission	533,473	$13,108
Opt-In eligibility assumptions (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low-volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS)	Opted-in To MIPS	6,516	$350
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**686,645**	**$54,564**
Not MIPS Eligible Clinicians			
Potentially MIPS Eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: (1) meet group eligibility; or (2) opt-in eligibility criteria)	Opt-in Eligible; Do not opt-in	178,216	$5,517
Potentially MIPS Eligible	Group Eligible; Did not Report	405,945	$9,502
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	129,806	$795
Excluded for other reasons (Non-eligible clinician type, newly enrolled)	Not applicable	60,471	$501
Qualified Participant (QP)***	Not applicable	359,816	$17,602
Total Number of Clinicians Not MIPS Eligible		1,134,254	**$33,916**
Total Number of Clinicians (MIPS and Not MIPS Eligible)		1,820,899	**$88,481**

* Participation excludes facility-based clinicians who do not have scores in the 2022 MIPS submission data.
** Allowed charges estimated in 2022 dollars. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.
*** Our QP estimate differs from that reported in section VII.E.17.b of this proposed rule because, for purposes of establishing the population used in our modeling, we estimate an absolute number of QPs rather than a range.

d. Modeling Approach and Methods for MIPs Value Pathways (MVPs) and Traditional MIPS

(1) Summary of Approach

In this proposed rule, we present several proposals which impact the measures and activities, the performance category scores, final score calculation, and the MIPS payment adjustment of MIPS eligible clinicians. We outline these changes in more detail in section VII.E.17.d.(3). Of this proposed rule as we describe our methodology to estimate MIPS payment adjustments for the CY 2025 performance period/2027 MIPS payment year. We then present the impact of the proposed policies in the CY 2025 performance period/2027 MIPS payment year and compare select metrics to the baseline model. By comparing the baseline model to the policies model, we are able to estimate

the incremental impact of the policies for the CY 2025 performance period/2027 MIPS payment year.

MIPS eligible clinician's final scores are calculated based on the clinician's performance on measures and activities under the four MIPS performance categories: quality, cost, improvement activities, and Promoting Interoperability. MIPS eligible clinicians can participate in the four MIPS performance categories as an individual, group, virtual group, APM Entity, clinicians participating in MIPS through the APM Performance Pathway (APP), or through an MVP. MIPS APM participants can participate in the APP as an individual, group, virtual group, APM Entity and are only scored on three MIPS performance categories: quality, improvement activities, and Promoting Interoperability. Our simulation applies the proposed and previously finalized policies to the existing MIPS scoring engine.

In the CY 2022 PFS final rule (86 FR 65394 through 65397), we finalized policies at § 414.1365 for implementing MIPS Value Pathways beginning in the CY 2023 performance period/2025 MIPS payment year. We incorporate MVP participation and scoring rules in this RIA where applicable as described in the following section.

(2) Methodology To Assess Impact for MIPS Value Pathways

(a) MVP Participant Assumptions

At § 414.1365(b), we require MVP Participants (which can be a group, individual, subgroup, or APM entity) to register prior to submitting an MVP. We assessed whether to use CY 2024 MVP registration data to estimate MVP participation but elected to again use the approach described in the CY 2024 PFS final rule (88 FR 79507) for two reasons. First, we do not presently have MVP scoring data, thus do not know the information of MVP registrants that may submit MVP data to MIPS. Secondly, our model is based on CY 2022 performance data. This data does not contain MVP scores and reconciliation between multiple years introduces uncertainty and complexity into our model. As MVP scoring data becomes available in the future, we will reassess our methodology for estimating MVP participation and final scores.

We assume for purposes of this model, that MVP Participants are MIPS eligible individual clinicians or groups that submit the required MVP measures. For the baseline model, we used the measures from the 16 MVPs finalized in the CY 2024 PFS final rule Appendix 3 (88 FR 79978 through 80047).

In section IV.A.4.a. and Appendix 3 of this proposed rule, we propose modifications to 7 existing MVPs and proposed 6 new MVPs. The 6 new proposed MVPs are:

- Complete Ophthalmologic Care
- Dermatological Care
- Gastroenterology Care
- Optimal Care for Patients with Urologic Conditions
- Pulmonology Care
- Surgical Care

For the proposed policies model, we incorporated the measure revisions for the existing MVPs described in Appendix 3 of this proposed rule. Due to data availability, we are unable to simulate scores for the following measures: 487, 488, 489, 490, 492, 493, 496, 497, 502, 503, 504, 505, ABG44, PIMSH13, UREQA10, 485, 486, 487, 488, 489, 490, 492, 493, 495, 496, 497, 499, 500, 501, 502, 503, 504, 505, AAD16, AAD17, AAD18, ABG44, GIQIC26, IA_PM_XX, IRIS61, MSK6, MSK7, MSK8, MSK9, MUC2023–141, MUC2023–161, MUC2023–162, MUC2023–190, MUC2023–211, PIMSH13, UREQA10.

For these MVP Participants, we calculate both an MVP and a traditional MIPS score and take the highest score consistent with the existing scoring hierarchy which was finalized in the CY 2023 PFS final rule (86 FR 65537).

Our MVP Participant assumptions have limitations: the measure list used to simulate MVP participation does not align completely with what is proposed in section IV.A.4.a. of this proposed rule, we are not incorporating subgroups due to a lack of data, not all of the assumed participants may elect to register for an MVP, and we may have additional clinicians or groups register for an MVP. However, we believe this is a reasonable approach to simulate the impact of MVPs and we sought comment on this assumption but did not receive any feedback.

(b) MVP Scoring Methods and Assumptions

We simulate an MVP score using the same data sources as we did for traditional MIPS. We scored according to § 414.1365(d) and (e) using the MVP reporting requirements listed in § 414.1365(c) with one exception. We did not restrict the improvement activities to the activities listed in the MVP inventory. We believed this would lower our estimated MVP score as clinicians and groups were not required to select from a limited inventory in the CY 2022 performance period (upon which our model is based). Therefore, we scored any improvement activities the MVP Participants submitted in 2022 as if those improvement activities are in the MVP inventory. Additionally, in section IV.A.4.b.(1)(b) of this proposed rule, we proposed to score all available population health measures for a clinician participating in an MVP and select the highest scoring of those measures for use in determining their category score. We incorporated this proposal into our simulation.

(3) Methodology To Assess Impact for Traditional MIPS

To estimate the impact of the policies on MIPS eligible clinicians, we generally used the CY 2022 performance period's data, including data submitted or calculated for the quality, cost, improvement activities, and Promoting Interoperability performance categories.

We supplemented this information with the most recent data available for CAHPS for MIPS and CAHPS for ACOs, administrative claims data for the new quality performance category measures, and other data sets. We calculated a hypothetical final score for the CY 2025 performance period/2027 MIPS payment year for the baseline and policies scoring models for each MIPS eligible clinician using score estimates for quality, cost, Promoting Interoperability, and improvement activities performance categories, and the application of our final scoring policies.

(a) Methodology To Estimate the Quality Performance Category Score

We used the CY 2024 PFS final rule final policies model as the starting point of our baseline model. Since there are no previously finalized policies impacting the quality performance category that were not already included in the CY 2024 PFS final rule policies model, we did not make any modifications to the quality performance category and the baseline model is identical to the CY 2024 PFS final rules policies model with respect to the quality category.

Our proposed policies model incorporates the following proposals from this proposed rule as outlined in section IV.A.4.e.(1) of this proposed rule:

In section IV.A.4.f.(1)(b)(i) of this proposed rule, to facilitate fairer scoring, we propose to remove the scoring cap and change the benchmarking approach for certain topped out measures applicable to clinicians facing both limited measure choice and limited scoring opportunities. We did not simulate the addition of quality measures described in section IV.A.4.e.(1)(d)(i) since we use

existing quality measure data from the CY 2022 performance period which does not include new measures. We do not simulate the removal of quality measures described in section IV.A.4.e.(1)(d)(ii) since we cannot predict how clinician behavior and measure selection would change in response.

(b) Methodology To Estimate the Cost Performance Category Score

We estimated the cost performance category score using a methodology similar to the methodology described in the CY 2024 PFS final rule (88 FR 79508) for the baseline and the proposed policies RIA models with the modifications described below.

For this proposed rule, the baseline policies RIA model used the same methodology as the final policies RIA model in the CY 2024 PFS final rule (88 FR 79508). The proposed policies RIA model incorporated and implemented the following changes:

- In section IV.A.4.e.(2)(a) of this proposed rule, we are proposing to adopt 6 new episode-based cost measures and modify 2 existing episode-based cost measures . We incorporated measure test data with the specifications for the new and modified measures.
- In section IV.A.4.f.(1)(d) of this proposed rule, we are proposing to modify our cost scoring methodology. The median cost for a measure would be assigned achievement points equal to 10 percent of the performance threshold (7.5 in the CY 2024 performance period/CY 2026 payment year). The cut-offs for benchmark ranges would be calculated as standard deviations from the median. This proposal is incorporated into our model based on the specifications explained in section IV.A.4.f.(1)(d)(ii)(B) of this proposed rule.

(c) Methodology To Estimate the Promoting Interoperability Performance Category Score

We estimated Promoting Interoperability performance category score by using the same methodology that we used in the CY 2024 PFS final rule (88 FR 79508). We did not incorporate any changes to this category in our model. In section IV.A.4.e.(4)(f) of this proposed rule, we are proposing minimum criteria for a qualifying data submission for the Promoting Interoperability performance category. We conducted an analysis of this proposal and determined that the impact on final scores and payment adjustments was negligible and therefore did not incorporate it into our model.

(d) Methodology To Estimate the Improvement Activities Performance Category Score

For the baseline and policies model we used the same method to estimate the improvement activities performance category score as described in the CY 2024 PFS final rule (88 FR 79508) including alignment with the clarification provided regarding IA automatic weighting for APM participants (88 FR 79366).

In section IV.A.4.e.(3)(b)(IV) of this proposed rule, we proposed to remove weighting of improvement activities. We conducted an analysis of this proposal and determined that the impact on final scores and payment adjustments was negligible and therefore did not incorporate it into our model.

(e) Methodology To Estimate the Complex Patient Bonus Points

For the baseline and policies RIA model, we used the previously established method to calculate the complex patient bonus as described in the CY 2022 PFS final rule (86 FR 64996).

(f) Methodology To Estimate the Final Score

We are not proposing any changes for how we calculated the MIPS final score. Our baseline and policies RIA models assigned a final score for each TIN/NPI by multiplying each estimated performance category score by the corresponding performance category weight, adding the products together, multiplying the sum by 100 points, adding the complex patient bonus, and capping at 100 points.

For both models, after adding any applicable bonus for complex patients, we reset any final scores that exceeded 100 points to equal 100 points. For MIPS eligible clinicians who were assigned a weight of zero percent for any performance category, we redistributed the weights according to § 414.1380(c).

For the purposes of this model, if a MIPS eligible clinician was approved for reweighting of one or more performance category to zero percent of their final score, and the category's weight redistributed to other performance category(ies), for the CY 2022 performance period/2024 MIPS payment year (which was the data source used in our model) in accordance with our reweighting policies under § 414.1380(c)(2), then we continue to apply that reweighting in our model by assigning them a neutral score equal to the performance threshold if all categories were reweighted or assigning the applicable weights to the categories which were reweighted. Although it is unlikely (but possible) that the exact same clinicians would apply for and receive reweighting in both the CY 2022 performance period/2024 MIPS payment year (which our data is based on) and the CY 2025 performance period/2027 MIPS payment year (which we are simulating), we believe that this assumption accurately reflects future clinician behavior for two reasons. First, while the exact same clinicians may not receive reweighting 2 years in a row, we believe that this assumption allows us to quantify the impact of the reweighting on a population level. In other words, even if the same clinicians do not apply for and receive reweighting 2 years in a row, the absolute number of reweighting and the characteristic of practices who receive reweighting is likely to remain similar. Secondly, if we were to not assign reweighting to those clinicians, many of them would receive a very low final score because they did not submit data for one or more performance categories during the year in which they received reweighting. We do not believe that it is realistic to assume that, in the absence of reweighting, those clinicians would continue to not submit data. For these reasons, clinicians who received reweighting in the CY 2022 performance period/2024 MIPS payment year also are approved for reweighting in the CY 2025 performance period/2027 MIPS payment year. These clinicians are assigned a score of the performance threshold (75) in our model because this corresponds with a neutral (0 percent) payment adjustment.

(g) Methodology To Estimate the MIPS Payment Adjustment

For the baseline and proposed policies RIA models, we applied the hierarchy as finalized in the CY 2022 PFS final rule (86 FR 65536 through 65537) to determine which final score should be used for the payment adjustment for each MIPS eligible clinician when more than one final score is available. We then calculated the parameters of an exchange function in accordance with the statutory requirements related to the linear sliding scale, budget neutrality, and minimum and maximum adjustment percentages.

For the baseline model, we applied the performance threshold of 75 points finalized in the CY 2024 PFS final rule (88 FR 79373). In section IV.A.4.g.(2)(c) of this proposed rule, we are proposing to again set the performance threshold at 75. Therefore, for both the baseline and final policies models we used a

performance threshold of 75 to calculate the exchange function used for MIPS payment adjustments. We note that the results of this exchange are not identical between the baseline and final policies model. This is because the scaling factor used to determine positive adjustments is dependent on the total dollar amount of negative payment adjustments and those adjustments differ as final scores are not identical between both models. For both the baseline and policies models, we used these resulting parameters to estimate the positive or negative MIPS payment adjustment based on the estimated final score and the allowed charges for covered professional services furnished by the MIPS eligible clinician.

(4) Simulation Results and Projected Impact to MIPS Eligible Clinicians

Based on the methodology described in the preceding sections we created a baseline and proposed policies simulation. Using this simulation, we estimate the impact of the policies proposed.

(a) Impact to Clinician Eligibility

In section VII.E.17.c.(2) of this proposed rule, we noted that we are not proposing any modification to clinician eligibility and therefore there is no difference in the total number of MIPS eligible clinicians between our models.

(b) Impact to Clinician's Final Scores

Table 137 shows the median final score by practice size and the percentage of MIPS eligible clinicians of each practice size with a positive or neutral or negative adjustment.

TABLE 137: CY 2025 Final Score Estimates by Practice Size

Practice Size*	Total Number of MIPS Eligible Clinicians	Median Final Score Estimate**	Percent Eligible Clinicians with Positive Payment Adjustment	Percent Eligible Clinicians with Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
			Baseline		
1) Solo	18,867	75.00	31.05%	22.00%	46.95%
2) 2-15	71,908	81.79	60.47%	14.97%	24.56%
3) 16-99	150,377	81.76	64.79%	10.32%	24.89%
4) 100+	445,493	82.80	74.84%	4.32%	20.84%
Overall	686,645	82.20	69.93%	7.23%	22.84%
			Proposed Policies		
1) Solo	18,867	75.00	32.41%	21.94%	45.65%
2) 2-15	71,908	86.02	64.29%	14.78%	20.93%
3) 16-99	150,377	85.87	72.41%	9.98%	17.61%
4) 100+	445,493	87.19	83.28%	4.13%	12.59%
Overall	686,545	86.42	77.51%	7.02%	15.47%

*Practice size is defined as the number of NPIs in a TIN

** The median final score includes clinicians who receive reweighting for all MIPS performance categories our policies at § 414.1380(c)(2). These clinicians who have all performance categories reweighted are assigned a score of 75 (neutral payment adjustment) in our model.

The median final score is 82.20 in our baseline model and 86.42 in our proposed policies model. There is an increase in the number of clinicians receiving a positive payment adjustment for all practice sizes and an increase in the median final score for all practice sizes except for solo practitioners.[828] We project that 69.93 percent of MIPS eligible clinicians will receive a positive adjustment in our baseline model and 77.51 percent of MIPS eligible clinicians will receive a positive adjustment in our proposed policies model. This increase is largely due to our proposed change to the cost scoring methodology discussed in section IV.A.4.f.(1)(d)(ii)(B) of this proposed rule. Table 138 shows the median cost score for MIPS eligible clinicians who are scored on the cost performance category for our baseline and final policies model. There is a substantial difference in median cost scores between our two models. This is true across all practice sizes. The median cost category score is 59.16 in our baseline model and 73.85 in our proposed policies model.

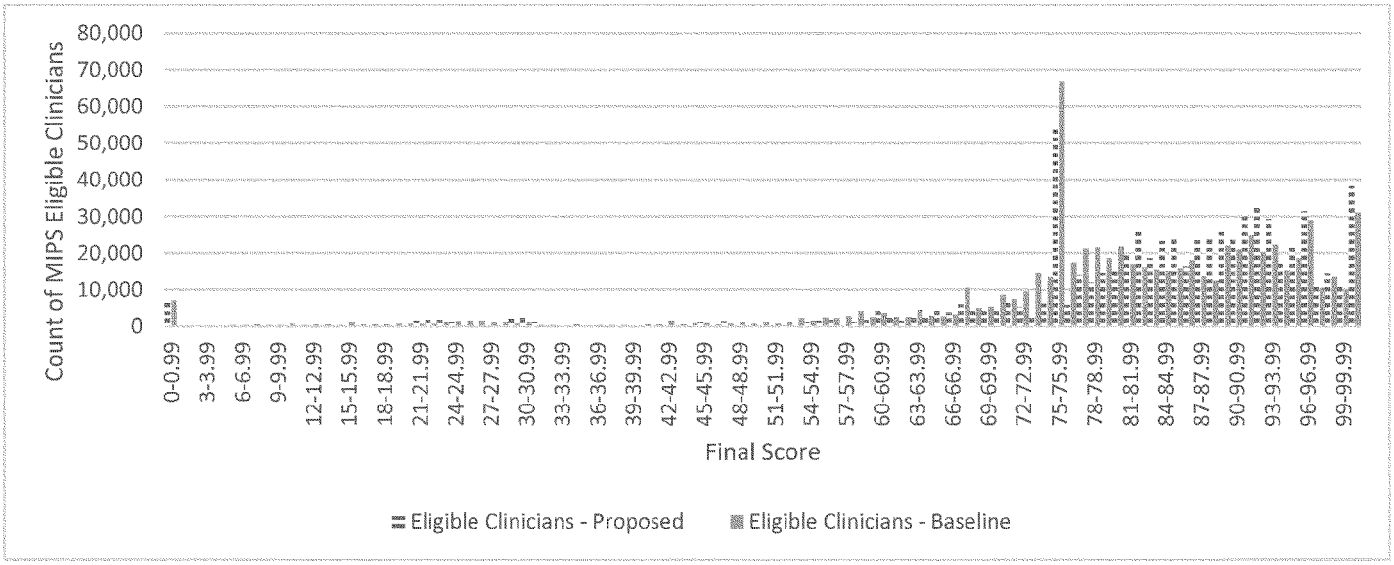
[828] See section VII.E.17.d.(b)(b)(i) of this proposed rule for a discussion of the performance of solo practitioners specifically.

TABLE 138: CY 2025 Cost Score Estimates by Practice Size

Practice Size	MIPS Eligible Clinicians Receiving Cost Score	Total Number of MIPS Eligible Clinicians	Proportion of MIPS Eligible Clinicians Receiving Cost Score	Median Cost Score Estimate
		Baseline		
1) Solo	7,380	18,867	39.12%	62.15
2) 2-15	32,476	71,908	45.16%	59.89
3) 16-99	65,428	150,377	43.51%	60.30
4) 100+	226,035	445,493	50.74%	59.02
Overall	331,319	686,645	48.25%	59.16
		Proposed Policies		
1) Solo	7,636	18,867	40.47%	75.24
2) 2-15	33,242	71,908	46.23%	74.34
3) 16-99	66,311	150,377	44.10%	74.35
4) 100+	227,601	445,493	51.09%	73.78
Overall	334,790	686,545	48.76%	73.85

Figure 6 shows the distribution of final scores for all MIPS eligible clinicians. Note that there are a relatively large number of MIPS eligible clinicians with a final score of 75. As stated in section VII.E.17.d.(3)(f) of this proposed rule MIPS eligible clinicians whom we approved for reweighting of all MIPS performance categories in accordance with our reweighting policies at § 414.1380(c)(2) are assigned a final score of exactly the performance threshold (75). Overall, the distribution is skewed to the right indicating that clinicians tend to receive final scores on the higher end of the distribution with many final scores clustered near the performance threshold of 75. Our proposed policies have the effect of shifting final scores to the right. Many clinicians with final scores just below the performance threshold in the baseline model see their scores increased to a value just above the performance threshold in the proposed policies model.

FIGURE 6: Count of MIPS Eligibles Clinicians by Final Score



(i) Impact to Small and Solo Practices

18,867 MIPS eligible clinicians or 2.7 percent of all MIPS eligible clinicians are solo practitioners in both the baseline and final policies models. The median final score for solo practitioners is exactly equal to the performance threshold in both the baseline and final policies model although the portion of solo practitioners receiving a positive adjustment is higher in the proposed policies model than in the baseline model. As stated in section VII.E.17.d.(3)(f) of this proposed rule, clinicians receiving reweighting under our policies at § 414.1380(c)(2) are assigned a final score exactly equal to the performance threshold if we approved for reweighting of all MIPS performance categories.

Section VII.E.17.d.(3)(f) of this proposed rule, clinicians receiving reweighting under our policies at § 414.1380(c)(2) are assigned a final score exactly equal to the performance threshold if we approved for reweighting of all MIPS performance categories.

These practitioners have a lower median final score than other practice sizes. This is largely due to the fact that many of these solo practitioners do not submit data to MIPS despite being MIPS eligible clinicians. Our analysis indicates that 49.45 percent of solo practitioners submit data to MIPS compared to 93.68 percent of all clinicians. The median final score in our baseline and proposed policies model is 75.00 for all solo practitioners, but for solo practitioners who submit data the median final score is 84.35 in the baseline and 87.03 in the proposed policies model. These findings indicate that the lower final scores among solo practitioners is likely due to not reporting data to MIPS. Figure 7 shows the distribution of final scores for solo practitioners as a box plot. While the median final score is 75 in both models, the bottom quartile increases from 17.52 to 22.33 between the baseline and proposed policies model. Figure 8 shows the final score distribution for all practice sizes. The first quartile of final scores is 75 in the baseline model and 77.45 in the proposed policies model. The range between Q1 and Q3 is significantly narrower for all practice sizes than it is for solo practitioners. Figure 9 shows the distribution of final scores for solo practitioners who submit data to MIPS. This distribution is much closer to the distribution of final scores in the overall population with the first quartile at 73.45 in the baseline and 75.00 in the proposed policies model. This is similar to the median final score for all practice sizes which is 86.42. This indicates that, while many solo practitioners do not submit data to MIPS, those who do submit data perform similarly or better than the overall population of MIPS eligible clinicians. This is further evidence that the main factor causing low final scores among solo practitioners is the high proportion who do not submit data.

FIGURE 7: Distribution of Final Scores for Solo Practitioners

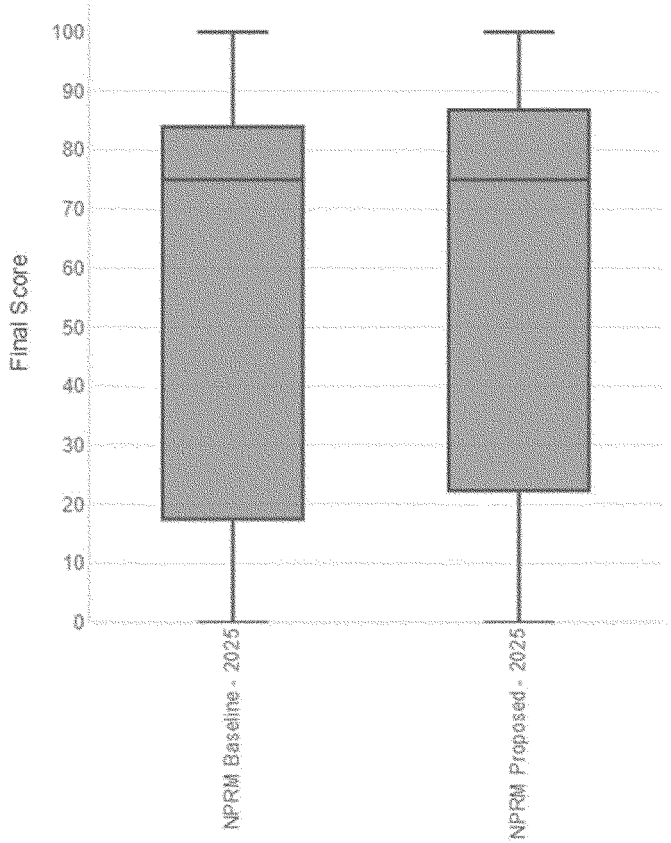


FIGURE 8: Distribution of Final Scores for All Practice Sizes

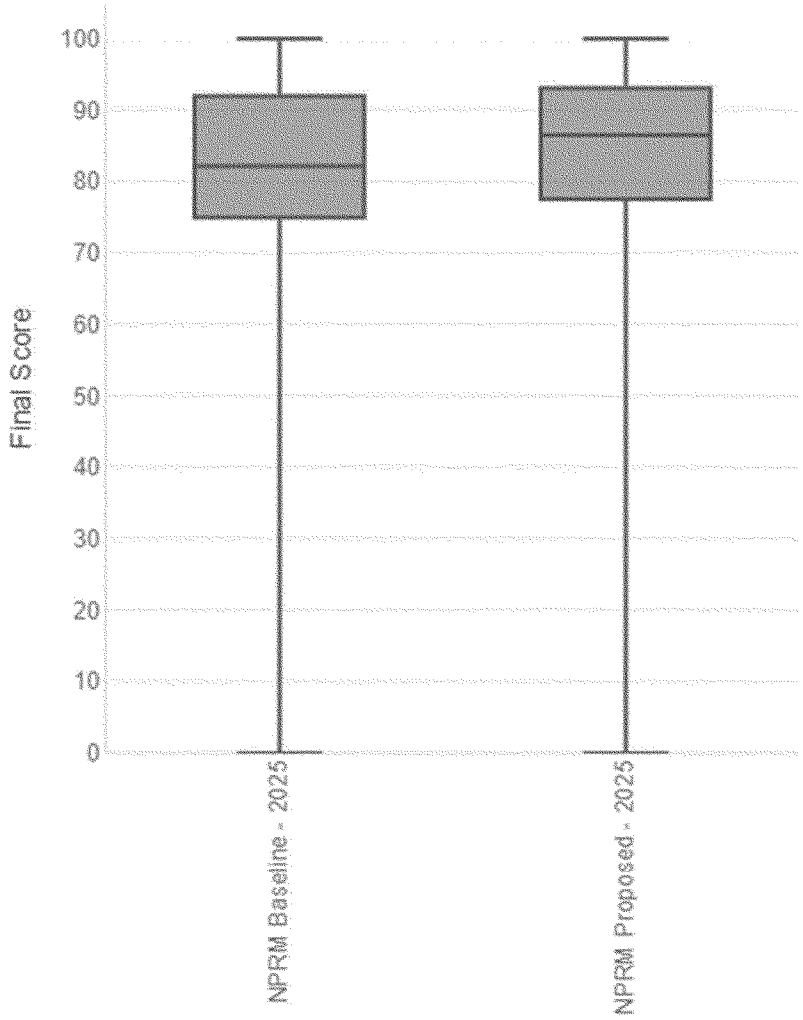
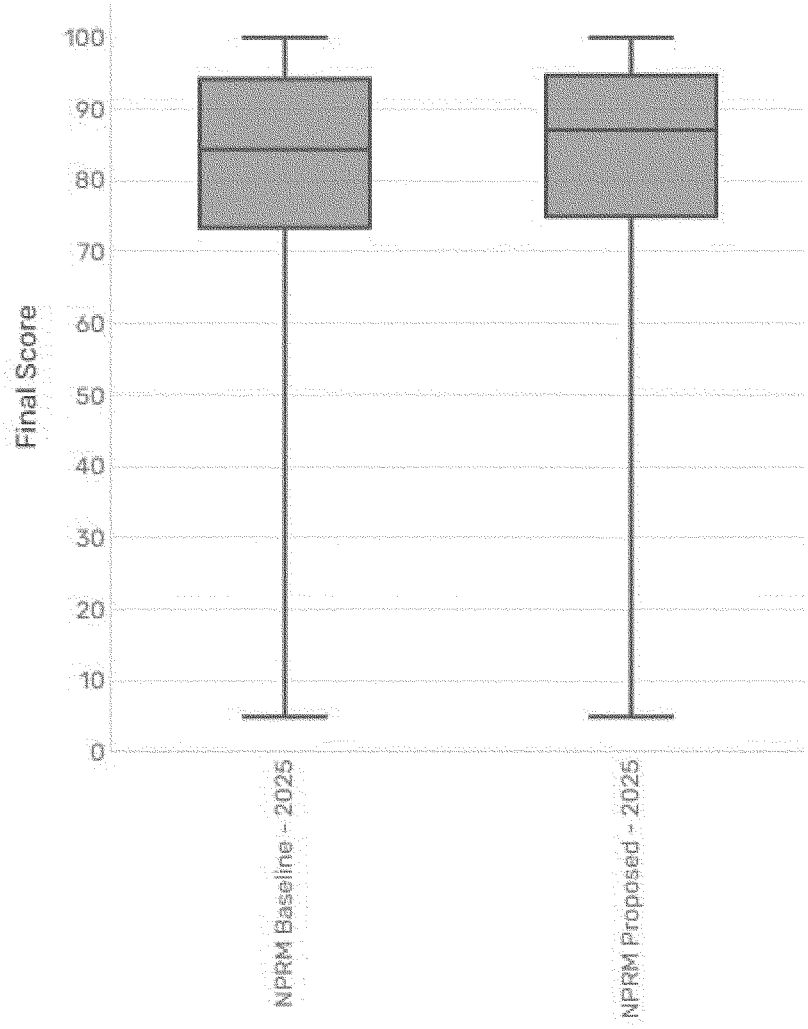


FIGURE 9: Distribution of Final Scores for Solo Practitioners who Submit Data



Small practices, defined as groups with a range between 2 and 15 clinicians, have a median final score of 81.79 in the baseline and 86.02 in the proposed policies model. This is similar but slightly lower than the median final score for all practice sizes of 86.42. Among small practices who submit data the median final score is 89.81 in the proposed policies model (and 86.83 in the baseline). This is significantly higher than the median final score for all clinicians who submit data which is 87.53. This indicates that small practices perform similarly to other practice sizes although a slightly larger proportion of small practices do not submit data. Table 141 shows the percentage of clinicians by practice size who either do or do not submit data to MIPS and the corresponding median final score. Note that the median final score for clinicians who do not submit data is 75 for all practice sizes except for solo practitioners. This indicates that many clinicians belonging to small, medium, or large practices (but not solo practitioners) who do not submit data to MIPS have been approved for reweighting of all of their MIPS performance categories under our policies at § 414.1380(c)(2). In contrast, many solo practitioners who do not submit data do so despite not being eligible for application of our reweighting policies or not applying for reweighting under those policies.

A large majority of all practice sizes except solo practitioners submit data to MIPS. It is possible that the small percentage of MIPS eligible clinicians in those practice sizes who do not submit data to MIPS are primarily MIPS eligible clinicians who have received reweighting under our policies at § 414.1380(c)(2). It should be noted that median final scores increase for solo and small practitioners between our baseline and proposed policies model indicating that the net effect of our proposed policies is an increase in their final scores.

TABLE 139: Percentage of MIPS Eligible Clinicians who Submit Data and Median Final Score

	Percentage **of MIPS** Eligible Clinicians who Submit Data (by practice size)	Median Final Score of MIPS Eligible Clinicians who Submit Data	**Median Final Score of MIPS Eligible Clinicians who Do not submit data.**
		Baseline	
1) Solo	49.39%	84.35	19.35
2) Small (2-15)	79.32%	86.83	75
3) Medium (16-99)	91.69%	83.42	75
4) Large(100+)	98.23%	83.15	75
Overall	93.47%	83.46	75
		Proposed Policies	
1) Solo	49.45%	87.03	22.89
2) Small (2-15)	79.46%	89.81	75
3) Medium (16-99)	92.03%	87.27	75
4) Large(100+)	98.41%	87.31	75
Overall	93.68%	87.53	75

(ii) Impact to Rural Providers

In our data we assign rural practitioners a special status. Analysis of this group of clinicians indicates that their final scores are similar to the overall population of MIPS Eligible Clinicians across all practice sizes. Table 140 shows the median final score and the percentage of eligible clinicians with a positive or neutral or negative adjustment by practice size.

TABLE 140: CY 2025 Final Score Estimates by Practice Size for *Rural Practitioners Only*

Practice Size	**Total Number of MIPS Eligible Clinicians**	**Median Final Score Estimate**	**Percent Eligible Clinicians with Positive Payment Adjustment**	**Percent Eligible Clinicians with Neutral Payment Adjustment**	**Percent Eligible Clinicians with Negative Payment Adjustment**
			Baseline		
1) Solo	2,694	75.00	34.89%	17.37%	47.74%
2) 2-15	11,760	83.89	65.94%	10.48%	23.58%
3) 16-99	30,444	85.05	71.38%	6.80%	21.82%
4) 100+	43,286	80.43	69.02%	5.08%	25.90%
Overall	88,184	81.29	68.38%	6.77%	24.85%
			Proposed Policies		
1) Solo	2,694	75.00	36.53%	17.33%	46.14%
2) 2-15	11,762	87.34	69.82%	10.42%	19.76%
3) 16-99	30,409	87.53	76.90%	6.37%	16.73%
4) 100+	43,281	84.27	81.78%	4.94%	13.28%
Overall	88,146	85.41	77.12%	6.54%	16.34%

The median final score for all rural practitioners is 81.29 in our baseline model and 85.41 in our proposed policies model. This is slightly lower than the median final score for all practitioners which is 82.20 in our baseline model and 86.42 in our proposed policies model. However, the median final score is identical for solo practitioners and higher for small and medium practices. Large rural providers have a slightly lower median final score compared to large practices generally. The lower overall median final scores for rural practitioners are driven by large rural practices who perform slightly worse than other practice sizes and when compared to large practices generally. It should be noted that median final scores increase for rural providers of all practice sizes between our baseline and proposed policies model indicating that the net effect of our proposed policies is an increase in their final scores.

(iii) Impact to Safety Net Providers

(a) Updated Definition of Safety Net Providers

In the CY 2023 PFS final rule (87 FR 70094), we finalized our complex patient bonus methodology. This bonus is composed of two distinct calculations which are added together: Medical Complexity and Social Risk. Medical Complexity is determined based on a MIPS eligible clinicians Hierarchical Conditions Categories risk score and social risk is determined based on the proportion of a MIPS eligible clinicians Medicare patient population who are dually eligible for both Medicare and Medicaid.

In the CY 2024 PFS final rule (88 FR 79513), we compared the performance of clinicians who received the complex patient bonus with our overall population. As we further developed our model, we decided to adopt a more precise definition of safety net providers. We believe that by narrowing our definition of safety net providers to the top 20 percent (80th percentile) of social risk we can identify the providers who are caring for the largest proportion of low-income or otherwise socially vulnerable individuals.

Table 143 shows the final score estimates for safety net providers under this new definition. Safety net provers have higher median final scores than the overall population of MIPS eligible clinicians across all practice sizes with the exception of small and solo practitioners. When our analysis is restricted to providers who submit data to MIPS this discrepancy disappears and small and solo safety net providers who submit data have higher median final scores than the overall population of small and solo MIPS eligible clinicians who submit data. However, only 43.65 percent of solo and 72.90 percent of small safety net providers submit data compared to 49.45 percent and 79.46 percent of the overall population of solo and small MIPS eligible clinicians respectively. These results are shown in Table 141. This indicates that the lower scores among small and solo safety net practitioners is likely due to a larger number of these practitioners not submitting data. It should be noted that median final scores increase for solo and small safety net providers between our baseline and proposed policies model indicating that the net effect of our proposed policies is an increase in their final scores.

TABLE 141: CY 2025 Final Score Estimates by Practice Size for *Safety Net Practitioners Only*

Practice Size	Total Number of MIPS Eligible Clinicians	Median Final Score Estimate	Percent Eligible Clinicians with Positive Payment Adjustment	Percent Eligible Clinicians with Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
			Baseline		
1) Solo	5,347	62.31	26.95%	20.07%	52.98%
2) 2-15	14,202	80.84	55.01%	15.56%	29.43%
3) 16-99	37,246	85.12	66.77%	12.97%	20.26%
4) 100+	82,916	86.18	83.59%	5.64%	10.77%
Overall	139,711	85.35	74.04%	9.15%	16.81%
			Proposed Policies		
1) Solo	5,347	65.78	27.70%	20.05%	52.25%
2) 2-15	14,208	84.50	57.18%	15.52%	27.30%
3) 16-99	37,212	88.31	70.48%	12.79%	16.73%
4) 100+	82,839	89.23	87.11%	5.53%	7.36%
Overall	139,606	88.59	77.36%	9.03%	13.61%

TABLE 142: CY 2025 Median Final Scores for *Safety Net Practitioners who Submit Data*

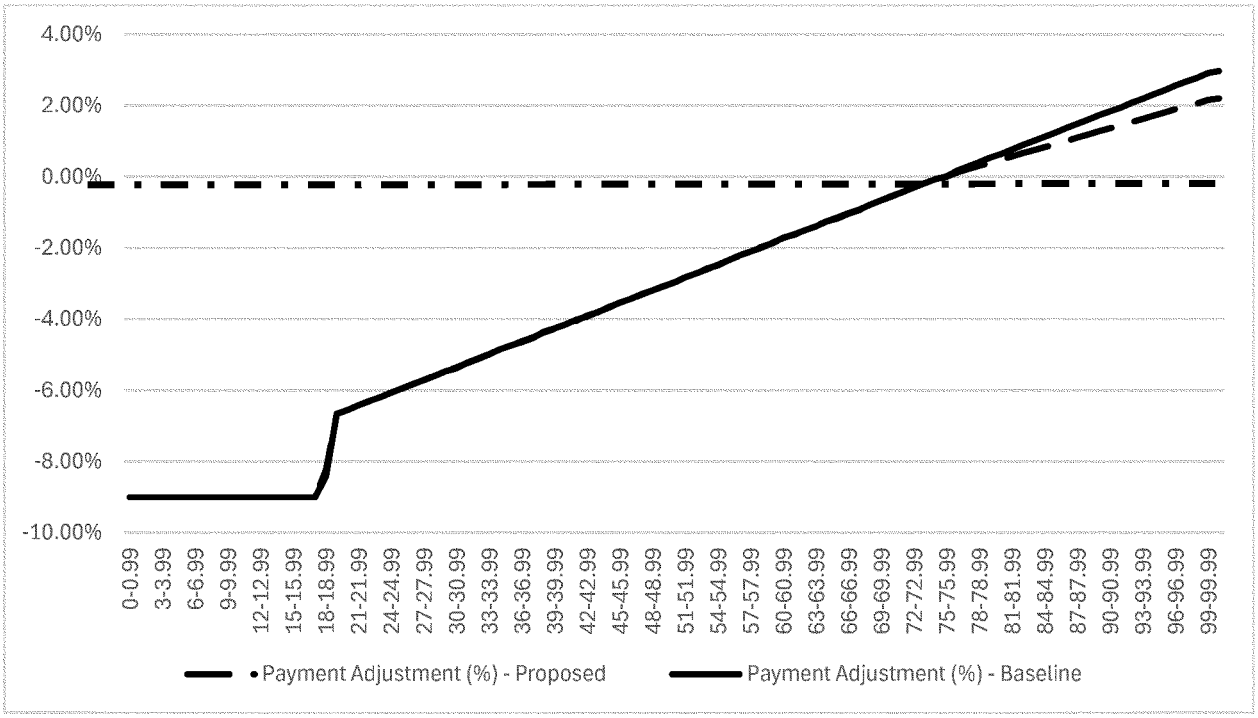
Practice Size	Percent of MIPS Eligible Clinicians who Submit Data	Median Final Score Estimate	Percent Eligible Clinicians with Positive Payment Adjustment	Percent Eligible Clinicians with Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
			Baseline		
1) Solo	43.63%	86.12	61.77%	10.84%	27.39%
2) 2-15	72.90%	89.51	75.46%	7.06%	17.48%
3) 16-99	91.73%	86.54	72.78%	8.45%	18.77%
4) 100+	98.47%	86.18	84.88%	4.45%	10.67%
Overall	91.97%	86.37	80.48%	5.85%	13.67%
			Proposed Policies		
1) Solo	43.65%	89.06	63.45%	10.84%	25.71%
2) 2-15	72.94%	92.29	78.39%	7.04%	14.57%
3) 16-99	91.90%	89.53	76.67%	8.44%	14.89%
4) 100+	98.58%	89.31	88.35%	4.45%	7.20%
Overall	92.08%	89.57	83.99%	5.83%	10.18%

(c) Impact to MIPS Eligible Clinicians' Payment Adjustments

We are not proposing an increase in the performance threshold in this proposed rule. However, payment adjustments differ between the baseline and final policies model. This is because our proposed policies increase final scores of MIPS eligible clinicians [829] and therefore a larger proportion of MIPS eligible clinicians receive a final score greater than the performance threshold and thus a positive payment adjustment. The parameters of the exchange function used to determine payment adjustments depends on the final score distribution of MIPS eligible clinicians. As the proportion of MIPS eligible clinicians receiving a negative payment adjustment decreases the budget neutral funds available for redistribution also decrease. In the baseline model we project redistributing $517 million and in the proposed policies model we project redistributing $458 million. This decrease means that the scaling factor for positive adjustments is reduced.

[829] This increase is largely due to the change in our cost performance category scoring policies discussed in section IV.A.4.f.(1)(d)(ii)(B) of this proposed rule.

FIGURE 10: Payment Adjustment Function



We also report the median positive and negative payment adjustments by practice size in Table 143.

TABLE 143: CY 2025 Median Positive and Negative Payment Adjustment Estimates By Practice Size

Practice Size	Median Positive Payment Adjustment*	Median Negative Payment Adjustment*
Baseline		
Solo (1)	2.06%	-9.00%
Small (2-15)	1.82%	-4.69%
Medium (16-99)	1.65%	-1.25%
Large (>99)	1.59%	-0.88%
Overall	1.65%	-1.10%
Proposed Policies Model		
Solo (1)	1.55%	-6.42%
Small (2-15)	1.46%	-5.88%
Medium (16-99)	1.35%	-1.44%
Large (>99)	1.28%	-1.08%
Overall	1.31%	-1.48%

*The median positive payment adjustment is defined as the medium payment adjustment among clinicians with a final score above the performance threshold. The median negative adjustment is defined as the medium payment adjustment among clinicians with a final score below the performance threshold. Neither median includes clinicians with a final score equal the performance threshold.

For all practices sizes except for solo practitioners the median negative payment adjustment increases in magnitude. This is because many MIPS eligible clinician's final scores are clustered near the performance

threshold. An increase in median final scores will cause many of those clinicians who have a minor negative adjustment to meet or exceed the performance threshold and therefore be removed from the population of clinicians with a negative adjustment. The remaining population of MIPS eligible clinicians with negative adjustments are more likely to have negative payment adjustments higher in magnitude. In contrast to other practice sizes. fewer solo practitioners with negative payment adjustments have a final score near the performance threshold and an increase in the final score of these MIPS eligible clinicians will reduce the size of their negative payment adjustment but is less likely to shift their final scores above the performance threshold in the manner described earlier. As discussed in section VII.E.17.d.(4)(b)(i) of this proposed rule, this is largely because many of these solo practitioners do not submit data to MIPS despite being MIPS eligible clinicians. Our analysis indicates that 49.45 percent of solo practitioners submit data to MIPS in our proposed policies model compared to 93.70 percent of all MIPS eligible clinicians. In Table 144, we report the proportion of MIPS eligible clinicians who either did or did not submit data with the maximum negative adjustment (−9 percent).

TABLE 144: CY 2024 CY 2024 Clinicians With The Maximum Negative Adjustment

Practice Size	Percent of **Clinicians who Did NOT Submit Data** with Maximum Negative Adjustment	Percent of **Clinicians Who Submit Data** With Maximum Negative Adjustment
Baseline (-9%)		
Solo (1)	48.94%	2.90%
Small (2-15)	35.75%	0.84%
Medium (16-99)	17.88%	0.37%
Large (>99)	11.71%	0.12%
Overall	29.35%	0.28%
Proposed Policies Model (-9%)		
Solo (1)	35.57%	2.26%
Small (2-15)	25.23%	0.72%
Medium (16-99)	12.52%	0.35%
Large (>99)	5.50%	0.10%
Overall	20.77%	0.24%

Across all practice sizes the proportion of clinicians who do not submit data who receive the max negative payment adjustment decreased between the baseline and proposed policies model. A larger proportion of solo practitioners (2.26 percent) who submit data receive the maximum negative adjustment.

The median positive adjustment for solo practitioners is 1.55 percent which is higher than the median positive adjustment for all practice sizes overall. This indicates that, while many solo practitioners do not submit data to MIPS, those solo practitioners who do report data to MIPS and receive a positive adjustment receive a similar median adjustment to other practice sizes.

e. Additional Impacts From Outside Payment Adjustments

(1) Burden Overall

In addition to policies affecting payment adjustments, we are proposing several policies that have an impact on burden in the CY 2025 performance period/2027 MIPS payment year. In section V.B.8. of this proposed rule, we outline estimates of the costs of data collection that include both the effect of proposed policy updates and adjustments due to the use of updated data sources. For each proposed provision included in this proposed rule that impacts our estimate of collection burden, we summarize the incremental burden in Table 145. We also provide proposed additional burden discussions that we are not able to quantify.

TABLE 145: Incremental Estimated Burden from Associated Proposed Policies

(Asterisks refer to paragraph directly following table)

Burden Description and Associated Proposed Provisions	Burden Hours	Burden Dollars
Total burden associated with the provision to continue the policies and ICRs set forth in the CY 2024 PFS final rule into the CY 2025 performance period/2027 MIPS payment year with updated data and assumptions (as outlined in section V.B.8. of this proposed rule).	657,110	$77,779,594
Burden change for MVP registration ICR due to the provision of additional MVPs (as outlined in section V.B.8.e.(7)(a)(i). of this proposed rule). *	+626	+$66,759
Burden change for Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type ICR for capturing reduced number of quality submissions due to the provision of additional MVPs (as outlined in section V.B.8.e.(4). of this proposed rule). *	-7,697	-$898,035
Burden change for Quality Data Submission by Clinicians: CQM/QCDR Collection Type ICR for capturing reduced number of quality submissions due to the provision of additional MVPs (as outlined in section V.B.8.e.(5). of this proposed rule). *	-6,866	-$823,269
Burden change for Quality Data Submission by Clinicians: eCQM Collection Type ICR for capturing reduced number of quality submissions due to the provision of additional MVPs (as outlined in section V.B.8.e.(6). of this proposed rule). *	-9,664	-$1,176,109
Burden change for MVP Quality Submission ICR submissions due to the provision of additional MVPs (as outlined in section V.B.8.e.(7)(a)(iii). of this proposed rule). *	+16,031	+$1,917,478
Total change in burden due to policy for CY 2025	-7,570	-$913,176
Total burden set forth in the CY 2025 PFS proposed rule	649,540	$76,866,418

* The total change in burden due to this proposed provision includes an increase in burden due to an anticipated increase in the number of respondents that will participate in MVP reporting based on the proposed addition of 6 new MVPs. Therefore, there will be a decrease in burden in the "Quality Data Submission: MIPS CQM and QCDR collection type," "Quality Data Submission: eCQM collection type," and "Quality Data Submission: Claims collection type" ICRs due to respondents who previously submitted MIPS through those collection types submitting data with reduced Quality submission requirements as a MVP participant. Total change in burden also includes the increase in submission burden due to the increase in the number of respondents for "MVP registration." See section V.B.8.e.(2).of this proposed rule.

(2) Additional Impacts to Clinicians

(a) Impact on Third Party Intermediaries

In section IV.A.4.j.(1)(b). of this rulemaking, we are proposing that as part of the Consumer Assessment of Healthcare Providers & Systems (CAHPS) vendor registration process, in addition to the previously established registration requirements, CAHPS vendors would provide information on the range of costs for their services beginning with the CY 2026 performance period/2028 MIPS payment year. We recognize that there may be additional minimal burden associated with the proposed cost information requirement for the CAHPS vendor registration. However, we assume that this information is brief and readily available to vendors completing the registration process. We are unable to quantify the additional impact for the proposed CAHPS vendor cost requirement.

(b) Modifications to the Improvement Activities Inventory

As discussed in section IV.A.4.e.(3)(b)(iii). of this proposed rule, we are proposing changes to the improvement activities inventory for the CY 2025 performance period/2027 MIPS payment year and future years as follows: adding two new improvement activities; modifying two existing improvement activity; and removing eight previously adopted improvement activities. We refer readers to Appendix 2 of this proposed rule for further details. We do not expect these changes to the improvement activities inventory to affect our currently approved information collection burden for the number of estimated respondents. Most of the improvement activities in the Inventory remain unchanged for the CY 2025 performance period/2027 MIPS payment year. We refer readers to section IV.A.4.e.(3)(b)(iii). of this proposed rule for additional information on changes to the improvement activities Inventory.

(c) Modifications to Improvement Activities Scoring and Reporting Policies

As discussed in section IV.A.4.e.(3)(b)(iv)., we are proposing two scoring and reporting policy changes for the improvement activities performance category effective for the CY 2025 performance period/2027 MIPS payment year and subsequent years. As noted in section V.B.8.h., we established our currently approved estimate that it will take a computer analyst 5 minutes to log in and manually attest that improvement activities were completed in the CY 2019 PFS final rule (83 FR 60016). In the CY 2024 PFS final rule (88 FR 79454 and 79455), this estimate included scenarios where participants might submit 1, 2, 3, or 4 activities for the improvement activities category, based on medium- or high-weighted

activities and any additional weighting scenarios such as for MIPs Value Pathways (MVP) Participants. We believe this proposal would decrease burden for MIPS participants who previously reported medium-weighted activities. As MIPS participants who previously only reported high weighted activities would have the same attestation requirements under this proposal, we propose to continue our currently approve estimates of 5 minutes to log in and attest that improvement activities are completed. We expect reduced reporting burden for clinicians who previously reported at least one medium-weighted activity; however, we are unable to estimate the aggregated impact of this proposal given the current weighting and scoring rules that affect the number of activities each clinician submits to receive full credit for the improvement activities performance category.

(d) MVP Maintenance Process

In section VII.E.17.e.(2)(d). of this proposed rule, we are proposing a modification to the MVP maintenance webinar process previously finalized in the CY 2022 PFS final rule (86 FR 65410) and modified in the CY 2023 PFS final rule (87 FR 70037). We communicated that if we identified any potentially feasible and appropriate submitted maintenance recommendations, we would host a public facing webinar open to interested parties and the general public through which they could offer their feedback on the potential maintenance updates we have identified.

Due to the low volume of submitted maintenance recommendations in past years, we are proposing to provide us more flexibility in how we communicate maintenance recommendations prior to proposing them in rulemaking. Allowing flexibility in communicating recommendations through alternative webinar formats or other public communication channels would offer similar opportunities for public review and feedback as a live public webinar. For example, in lieu of a live webinar, we could choose to communicate submitted maintenance recommendations via a pre-recorded webinar, which will encourage interested parties to submit their feedback on the submitted recommendations in writing by email before maintenance updates are formally proposed in rulemaking.

As with the CY 2023 PFS final rule (87 FR 70210 through 70211), we acknowledge that there is administrative burden associated with the monitoring and review of the candidate MVPs. We are uncertain on the number of interested parties and members of the general public that will submit their recommendations for potential revisions to established MVPs for an applicable performance period. We are also uncertain if CMS will host a public webinar, webinar alternative, or other communications based on the review of the recommendations. In summary, we are unable to quantify the impact associated with the proposed changes to the MVP development and maintenance process.

(e) Reweighting Performance Categories When Data Is Not Submitted Due to Reasons Outside the Clinician's Control

In section IV.A.4.i.(2) of this rulemaking, we are proposing to adopt a new reweighting policy at 42 CFR 414.1380(c)(2)(i)(A)(*10*) and (c)(2)(i)(C)(*12*). Specifically, we are proposing that, beginning with the CY 2024 performance period/2026 MIPS payment year, we may reweight one or more of the performance categories (specifically, quality, improvement activities, or Promoting Interoperability), where we determine, based on information submitted to us on or before November 1st of the year preceding the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because the MIPS eligible clinician delegated submission of the data to their third party intermediary, evidenced by a written agreement between the MIPS eligible clinician and third party intermediary, and the third party intermediary did not submit the data for the performance category(ies) on behalf of the MIPS eligible clinician in accordance with applicable deadlines. We also are proposing that, to determine whether to apply reweighting to the affected performance category(ies), we will consider: whether the MIPS eligible clinician knew or had reason to know of the issue with its third party intermediary's submission of the clinician's data for the performance category(ies); whether the MIPS eligible clinician took reasonable efforts to correct the issue; and whether the issue between the MIPS eligible clinician and their third party intermediary caused no data to be submitted for the performance category(ies) in accordance with applicable deadlines. More details on this proposed reweighting policy are provided in section V.B.8.g.(2) of this proposed rule.

Because this is a new policy and we believe these occurrences would be rare based on our experience, we are unable to estimate the number of clinicians, groups, or third party intermediaries that may apply for reweighting based on this policy. Similarly, the extent and source of documentation provided to us for each event may vary considerably. Therefore, we are not proposing any changes to our currently approved burden estimates as a result of this proposal.

(f) Advanced Primary Care Management

As discussed in section II.G.2. of this proposed rule, we are proposing to adopt specific coding and payment policies for advanced primary care management (APCM) services for use by practitioners who are providing services under this specific model of ''advanced primary care,'' beginning January 1, 2025. These services would be furnished under the direction of a physician or other qualified health care professional who is responsible for all primary care (*e.g.,* physicians and non-physician practitioner, including nurse practitioner, physician assistant, certified nurse midwife and clinical nurse specialist), and serve as the continuing focal point for all needed health care services, during a calendar month. We are proposing three new APCM codes that would recognize the resources involved in furnishing ongoing, beneficiary-centered care management services under the broad model of advanced primary care without paying for each activity separately while allowing for flexibility in addressing patient needs. APCM payment would incorporate several specific, existing care management and communication technology-based services into a bundle and require reporting the Value in Primary Care MVP beginning in the CY 2025 performance period/2027 MIPS payment year. Billing practitioners who are not MIPS eligible clinicians (as defined at 42 CFR 414.1305) would not be required to report the MVP in order to furnish and bill for APCM services. As discussed in section V.B.8.e.(7)(a) of this proposed rule, we are unable to estimate the effect of this proposal on MVP submissions and registrations for the CY 2025 performance period/2027 MIPS payment year as the codes are newly proposed. Specifically, we are unable to determine how many additional clinicians or practices would submit the Value in Primary Care MVP measures for the CY 2025 performance period/2027 MIPS payment year above our current estimates. Similarly, we cannot assess what participation levels clinicians or practices who might use these APCM codes, if finalized, have reported MIPS in the past (for example,

eligibility requirements and special statuses, participation at the individual, group, virtual group, or Alternative Payment Model (APM) Entity level, or reporting via traditional MIPS, the APM Performance Pathway (APP), or MVPs), or if they will be MIPS eligible clinicians in future years. For MIPS eligible clinicians who move from reporting traditional MIPS to MVPs, we expect a decrease in overall program burden due to the reduced number of measures required for reporting the quality performance category. We will update these assumptions for MVP quality performance category reporting and MVP registration as more information is available.

(g) Mandatory Subgroup Registration

As summarized in section IV.A.3.c.(1). we established a voluntary subgroup participation option for clinicians choosing to report an MVP beginning in the CY 2023 performance period/2025 MIPS payment year. We finalized a mandatory subgroup reporting requirement for multispecialty groups choosing to report as an MVP Participant beginning in the CY 2026 performance period/2028 MIPS payment year (§ 414.1305; 86 FR 65394 through 65397). Beginning with the CY 2026 performance period/2028 MIPS payment year, a single specialty group may continue to submit data for an MVP at the group level, and a multispecialty group must form subgroups to report an MVP. Under the existing subgroup reporting policies, a group could place clinicians providing similar scope of care into one or more subgroups for reporting a relevant MVP. Each clinician may participate in one subgroup per tax identification number (TIN). The remaining clinicians under the group TIN not part of a subgroup could participate as individuals to report an MVP or traditional MIPS. The entire group TIN (including the clinicians that are part of the subgroup) could also submit data as a group in traditional MIPS. We note section IV.A.3.d. includes a Request for Information (RFI) to obtain feedback on what guidance/parameters are needed for multispecialty groups to place clinicians into subgroups for reporting an MVP relevant to the scope of care provided. Absent available submission data on MVP and subgroup reporting as discussed in section V.B.8.e.(7)(a)(ii), we are unable to estimate the effect of this established policy on reporting for the CY 2026 performance period/2028 MIPS payment year.

(h) APM Performance Pathway Plus Quality Measure Set

In section IV.A.4.c.(2). of this proposed rule, we are proposing to establish the APP Plus quality measure set beginning in the CY 2025 performance period/2027 MIPS payment year. As described in section V.B.8.a.(4)., clinicians reporting the proposed APP Plus quality measure set would report via one of the available collection types per measure: eight measures for the CY 2025 performance period/2027 MIPS payment year; nine measures for the CY 2026 and 2027 performance periods/2028 and 2029 MIPS payment years; and eleven measures for the CY 2028 performance period/2030 MIPS payment period. For the available collection types per measure, please see Tables 55, 56, and 57 in section IV.A.4.c.(3)(f).

In section V.B.8.a.(4). of this proposed rule, we compare the quality performance category burden for MIPS eligible clinicians who elect to report the proposed APP Plus quality measure set compared to the current APP quality measure set, traditional MIPS, and MVPs. We focus these analyses on quality measures required for MIPS eligible clinicians under the eCQM, CQM/QCDR, and Medicare Part B claims collection types. We note, these assumptions for actively submitting to assess clinician burden may differ from MIPS scoring policy. In that comparison, we assume MIPS eligible clinicians incur no burden for reporting the two administrative claims quality measures currently required under the APP quality measure set. Additionally, burden estimates for the CAHPS for MIPS registration and patient reporting are provided in the CAHPS for MIPS PRA package under OMB control number 0938–1222 (CMS–10450); we do not assume that MIPS eligible clinicians incur additional reporting burden for reporting the CAHPS for MIPS quality measure under the current APP quality measure set. Therefore, MIPS eligible, clinicians reporting the proposed APP Plus quality measure set beginning in the CY 2025 performance period/2027 MIPS payment year would need to actively submit performance data for more quality measures than clinicians reporting via MVPs or the APP. Compared to clinicians reporting via traditional MIPS, clinicians reporting the proposed APP Plus quality measure set would actively submit performance data for fewer quality measures for the CY 2025 performance period/2027 MIPS payment year; the same number of quality measures for the CY 2026 and 2027 performance periods/2028 and 2029 MIPS payment years, and more measures for the CY 2028 performance period/2030 MIPS payment year.

As noted in the CY 2021 PFS final rule, one goal of the APP quality measure set was to reduce the reduce the burden of reporting quality measures twice; once to MIPS and once to their APMs; therefore, clinicians reporting the APP and APP Plus who are require by their APMs to submit the same measure sets incur limited additional burden (88 FR 84862). We assume that all Shared Savings Program ACOs will report the APP via the APP Plus measure set for the CY 2025 performance period/2027 MIPS payment year. Per section 1899(e) of the Act, submissions received from eligible clinicians in ACOs are not included in burden estimates for this proposed rule because quality data submissions to fulfill requirements of the Shared Savings Program are not subject to the PRA. As the APP Plus is a new and optional quality measure set for non-Shared Savings Program ACOs with greater reporting burden than the current APP quality measure set and APM specific requirements may vary, we are unable to estimate how many individual MIPS eligible clinicians, groups, or APM Entities would submit quality measures via the APP Plus at this time. Our burden estimates currently assume MIPS eligible clinicians in non-Shared Savings ACO APM Entities will participate through traditional MIPS or MVPs, submitting as an individual or group rather than as an APM Entity. We will update these estimates and assumptions as additional data are available.

i. Assumptions & Limitations

In our MIPS eligible clinician assumptions, we assumed that clinicians who elected to opt-in for the CY 2022 Quality Payment Program and submitted data will continue to elect to opt-in for the CY 2025 performance period/2027 MIPS payment year.

As discussed in section V.B.8. of this proposed rule, we are unable to predict which specific MIPS eligible clinicians would receive reweighting for one or more performance categories under policies at § 414.1380(c)(2) in the CY 2025 performance period/2027 MIPS payment rear. On this basis, we assume that those MIPS eligible clinicians for whom we approved reweighting of one or more performance categories under our policies are representative of the number and attributes of MIPS eligible clinicians who will receive reweighting under these policies in the future.

In addition to the limitations described throughout the methodology

sections, to the extent that there are year-to-year changes in the data submission, volume, and mix of services provided by MIPS eligible clinicians, the actual impact on total Medicare revenues will be different from those shown in Table 137.

F. Alternatives Considered

This proposed rule contains a range of policies, including some proposals related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when we exercise agency discretion, presents rationale for our policies, and, where relevant, alternatives that were considered. For purposes of the payment impact on PFS services of the policies contained in this proposed rule, we present above the estimated impact on total allowed charges by specialty.

1. Alternatives Considered Related to Strategies for Improving Global Surgery Payment Accuracy

As discussed previously and in section II.G. of this proposed rule, beginning for services furnished in 2025, we are proposing to broaden the applicability of the transfer of care modifiers for the 90-day global packages. We are proposing to require the use of the appropriate transfer of care modifier (modifier –54, –55, or –56) for all 90-day global surgical packages in any case when a practitioner (or another within the same group practice) expects to furnish only a portion of a global package (including but not limited to when there is a formal, documented transfer of care as under current policy or an informal, non-documented but expected, transfer of care). Practitioners billing for a global package procedure code with modifier –54 and other practitioners in the same group practice as that practitioner would still be able to bill during the global period for any separately identifiable E/M services they furnish to the patient that are unrelated to the global package procedure. Additionally, we are proposing a global surgical add-on code, HCPCS code GPOC1, which we expect will be billed during the postoperative period of 90 days following the procedure. We expect that this code will be billed once during that timeframe when the patient is seen for an office/outpatient (O/O) evaluation and management (E/M) visit that is related to the recent surgical procedure. We believe that this code will be billed by a physician or practitioner who is seeing the patient for a visit during the post-operative period and did not furnish the surgical procedure.

As we were developing this proposal, we analyzed a few different policy options to best achieve our goal of improving the payment accuracy of the global packages. We considered whether to propose to revalue the 10 and 90-day global packages on the PFS utilizing our findings and data under the MACRA requirement to improve payment accuracy on the fee schedule, however we are precluded from doing so under MACRA. We also considered revaluing services specifically included in the RAND study,[830] which looked at claims for which reporting of follow up visits was requested. We also considered proposing requiring separate billing, which would result in separate payments for the procedures and post operative visits in global packages, based on our current research and analysis of how practitioners may be furnishing care described by global packages. We considered this alternative policy as an initial step towards more accurately paying for global packages, specifically for services including high utilization global packages discussed in the RAND study. We also considered proposing revisions to all global surgical packages in a phased approach starting with the subset of packages described above and gradually revising other global packages over time, to manage payment predictability and stability within the PFS, rec.

2. Alternatives Considered Related to the Supervision of Outpatient Therapy Services in Private Practices

As discussed in section II.H of this proposed rule, we are proposing to allow for the general supervision of occupational therapy assistants (OTAs) and physical therapist assistants (PTAs), by OT's and PT's in private practice (OTPPs and PTPPs, respectively) who are enrolled as suppliers in Medicare. Currently, and since 2005, OTPPs and PTPPs are required to provide direct supervision of their OTAs and PTAs which requires the OTPP/PTPP to be immediately available to furnish assistance and direction throughout the performance of the procedure in the office suite or in the patient's home when Medicare patients are treated in order to bill for therapy services furnished by their supervised OTAs and PTAs.

In developing our proposal to allow for general supervision in these private practice settings, we considered the possibility of allowing for virtual direct supervision by the OTPP/PTPP instead, as we have included OTPPs/PTPPs as ''supervising practitioners'' in the application of our virtual direct supervision policy since October 6, 2021, which is now extended through CY 2024. Due to the private practice direct supervision regulatory requirement, when using virtual direct supervision, this means (per our clarification in the CY 2021 PFS final rule (85 FR 84539)) that the OTPP or PTPP could meet the virtual direct supervision requirement by being immediately available to engage via audio/video technology (excluding audio-only), and would not require real-time presence or observation of the service via interactive audio and video technology throughout the performance of the service.

However, if this alternative policy were selected, it would leave the direct supervision requirement in place for OTPPs and PTPPs and they'd still have to be immediately available to engage via audio/video technology and ensure their availability to do so. On the other hand, with general supervision, the OTPP's/PTPP's physical or virtual presence is not required when the OTA/PTA furnishes services, although the services continue to be furnished under their overall direction and control allowing the OTPP/PTPP, for example, to provide an evaluative service in the office while the OTA/PTA is off-site furnishing therapy services in a patient's home.

3. Alternatives Considered for the Quality Payment Program

For purposes of the payment impact on the Quality Payment Program, we view the performance threshold as a critical factor affecting the distribution of payment adjustments. In section IV.A.4.g.(2)(c) of this proposed rule, we proposed to set the performance threshold to 75 points for the CY 2025 MIPS performance period/CY 2027 MIPS payment year. Eighty-six (86) is a possible alternative value (mean of the CY 2019 performance period/2021 MIPS payment year) which we did not propose. To assess this alternative value, we ran a separate RIA model with a performance threshold of 86. This model has the same mean and median final score as our proposed policies RIA model since the alternative performance threshold which we are assessing in this model does not change the final score. In our analysis of the alternative performance threshold of 86, which we considered but did not propose, 55.98 percent of MIPS eligible clinicians who

[830] Using Claims-Based Estimates of Post-Operative Visits to Revalue Procedures with 10- and 90-Day Global Periods; Updated Results Using Calendar Year 2019 Data.

submitted data would receive a negative payment adjustment in the baseline and 45.08 percent of MIPS eligible clinicians who submit data would receive a negative adjustment in the proposed policies model.

We also reported the findings for the baseline RIA model which describes the impact for the CY 2025 performance period/2027 MIPS payment year if this proposal is not finalized. The baseline RIA model has a median final score of 82.20. We estimated that $517 million would be redistributed based on the budget neutrality requirement in the baseline model. The baseline includes a maximum payment adjustment of 2.98 percent and 22.84 percent of MIPS eligible clinicians would receive a negative payment adjustment.

G. Impact on Beneficiaries

1. Medicare Shared Savings Program Provisions

As noted previously in this proposed rule, the proposed HEBA would mainly provide upwards adjustments to benchmarks for—and likely draw increased participation from—new ACOs with particular focus on coordinating care for beneficiaries in underserved communities. New ACOs of this type are therefore projected to ultimately increase assignment to the Shared Savings Program by roughly 500,000 beneficiaries per year, ranging from 50,000 to 1.0 million at the low and high ends of this projection range.

ACOs have been found to perform better on certain patient-experience and performance measures than physician groups participating in the MIPS. In performance year 2022, ACOs had a higher average performance on quality measures they are required to report in order to share in savings compared to other similarly sized clinician groups not in the Shared Savings Program.[831] This includes statistically significant higher performance for quality measures related to diabetes and blood pressure control; breast cancer and colorectal cancer screening; tobacco screening and smoking cessation; and depression screening and follow-up.[832] We anticipate that ACOs will continue to improve the quality of care for their Medicare fee-for-service beneficiaries through the reporting of Medicare CQMs, and that ACOs will continue to improve the quality of care for their all payer/all patient population through the reporting of eCQMs.

Increased participation in the Shared Savings Program will extend ACO care coordination and quality improvement to segments of the beneficiary population that potentially have more to benefit from care management.

2. Quality Payment Program

There are several changes in this proposed rule that are expected to have a positive effect on beneficiaries. In general, we believe that many of these changes, including the MVP and subgroup provisions, if finalized, will lead to meaningful feedback to beneficiaries on the type and scope of care provided by clinicians. Additionally, beneficiaries could use the publicly reported information on clinician performance in subgroups to identify and choose clinicians in multispecialty groups relevant to their care needs. Consequently, we anticipate the policies in this proposed rule would improve the quality and value of care provided to Medicare beneficiaries. For example, several of the new quality measures include patient-reported outcome-based measures, which could be used to help patients make more informed decisions about treatment options. Patient-reported outcome-based measures provide information on a patient's health status from the patient's point of view and could also provide valuable insights on factors such as quality of life, functional status, and overall disease experience, which would not otherwise be available through routine clinical data collection. Patient-reported outcome-based measured are factors frequently of interest to patients when making decisions about treatment.

H. Estimating Regulatory Familiarization Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this rulemaking, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assumed that the total number of unique commenters on this year's proposed rule will be the number of reviewers of last year's proposed rule. We acknowledged that this assumption may understate or overstate the costs of reviewing this rulemaking. It is possible that not all commenters will review this year's proposed rule in detail, and it is also possible that some reviewers will choose not to comment on the proposed rule. For these reasons we believe that the number of commenters will be a fair estimate of the number of reviewers of this year's proposed rule.

We also recognized that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rulemaking.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rulemaking is $123.06, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm*. Assuming an average reading speed, we estimate that it would take approximately 8.0 hours for the staff to review half of this proposed rule. For each facility that reviews the rule, the estimated cost is $984.48 (8.0 hours × $123.06). Therefore, we estimated that the total cost of reviewing this regulation is 21,677,265 ($984.48 × 22,019 reviewers on this year's proposed rule).

As for the Medicare Diabetes Prevention Program, given that we tried to align this rulemaking as much as possible with the CDC DPRP Standards, there should be minimal regulatory familiarization costs. This rulemaking impacts only enrolled MDPP suppliers and eligible beneficiaries who have started the MDPP program or are interested in enrolling in MDPP.

I. Accounting Statement

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), in Tables 146 through 148 (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2024 to CY 2025 based on the FY 2025 President's Budget baseline.

[831] CMS, Press Release, ''Medicare Shared Savings Program Saves Medicare More Than $1.8 Billion in 2022 and Continues to Deliver High-quality Care'' (August 24, 2023). Available at *https://www.cms.gov/newsroom/press-releases/medicare-shared-savings-program-saves-medicare-more-18-billion-2022-and-continues-deliver-high*.

[832] *Id.*

TABLE 146: Accounting Statement: Classification of Estimated Expenditures

CATEGORY	TRANSFERS
CY 2025 Annualized Monetized Transfers	Estimated decrease in expenditures of $1.8 billion for PFS CF update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE 147: Accounting Statement: Classification of Estimated Costs, Transfer, and Savings

CATEGORY	TRANSFER
CY 2025 Annualized Monetized Transfers of beneficiary cost coinsurance.	-$0.4 billion
From Whom to Whom?	Beneficiaries to Federal Government.

TABLE 148: Accounting Statement for Provisions for Medicare Shared Savings Program (CYs 2025-2034) ($ Millions)

Category	Primary Estimate	Minimum Estimate	Maximum Estimate	Source Citation
BENEFITS				
Annualized monetized: Discount rate: 2%	-$12.6 million	-$148.9 million	$92.6 million	Tables 132 through 134; summarized in total in Table 135

Notes: Negative values reflect reduction in Federal net cost resulting from care management by ACOs. Estimates may be a combination of benefits and transfers. To the extent that the incentives created by Medicare payments change the amount of resources society uses in providing medical care, the more accurate categorization of effects would be as costs (positive values) or benefits/cost savings (negative values), rather than as transfers.

J. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provided an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides an RIA. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on June 25, 2024.

List of Subjects

42 CFR Part 401

Claims, Freedom of information, Health facilities, Medicare, Privacy.

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, and X-rays.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 427

Administrative practice and procedure, Biologics, Inflation rebates, Medicare, Prescription drugs.

42 CFR Part 428

Administrative practice and procedure, Biologics, Inflation rebates, Medicare, Prescription drugs.

42 CFR Part 491

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

■ 1. The authority citation for part 401 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, 1395w–5, and 1395kk–2.

■ 2. Section 401.305 is amended by revising paragraphs (b)(1) introductory text and (b)(2) introductory text and adding paragraph (b)(3) to read as follows:

§ 401.305 Requirements for reporting and returning of overpayments.

* * * * *

(b) * * *

(1) Except as provided in paragraphs (b)(2) and (3) of this section, a person who has received an overpayment must report and return the overpayment by the later of either of the following:

* * * * *

(2) The deadline for returning overpayments will be suspended (or will continue to be suspended following the completion of a timely, good faith investigation in accordance with paragraph (b)(3) of this section) when any of the following occurs:

* * * * *

(3)(i) The deadline for reporting and returning overpayments will be suspended when both of the following occurs:

(A) A person has identified an overpayment but has not yet completed a good-faith investigation to determine the existence of related overpayments that may arise from the same or similar cause or reason as the initially identified overpayment; and

(B) The person conducts a timely, good-faith investigation to determine whether related overpayments exist.

(ii) If the conditions of paragraph (b)(3)(i) of this section are satisfied, the deadline for reporting and returning the initially identified overpayment and related overpayments that arise from the same or similar cause or reason as the initially identified overpayment will remain suspended until the earlier of:

(A) The date that the investigation of related overpayments has concluded and the aggregate amount of the initially identified overpayments and related overpayments is calculated; or

(B) The date that is 180 days after the date on which the initial identified overpayment was identified.

* * * * *

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 3. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 4. Section 405.2410 is amended by revising paragraphs (c)(1) and (2) to read as follows:

§ 405.2410 Application of Part B deductible and coinsurance.

* * * * *

(c) * * *

(1) For RHCs, the coinsurance amount is determined as described in paragraph (b)(1) of this section; or

(2) For FQHCs, the coinsurance amount is 20 percent of the lesser of—

(i) The FQHC's actual charge; or

(ii) The payment determined under § 405.2462(j)(2).

■ 5. Section 405.2462 is amended by—

■ a. In paragraphs (f) heading, (f)(1) introductory text, (f)(2), and (g)(1)(ii), removing ''grandfathered'' and adding in its place ''historically excepted''; and

■ b. Revising and republishing paragraph (j).

The revisions and republications read as follows:

§ 405.2462 Payment for RHC and FQHC services.

* * * * *

(j) *Payment amount for intensive outpatient services.* (1) An RHC is paid the payment rate determined under § 419.21(a) of this chapter for services described under § 410.44 of this chapter. There are no adjustments to this rate.

(i) If the deductible has been fully met by the beneficiary prior to the RHC service, Medicare pays eighty (80) percent of the payment amount determined under this paragraph (j)(1).

(ii) If the deductible has not been fully met by the beneficiary prior to the RHC service, Medicare pays eighty (80) percent of the difference between the remaining deductible and the payment amount determined under this paragraph (j)(1); or

(iii) If the deductible has not been fully met by the beneficiary prior to the RHC service, no payment is made to the RHC if the deductible is equal to or exceeds the payment amount determined under this paragraph (j)(1).

(2) FQHCs are paid the payment rate determined under § 419.21(a) of this chapter for services described under § 410.44 of this chapter. There are no adjustments to this rate, except that historically excepted tribal FQHCs are paid pursuant to paragraph (j)(2)(ii) of this section.

(i) Medicare pays eighty (80) percent of the lesser of the FQHC's actual charge or the payment rate determined under paragraph (j)(1)(ii) of this section; or

(ii) Medicare pays eighty (80) percent of the lesser of a historically excepted tribal FQHC's actual charge or the amount described under paragraphs (f)(2) and (3) of this section.

(iii) No deductible is applicable to FQHC services.

■ 6. Section 405.2463 is amended by—

■ a. Revising paragraph (b)(3) introductory text;

■ b. In paragraph (c)(4) introductory text, removing ''grandfathered'' and adding in its place ''historically excepted''.

The revision reads as follows:

§ 405.2463 What constitutes a visit.

* * * * *

(b) * * *

(3) *Visit-Mental health.* A mental health visit is a face-to-face encounter or an encounter furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where the patient is not capable of, or does not consent to, the use of video technology for the purposes of diagnosis, evaluation or treatment of a mental health disorder, including an in-person mental health service, beginning January 1, 2026, furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record, between an RHC or FQHC patient and one of the following:

* * * * *

■ 7. Section 405.2464 is amended by revising paragraphs (c) and (d) and adding paragraphs (g) and (h) to read as follows:

§ 405.2464 Payment rate.

* * * * *

(c) *Payment for care coordination services.* RHCs and FQHCs are paid for the non-face-to-face care management work involved in coordinating care.

(1) For Chronic Care Management (CCM) services furnished between January 1, 2016, and December 31, 2017, payment to RHCs and FQHCs is based on the physician fee schedule national non-facility payment rate.

(2) For psychiatric collaborative care model (CoCM) services furnished on or

after January 1, 2018, payment is based on the average of the national non-facility PFS payment rate set for each psychiatric CoCM service and updated annually based on the PFS amounts.

(3) For CCM and general Behavioral Health Integration (BHI) services furnished between January 1, 2018, and December 31, 2020, payment is based on the average of the national non-facility PFS payment rate set for each CCM and general BHI service and updated annually based on the PFS amounts.

(4) For CCM, general BHI, and Principal Care Management (PCM) services furnished between January 1, 2021, and December 31, 2022, payment is based on the average of the national non-facility PFS payment rate set for each CCM, general BHI, and PCM service and updated annually based on the PFS amounts.

(5) For CCM, general BHI, PCM, Chronic Pain Management (CPM) services furnished between January 1, 2023, and December 31, 2023, payment is based on the average of the national non-facility PFS payment rate set for each CCM, general BHI, PCM and CPM service and updated annually based on the PFS amounts.

(6) For CCM, general BHI, PCM, CPM, Remote Physiologic Monitoring (RPM), Remote Therapeutic Monitoring (RTM), Community Health Integration (CHI), Principal Illness Navigation (PIN), and PIN—Peer Support services furnished between January 1, 2024, and December 31, 2024, the payment amount is based on a weighted average of each CCM, general BHI, PCM, CPM, RPM, RTM, CHI, PIN, and PIN—Peer Support service using the most recently available PFS utilization data.

(7) For CCM, general BHI, PCM, CPM, RPM, RTM, CHI, PIN, PIN—Peer Support, and Advance Primary Care Management services furnished on or after January 1, 2025, payment is based on the PFS national non-facility payment rate.

(d) *Payment for FQHCs that are authorized to bill as historically excepted tribal FQHCs.* Historically excepted tribal FQHCs are paid at the outpatient per visit rate for Medicare as set annually by the Indian Health Service for each beneficiary visit for covered services. There are no adjustments to this rate.

* * * * *

(g) *Payment for non-behavioral health telecommunication technology services.* For an encounter furnished using interactive, real-time, audio and video telecommunications technology or for certain audio-only interactions in cases where the patient is not capable of, or does not consent to, the use of video technology services that are not described in § 405.2463(b)(3), payment to RHCs and FQHCs are subject to the national average payment rates for comparable services under the physician fee schedule (PFS) and costs associated with these services shall not be used in determining payments under the RHC all-inclusive rate or the FQHC prospective payment system.

(h) *Payment for drugs covered as additional preventive services (DCAPS).* For drugs covered as additional preventive services, as defined at § 410.64 of this subchapter, and for the administration and supplying fees for those drugs, payment to RHCs or FQHCs is 100 percent of the Medicare payment amount per § 405.2410(b) and § 410.152(l)(11) of this chapter, subject to the payment limitations described at § 410.152(o) of this chapter.

■ 8. Section 405.2466 is amended by revising paragraph (b)(1)(iv) to read as follows:

§ 405.2466 Annual reconciliation.

* * * * *

(b) * * *

(1) * * *

(iv) For RHCs and FQHCs, payment for pneumococcal, influenza, hepatitis B and COVID–19 vaccine and their administration is 100 percent of Medicare reasonable cost.

* * * * *

§ 405.2469 [Amended]

■ 9. Section 405.2469 is amended in paragraph (a)(2) by removing ''grandfathered'' and adding in its place ''historically excepted''.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 10. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 11. Section 410.26 is amended by revising paragraph (a)(2) to read as follows:

§ 410.26 Services and supplies incident to a physician's professional services: Conditions.

(a) * * *

(2) *Direct supervision* means, except as provided in paragraphs (a)(2)(i) and (ii) of this section, the level of supervision by the physician (or other practitioner) of auxiliary personnel as defined in § 410.32(b)(3)(ii). For the following services furnished after December 31, 2025, the presence of the physician (or other practitioner) required for direct supervision shall include virtual presence through audio/video real-time communications technology (excluding audio-only):

(i) Services furnished incident to a physician of other practitioner's service provided by auxiliary personnel employed by the billing practitioner and working under their direct supervision and for which the underlying Healthcare Common Procedure Coding System (HCPCS) code has been assigned a PC/TC indicator of '5'.

(ii) Office or other outpatient visits for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care practitioner.

* * * * *

■ 12. Section 410.30 is amended by revising paragraph (a) to read as follows:

§ 410.30 Prescription drugs used in immunosuppressive therapy.

(a) *Scope.* Payment may be made for prescription drugs used in immunosuppressive therapy that meet one of the following conditions:

(1) The drug has been approved for marketing by the FDA and—

(i) The approved labeling includes an indication for preventing or treating the rejection of a transplanted organ or tissue; or

(ii) The approved labeling includes the indication for use in conjunction with immunosuppressive drugs to prevent or treat rejection of a transplanted organ or tissue.

(2) The drug has been approved for marketing by FDA and determined by a Medicare Administrative Contractor (MAC) (in accordance with part 421, subpart C, of this chapter), in processing a Medicare claim, to be reasonable and necessary for the specific purpose of preventing or treating the rejection of a patient's transplanted organ or tissue, or for use in conjunction with immunosuppressive drugs for the purpose of preventing or treating the rejection of a patient's transplanted organ or tissue. (In making these determinations, the MACs may consider factors such as authoritative drug compendia, current medical literature, recognized standards of medical practice, and professional medical publications.)

(3) The drug is a compounded formulation with active ingredients derived only from a drug described in paragraph (a)(1) or (2) of this section and is orally or enterally administered.

* * * * *

■ 13. Section 410.32 is amended by revising paragraph (b)(3)(ii) to read as follows:

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

* * * * *

(b) * * *

(3) * * *

(ii) *Direct supervision* in the office setting means that the physician (or other supervising practitioner) must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the service. It does not mean that the physician (or other supervising practitioner) must be present in the room when the service is performed. Through December 31, 2025, the presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only).

* * * * *

■ 14. Section 410.37 is amended by—

■ a. In paragraph (a)(1)(iv), removing the text ''barium enemas'' and adding in its place ''computed tomography colonography'';

■ b. Revising paragraph (a)(4);

■ c. In paragraph (e)(2), removing the text ''barium enema'' and adding in its place ''computed tomography colonography'';

■ d. In paragraph (g)(2), removing the text ''barium enema'' and adding in its place ''computed tomography colonography'';

■ e. Revising paragraphs (h), (i), and (k).

The revisions read as follows:

§ 410.37 Colorectal cancer screening tests: Conditions for and limitations on coverage.

* * * * *

(a) * * *

(4) *Screening computed tomography colonography* means a test that uses X-rays and computers to produce images of the entire colon (including image processing and a physician's interpretation of the results of the procedure).

* * * * *

(h) *Conditions for coverage of screening computed tomography colonography.* Medicare Part B pays for a screening computed tomography colonography if it is ordered in writing by the beneficiary's attending physician who is a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act); or by a physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5) of the Act).

(i) *Limitations on coverage of screening computed tomography colonography.* (1) In the case of an individual age 45 or over who is not at high risk of colorectal cancer, payment may be made for a screening computed tomography colonography performed after at least 59 months have passed following the month in which the last screening computed tomography colonography or 47 months have passed following the month in which the last screening flexible sigmoidoscopy or screening colonoscopy was performed.

(2) In the case of an individual who is at high risk for colorectal cancer, payment may be made for a screening computed tomography colonography performed after at least 23 months have passed following the month in which the last screening computed tomography colonography or the last screening colonoscopy was performed.

* * * * *

(k) *A complete colorectal cancer screening.* Effective January 1, 2025, colorectal cancer screening tests include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based colorectal cancer screening test or blood-based biomarker colorectal cancer screening test returns a positive result. The instance of the follow-on screening colonoscopy in the context of a complete colorectal cancer screening must not apply to the frequency limitations for colorectal cancer screening.

■ 15. Section 410.59 is amended by revising paragraphs (a)(3)(ii) and (c)(2) to read as follows:

§ 410.59 Outpatient occupational therapy services: Conditions.

(a) * * *

(3) * * *

(ii) By, or under the general supervision (or as specified otherwise) of, an occupational therapist in private practice as described in paragraph (c) of this section; or

* * * * *

(c) * * *

(2) *Supervision of occupational therapy services.* Except as otherwise provided in this paragraph (c)(2), occupational therapy services are performed by, or under the general supervision of, an occupational therapist in private practice. All services not performed personally by the therapist must be performed by employees of the practice, generally supervised by the therapist, and included in the fee for the therapist's services. Occupational therapy services may be performed by an occupational therapy assistant under the general supervision of the occupational therapist in private practice; services performed by an unenrolled occupational therapist must be under the direct supervision of the occupational therapist.

* * * * *

■ 16. Section 410.60 is amended by revising paragraphs (a)(3)(ii) and (c)(2) to read as follows:

§ 410.60 Outpatient physical therapy services: Conditions.

(a) * * *

(3) * * *

(ii) By, or under the general supervision (or as specified otherwise) of, a physical therapist in private practice as described in paragraph (c) of this section; or

* * * * *

(c) * * *

(2) *Supervision of physical therapy services.* Except as otherwise provided in this paragraph (c)(2), physical therapy services are performed by, or under the general supervision of, a physical therapist in private practice. All services not performed personally by the therapist must be performed by employees of the practice, generally supervised by the therapist, and included in the fee for the therapist's services. Physical therapy services may be performed by a physical therapist assistant under the general supervision of the physical therapist in private practice; services performed by an unenrolled physical therapist must be under the direct supervision of the physical therapist.

* * * * *

■ 17. Section 410.63 is amended by—

■ a. Revising paragraph (a) introductory text;

■ b. Removing the word ''and'' at the end of paragraph (a)(2)(ii);

■ c. Removing the period at the end of paragraph (a)(2)(iii) and adding in its place ''; and'';

■ d. Adding paragraph (a)(2)(iv); and

■ e. Revising paragraphs (b) and (c)(1).

The revisions and addition read as follows:

§ 410.63 Hepatitis B vaccine and blood clotting factors: Conditions.

* * * * *

(a) *Hepatitis B vaccine: Conditions.* Effective January 1, 2025, hepatitis B vaccinations are reasonable and necessary for the prevention of illness for those individuals who are at high or intermediate risk of contracting hepatitis B as listed in paragraphs (a)(1) through (3) of this section:

* * * * *

(2) * * *

(iv) Individuals who have not previously received a completed hepatitis B vaccination series or whose

previous vaccination history is unknown.

* * * * *

(b) *Blood clotting factors: Conditions.* Effective July 18, 1984, blood clotting factors that are self-administered and control bleeding for hemophilia patients competent to use these factors without medical or other supervision, and items related to the administration of those factors. The amount of clotting factors covered under this provision is determined by the carrier based on the historical utilization pattern or profile developed by the carrier for each patient, and based on consideration of the need for a reasonable reserve supply to be kept in the home in the event of emergency or unforeseen circumstance.

(c) * * *

(1) Effective January 1, 2005, a furnishing fee of $0.14 per unit of clotting factor is paid to entities that furnish blood clotting factors, as described in paragraph (b) of this section, unless the costs associated with furnishing the clotting factor are paid through another payment system, for example, hospitals that furnish clotting factor to patients during a Part A covered inpatient hospital stay, or practitioners that furnish clotting factor to patients in an outpatient setting and are paid for under the Physician Fee Schedule.

* * * * *

■ 18. Section 410.67 is amended in paragraph (b), in the definition of ''Opioid use disorder treatment service,'' by revising paragraphs (vi) and (vii) to read as follows:

§ 410.67 Medicare coverage and payment of Opioid use disorder treatment services furnished by Opioid treatment programs.

* * * * *

(b) * * *

Opioid use disorder treatment service

* * *

(vi) Intake activities, including initial medical examination services required under § 8.12(f)(2) of this title and initial assessment services required under § 8.12(f)(4) of this title.

(A) For intake activities furnished via communications technology, the following flexibilities apply:

(*1*) Services to initiate treatment with buprenorphine may be furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. In cases where audio-video communications technology is not available to the beneficiary, services to initiate treatment with buprenorphine may be furnished using audio-only telephone calls if all other applicable requirements are met.

(*2*) Services to initiate treatment with methadone may be furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements, if an OTP determines that an adequate evaluation of the patient can be accomplished through audio-video communication technology.

(B) [Reserved]

(vii) Periodic assessment services required under § 8.12(f)(4) of this title, that are furnished during a face-to-face encounter, including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. In cases where a beneficiary does not have access to two-way audio-video communications technology, periodic assessments can be furnished using audio-only telephone calls if all other applicable requirements are met.

* * * * *

■ 19. Section 410.78 is amended by revising paragraph (a)(3) read as follows:

§ 410.78 Telehealth services.

(a) * * *

(3) *Interactive telecommunications system* means, except as otherwise provided in this paragraph (a)(3), multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. Interactive telecommunications system may also include two-way, real-time audio-only communication technology for any telehealth service furnished to a patient in their home if the distant site physician or practitioner is technically capable of using an interactive telecommunications system as defined in the previous sentence, but the patient is not capable of, or does not consent to, the use of video technology. The following modifiers must be appended to a claim for telehealth services furnished using two-way, real-time audio-only communication technology to verify that the conditions set forth in the prior sentence have been met:

(i) Current Procedural Terminology (CPT) modifier ''93''; and

(ii) For rural health clinics (RHCs) and federally qualified health centers (FQHCs), Medicare modifier ''FQ''.

* * * * *

■ 20. Section 410.79 is amended by—

■ a. In paragraph (b):

■ i. Removing the definition of ''Combination delivery'';

■ ii. Adding the definitions of ''Combination with an online component,'' ''In-person with a distance learning component,'' and ''Online'' in alphabetical order;

■ iii. Removing the definition of ''Online delivery''; and

■ iv. Revising the definition of ''Set of MDPP services''; and

■ b. Revising paragraphs (d)(1) introductory text, (e)(3)(iii)(C), (e)(3)(iv)(F)(*3*), and (e)(3)(v)(F)(*2*).

The additions and revisions read as follows:

§ 410.79 Medicare Diabetes Prevention Program expanded model: Conditions of coverage.

* * * * *

(b) * * *

Combination with an online component refers to sessions that are delivered as a combination of online (non-live) with in-person or distance learning.

* * * * *

In-person with a distance learning component refers to DPP sessions that are delivered in person by trained Coaches where participants have the option of attending sessions via MDPP distance learning.

* * * * *

Online means sessions that are delivered 100 percent through the internet via phone, tablet, or laptop in an asynchronous (non-live) classroom where participants are experiencing the content on their own time without a live (including non-artificial intelligence (AI)) Coach teaching the content. These sessions must be furnished in a manner consistent with the DPRP Standards for online sessions. Live Coach interaction must be offered to each participant during weeks when the participant has engaged with content. Emails and text messages can count toward the requirement for live Coach interaction if there is bi-directional communication between the Coach and participant. Chat bots and AI forums do not count as live Coach interaction.

* * * * *

Set of MDPP services means the series of MDPP sessions, composed of core sessions and core maintenance sessions, and subject to paragraph (c)(3) of this section offered over the course of the MDPP services period.

* * * * *

(d) * * *

(1) An MDPP supplier may offer a make-up session to an MDPP beneficiary who missed a regularly scheduled session. MDPP make-up sessions may only use in-person or distance learning delivery. If an MDPP

supplier offers one or more make-up sessions to an MDPP beneficiary, each such session must be furnished in accordance with the following requirements:

* * * * *

(e) * * *

(3) * * *

(iii) * * *

(C) Self-reported weight measurements from the at-home digital scale of the MDPP beneficiary. Self-reported weights must be obtained during live, synchronous online video technology, such as video chatting or video conferencing, wherein the MDPP Coach observes the beneficiary weighing themselves and views the weight indicated on the at-home digital scale, or the MDPP supplier receives 2 (two) date-stamped photos or a video recording of the beneficiary's weight, with the beneficiary visible on the scale, submitted by the MDPP beneficiary to the MDPP supplier. Photo or video must clearly document the weight of the MDPP beneficiary as it appears on their digital scale on the date associated with the billable MDPP session. If choosing to submit 2 photos, one photo must show the beneficiary's weight on the digital scale, the second photo must show the beneficiary visible in their home, and both photos must be date-stamped.

* * * * *

(iv) * * *

(F) * * *

(*3*) No more than 12 virtual sessions offered monthly during the ongoing maintenance session intervals, months 13 through 24 for beneficiaries enrolled before January 1, 2022.

* * * * *

(v) * * *

(F) * * *

(*2*) For an MDPP beneficiary who began receiving the Set of MDPP services on or after January 1, 2021, has suspended services during an applicable 1135 waiver event, the MDPP supplier must use the baseline weight recorded at the beneficiary's first core session.

* * * * *

■ 21. Section 410.152 is amended by adding paragraph (o) to read as follows:

§ 410.152 Amounts of payment.

* * * * *

(o) *Amount of payment: Drugs covered as additional preventive services (DCAPS).* For a drug covered as an additional preventive service, as defined at § 410.64, payment must be made as follows:

(1) Payment for a drug covered as an additional preventive service, per section 1861(a)(1)(W)(ii) of the Act and paragraphs (l)(11) of this section and § 410.160(b)(13), is 100 percent of the lesser of—

(i) The actual charge on the claim for program benefits; or

(ii) The amount determined under the fee schedule as described in paragraph (o)(3) of this section.

(2) Payment for the supplying or administration of a drug covered as an additional preventive service per section 1861(a)(1)(W)(ii) of the Act and paragraphs (l)(11) of this section and § 410.160(b)(13), is 100 percent of the lesser of—

(i) The actual charge on the claim for program benefits; or

(ii) The amount determined under the fee schedule as described in paragraph (o)(4) of this section.

(3) The payment limit for a drug covered as an additional preventive service, as defined at § 410.64, appears on the DCAPS fee schedule and is determined as follows:

(i) If Average Sales Price (ASP) data is available for the drug, consistent with part 414, subpart J, of this chapter, then the payment limit is determined using the methodology set forth in section 1847A of the Act and according to the provisions in part 414, subpart K, of this chapter.

(ii) If ASP data is not available, then the payment limit is determined according to an average of the most recently published National Average Drug Acquisition Cost (NADAC) prices for the drug.

(iii) If ASP data and NADAC prices are not available, then the payment limit is determined according to an average of the most recently published pharmaceutical pricing data for the drug as included in the Federal Supply Schedule (FSS), as managed by the Department of Veterans Affairs per 48 CFR part 38.

(iv) If ASP data, NADAC prices, and FSS pharmaceutical prices are not available, then the payment limit is the invoice price determined by the MAC.

(4) The payment limits for supplying and administering a drug covered as an additional preventive service, as defined at § 410.64, appear on the DCAPS fee schedule and are determined as follows:

(i) For a drug that is supplied by a pharmacy, the payment limit for a supplying fee is as follows:

(A) For the first prescription that the pharmacy provides to a beneficiary in a 30-day period for a drug covered as an additional preventive service, $24.

(B) For all subsequent prescriptions that the pharmacy provides to a beneficiary in a 30-day period for a drug covered as an additional preventive service, $16.

(ii) For a drug that is administered by a physician or a non-physician practitioner, the payment limit for administration is set in accordance with part 414, subpart B, of this chapter. This fee is not subject to the Part B deductible, per § 410.160(b)(13). This fee is equal to 100 percent of the Medicare payment amount established under the applicable payment methodology, per paragraph (l)(11) of this section.

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 22. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

■ 23. Section 411.15 is amended by revising paragraph (i)(3)(i)(A) to read as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(i) * * *

(3) * * *

(i) * * *

(A) Dental or oral examination performed as part of a comprehensive workup prior to, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, the following Medicare-covered services: organ transplant, hematopoietic stem cell transplant, bone marrow transplant, cardiac valve replacement, valvuloplasty procedures, chemotherapy when used in the treatment of cancer, chimeric antigen receptor (CAR) T-cell therapy when used in the treatment of cancer, administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer, and dialysis services in the treatment of end stage renal disease.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 24. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 25. Section 414.84 is amended by—

■ a. In paragraph (a), removing the definition of ''Bridge payment'';

■ b. Revising paragraphs (b)(1) introductory text and (b)(2) introductory text;

■ c. Adding paragraph (c)(4);

■ d. Removing paragraph (d);

■ e. Redesignating paragraph (e) as paragraph (d); and
■ f. Revising newly redesignated paragraph (d).

The revisions and addition read as follows:

§ 414.84 Payment for MDPP services.

* * * * *

(b) * * *

(1) *Performance Goal 1: Achieves the required minimum 5-percent weight loss.* CMS makes a performance payment to an MDPP supplier for an MDPP beneficiary who achieves the required minimum weight loss as measured in-person or during a distance learning session during a core session or core maintenance session furnished by that supplier. The amount of this performance payment is determined as follows:

* * * * *

(2) *Performance Goal 2: Achieves 9-percent weight loss.* CMS makes a performance payment to an MDPP supplier for an MDPP beneficiary who achieves at least a 9-percent weight loss as measured in-person or in a distance learning session during a core session or core maintenance session furnished by that supplier. The amount of this performance payment is determined as follows:

* * * * *

(c) * * *

(4) Current Procedural Terminology (CPT) Modifier 79 (repeat services by same physician) must be appended to any claim for G9886 or G9887 to identify a MDPP make-up session that was held on the same day as a regularly scheduled MDPP session.

(d) *Updating performance payments and attendance payments.* The performance payments and attendance payments will be adjusted each calendar year by the percent change in the Consumer Price Index for All Urban Consumers (CPI–U) (U.S. city average) for the 12-month period ending June 30th of the year preceding the update year. The percent change update will be calculated based on the level of precision of the index as published by the Bureau of Labor Statistics (BLS) and applied based on one decimal place of precision. The annual MDPP services payment update will be published by CMS transmittal.

■ 26. Section 414.502 is amended by revising the definitions of ''Data collection period'' and ''Data reporting period'' to read as follows:

§ 414.502 Definitions.

* * * * *

Data collection period is the 6 months from January 1 through June 30, during which applicable information is collected and that precedes the data reporting period, except that for the data reporting period of January 1, 2025, through March 31, 2025, the data collection period is January 1, 2019, through June 30, 2019.

Data reporting period is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period, except that for the data collection period of January 1, 2019, through June 30, 2019, the data reporting period is January 1, 2025, through March 31, 2025.

* * * * *

§ 414.504 [Amended]

■ 27. Section 414.504 is amended in paragraph (a)(1) by removing the reference ''January 1, 2024'' and adding in its place the reference ''January 1, 2025''.

■ 28. Section 414.507 is amended by revising paragraphs (d) introductory text and (d)(7) and adding paragraph (d)(10) to read as follows:

§ 414.507 Payment for clinical diagnostic laboratory tests.

* * * * *

(d) *Phase-in of payment reductions.* For years 2018 through 2027, the payment rates established under this section for each CDLT that is not a new ADLT or new CDLT, may not be reduced by more than the following amounts for—

* * * * *

(7) 2024—0.0 percent of the payment rate established in 2023.

* * * * *

(10) 2027—15 percent of the payment rate established in 2026.

* * * * *

■ 29. Section 414.605 is amended in the definition of ''Advanced life support, level 2 (ALS2)'' by adding paragraph (8) to read as follows:

§ 414.605 Definitions.

* * * * *

Advanced life support, level 2 (ALS2) * * *

(8) Administration of low titer O+ whole blood transfusion.

* * * * *

■ 30. Section 414.902 is amended by revising the definition ''Refundable single-dose container or single-use package drug'' to read as follows:

§ 414.902 Definitions.

* * * * *

Refundable single-dose container or single-use package drug, as used in this subpart:

(1) Means a single source drug or biological or a biosimilar biological product for which payment is made under this part and is—

(i) Furnished from a single-dose container or single-use package based on Food and Drug Administration (FDA)-approved labeling or product information; or

(ii) Furnished from an ampule for which product labeling does not have discard statement or language indicating if the container is single-dose container, single-use package, multiple-dose container, or single-patient-use container; or

(iii) Furnished from a container with a total labeled volume of 2 mL or less for which product labeling does not have language indicating if the container is single-dose container, single-use package, multiple-dose container, or single-patient-use container.

(2) And excludes—

(i) A drug that is a therapeutic radiopharmaceutical, a diagnostic radiopharmaceutical, or an imaging agent as identified in the drug's FDA-approved labeling.

(ii) A drug for which the FDA-approved labeling for any National Drug Code assigned to a billing and payment code of such drug requires filtration during the drug preparation process, prior to dilution and administration and that any unused portion of such drug after the filtration process be discarded after the completion of such filtration process.

(iii) A drug approved or licensed by the FDA on or after November 15, 2021, until the last day of the sixth full quarter for which the drug has been marketed (as reported to CMS) for the first National Drug Code assigned to the billing and payment code of such drug.

(iv) A drug approved or licensed by FDA on or after November 15, 2021 and for which the date of first sale as reported to CMS does not adequately approximate the date of first payment under Part B due to an applicable national coverage determination, until the last day of the sixth full quarter for which the drug has been covered and paid under Medicare Part B for the first National Drug Code assigned to the billing and payment code of such drug.

* * * * *

■ 31. Section 414.904 is amended by adding paragraph (e)(6) and revising paragraph (i) to read as follows:

§ 414.904 Average sales price as the basis for payment.

* * * * *

(e) * * *

(6) *Radiopharmaceuticals furnished in settings other than the hospital outpatient department.* Medicare administrative contractors must determine payment limits for radiopharmaceuticals based on any methodology used to determine payment limits for radiopharmaceuticals in place on or prior to November 2003. Such methodology may include, but is not limited to, the use of invoice-based pricing.

* * * * *

(i) *Manufacturer's average sales price (ASP) data not available prior to the publication deadline for quarterly payment limits.* For circumstances in which manufacturer's ASP data is not available prior to the publication deadline for quarterly payment limits as described in this section, payment limit must be determined as follows:

(1) For a multiple source drug (as defined in § 414.902)—

(i) In circumstances in which negative or zero manufacturer's ASP data is reported for one or more, but not all, National Drug Codes (NDCs) associated with a billing and payment code for that drug for a given quarter, the payment limit for the given quarter is calculated using only NDCs for that drug with positive manufacturer's ASP data, except in circumstances described in paragraph (i)(1)(iii) of this section.

(ii) In circumstances in which negative or zero manufacturer's ASP data is reported for all NDCs associated with a billing and payment code for that drug for a given quarter, the payment limit for the given quarter is calculated by carrying over all positive manufacturer's ASP data from the most recently available previous quarter with positive manufacturer's ASP data for at least one NDC until at least one NDC for the drug has positive manufacturer's ASP data for a quarter.

(iii) In circumstances in which manufacturer's ASP data is not available and the unavailability of the manufacturer's ASP data results in a significant change in the ASP payment limit compared to the previous quarter, the payment limit is calculated by carrying over the most recent available ASP data for the individual NDC(s), adjusted by the weighted average of the change in the manufacturer's ASP data for the NDCs that were reported for both the most recently available previous quarter and the current quarter.

(2) For a single source drug, excluding biosimilar biological products (both as defined in § 414.902)—

(i) In circumstances in which negative or zero manufacturer's ASP data is reported for one or more, but not all, NDCs associated with a billing and payment code for that drug for a given quarter, the payment limit for the given quarter is calculated using only NDCs for that drug with positive manufacturer's ASP data.

(ii) In circumstances in which negative or zero manufacturer's ASP data is reported for all NDCs associated with a billing and payment code for that drug for a given quarter, the payment limit for the given quarter is the lesser of the following until at least one NDC for the drug has positive manufacturer's ASP data for a quarter:

(A) 106 percent of the volume-weighted average of the most recent available positive manufacturer's ASP data from a previous quarter in which at least one NDC for the drug has positive manufacturer's ASP data for the quarter. If the payment limit from such quarter was based on 106 percent of the wholesale acquisition cost because of the application of paragraph (d)(1) of this section, that payment limit is carried over; or

(B) 106 percent of the wholesale acquisition cost. If there is more than one WAC per billing unit for the drug, the payment limit is set using the lowest WAC per billing unit.

(3) For a biosimilar biological product (as defined in § 414.902)—

(i) In circumstances in which negative or zero manufacturer's ASP data is reported for one or more, but not all, NDCs for a given quarter, the payment limit for the given quarter is calculated using only NDCs with positive manufacturer's ASP data.

(ii) In circumstances in which negative or zero manufacturer's ASP data is reported for all NDCs for a given quarter, and other biosimilars referencing the same reference product report positive ASP data for the given quarter, the payment limit for the given quarter is the sum of the following until at least one NDC for the drug has positive manufacturer's ASP data for a quarter:

(A) the volume-weighted average of the ASP data from all other biosimilars of the same reference product; and

(B) Either:

(*1*) If the biosimilar is not a qualifying biosimilar (as both are defined at § 414.902), 6 percent of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in § 414.902) for the given quarter; or

(*2*) If the biosimilar is a qualifying biosimilar (as both are defined at § 414.902), 8 percent of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in § 414.902) for the given quarter.

(iii) In circumstances in which negative or zero manufacturer's ASP data is reported for all NDCs for a given quarter and either no other biosimilars have been approved for the same reference product or no other biosimilars of the same reference product report positive manufacturer's ASP data for the given quarter, the payment limit for the given quarter is the sum of the following until at least one NDC for the drug has positive manufacturer's ASP data for a quarter:

(A) The volume-weighted average of the most recent available positive manufacturer's ASP data from a previous quarter; and

(B) Either:

(*1*) If the biosimilar is not a qualifying biosimilar (as both are defined at § 414.902), 6 percent of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in § 414.902) for the given quarter; or

(*2*) If the biosimilar is a qualifying biosimilar (as both are defined at § 414.902), 8 percent of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in § 414.902) for the given quarter.

* * * * *

■ 32. Section 414.1001 is amended by—
■ a. Revising paragraph (a);
■ b. Removing paragraph (b);
■ c. Redesignating paragraphs (c) and (d) as paragraphs (b) and (c), respectively;
■ d. In newly redesignated paragraph (b)(2), removing ''(c)(1)'' and adding in its place ''(b)(1)''.

The revision reads as follows:

§ 414.1001 Basis of payment.

(a) *Supplying fees.* Beginning in CY 2006—

(1) A supplying fee of $24 is paid to a pharmacy (no more often than once every 30 days) for the first prescription of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act, that the pharmacy provided to a beneficiary, except as provided in paragraph (a)(2) of this section.

(2) A supplying fee of $50 is paid to pharmacy for the initial supplied prescription of drugs and biologicals described in section 1861(s)(2)(J) of the Act, that the pharmacy provided to a patient during the first 30-day period following a transplant.

(3) A supplying fee of $16 is paid to a pharmacy (no more often than once every 30 days) for each prescription following the first prescription (as

specified in paragraphs (a)(1) and (2) of this section) of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act, that the pharmacy provided to a beneficiary.

(4) A separate supplying fee is paid to a pharmacy for each prescription of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act.

* * * * *

■ 33. Section 414.1305 is amended in the definition of ''Attribution-eligible beneficiary'' by revising paragraph (6) to read as follows:

§ 414.1305 Definitions.

* * * * *

Attribution-eligible beneficiary * * *

(6) Has a minimum of one claim for any covered professional service furnished by an eligible clinician who is on the Participation List for an Advanced APM Entity at any determination date during the QP Performance Period.

* * * * *

■ 34. Section 414.1325 is amended by adding paragraphs (a)(1)(i) through (iii) and (f) to read as follows:

§ 414.1325 Data submission requirements.

(a) * * *

(1) * * *

(i) For the quality performance category, a data submission must include numerator and denominator data for at least one MIPS quality measure from the final list of MIPS quality measures.

(ii) For the improvement activities performance category, a data submission must include a response of ''yes'' for at least one activity in the MIPS improvement activities inventory.

(iii) For the Promoting Interoperability performance category, a data submission must include all of the following elements:

(A) Performance data, including any claim of an applicable exclusion, for the measures in each objective, as specified by CMS;

(B) Required attestation statements, as specified by CMS;

(C) CMS EHR Certification ID (CEHRT ID) from the Certified Health IT Product List (CHPL); and

(D) The start date and end date for the applicable performance period as set forth in § 414.1320.

* * * * *

(f) *Treatment of multiple data submissions.* (1) For multiple data submissions received in the quality and improvement activities performance categories in accordance with paragraphs (a)(1)(i) and (ii) of this section for an individual MIPS eligible clinician, group, subgroup, or virtual group from submitters in multiple organizations (for example, qualified registry, practice administrator, or EHR vendor), CMS will calculate and score each submission received and assign the highest of the scores. For multiple data submissions received for an individual MIPS eligible clinician, group, subgroup, or virtual group from one or multiple submitters in the same organization, CMS will score the most recent submission.

(2) For multiple data submissions received for the Promoting Interoperability performance category, CMS will calculate a score for each data submission received and assign the highest of the scores.

■ 35. Section 414.1330 is amended by adding paragraph (c) to read as follows.

§ 414.1330 Quality performance category.

* * * * *

(c)(1) CMS uses the following criteria to determine the removal of a quality measure:

(i) If the Secretary determines that the quality measure is no longer meaningful, such as measures that are topped out.

(ii) If a measure steward is no longer able to maintain the quality measure.

(iii) If the quality measure reached extremely topped out status.

(iv) If the quality measure does not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods.

(v) If the quality measure is duplicative.

(vi) If the quality measure is not updated to reflect current clinical guidelines, which are not reflective of a clinician's scope of practice.

(vii) If the quality measure is a process measure.

(viii) If the quality measure addresses a measurement gap.

(ix) If the quality measure is a patient-reported outcome.

(x) If the quality measure is not available for MIPS quality reporting by or on behalf of all MIPS eligible clinicians.

(xi) The robustness of the quality measure.

(xii) Consideration of the quality measure in developing MIPS Value Pathways (MVPs).

(2) A quality measure that otherwise meets the criteria for removal in paragraph (c)(1) of this section may nonetheless be retained based on the following considerations:

(i) Whether the removal of the process measure impacts the number of measures available for a specific specialty.

(ii) Whether the quality measure addresses a priority area.

(iii) Whether the quality measure promotes positive outcomes in patients.

(iv) Whether the quality measure is designated as high priority or not.

(v) Whether the quality measure has reached extremely topped out status.

(vi) Evaluation of the quality measure's performance data.

■ 36. Section 414.1335 is amended by revising paragraph (a) introductory text and adding paragraph (b) to read as follows.

§ 414.1335 Data submission criteria for the quality performance category.

(a) *Criteria.* Except as provided in paragraph (b) of this section, a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity must submit data on MIPS quality measures in one of the following manners, as applicable:

* * * * *

(b) *Special rule for the APM Performance Pathway (APP) Plus measure set.* A MIPS eligible clinician, group, or APM Entity that reports the APP Plus measure set via the APP must report on all measures included in the APP Plus measure set, except for administrative claims-based quality measures as provided in § 414.1325(a)(2)(i).

■ 37. Section 414.1340 is amended by revising paragraphs (a)(4), (b)(4), (d) introductory text, and (d)(1) to read as follows:

§ 414.1340 Data completeness criteria for the quality performance category.

(a) * * *

(4) At least 75 percent of the MIPS eligible clinician, group, virtual group, subgroup, and APM Entity's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2026, 2027, 2028, 2029, and 2030.

(b) * * *

(4) At least 75 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment years 2026, 2027, 2028, 2029, and 2030.

* * * * *

(d) APM Entities, specifically Medicare Shared Savings Program Accountable Care Organizations that meet reporting requirements under the APP, submitting quality measure data on Medicare CQMs must submit data on:

(1) At least 75 percent of the applicable beneficiaries eligible for the Medicare CQM, as defined at § 425.20 of this chapter, who meet the measure's

denominator criteria for MIPS payment years 2026, 2027, 2028, 2029, and 2030.

* * * * *

■ 38. Section 414.1350 is amended by adding paragraph (e) to read as follows:

§ 414.1350 Cost performance category.

* * * * *

(e) *Cost measure removal criteria.* CMS may remove a cost measure from MIPS based on one or more of the following factors, provided however CMS may retain a cost measure that meets one or more of the following factors if CMS determines the benefit of retaining the measure outweighs the benefit of removing it.

(1) It is not feasible to implement the measure specifications.

(2) A measure steward is no longer able to maintain the cost measure.

(3) The implementation costs or negative unintended consequences associated with a cost measure outweigh the benefit of its continued use in the MIPS cost performance category.

(4) The measure specifications do not reflect current clinical practice or guidelines.

(5) The availability of a more applicable measure, including a measure that applies across settings, applies across populations, or is more proximal in time to desired patient outcomes for the particular topic.

■ 39. Section 414.1355 is amended by adding paragraph (d) to read as follows:

§ 414.1355 Improvement activities performance category.

* * * * *

(d) CMS may remove an improvement activity from MIPS based on one or more of the following factors, provided however CMS may retain an improvement activity that meets one or more of the following factors if CMS determines the benefit of retaining the activity outweighs the benefit of removing it:

(1) Factor 1: Activity is duplicative of another activity.

(2) Factor 2: There is an alternative activity with a stronger relationship to quality care or improvements in clinical practice.

(3) Factor 3: Activity does not align with current clinical guidelines or practice.

(4) Factor 4: Activity does not align with at least one meaningful measures area.

(5) Factor 5: Activity does not align with the quality, cost, or Promoting Interoperability performance categories.

(6) Factor 6: There have been no attestations of the activity for 3 consecutive years.

(7) Factor 7: Activity is obsolete.

■ 40. Section 414.1365 is amended by revising paragraphs (b)(2)(i), (c)(3)(i) and (ii), (c)(4)(i)(A), (d)(3)(i)(A) introductory text, (d)(3)(i)(A)(*1*), (d)(3)(ii) introductory text, (d)(3)(ii)(A), and (d)(3)(iii) to read as follows:

§ 414.1365 MIPS Value Pathways.

* * * * *

(b) * * *

(2) * * *

(i) For the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, each MVP Participant must select an MVP, one population health measure included in the MVP, and any outcomes-based administrative claims measure on which the MVP Participant intends to be scored. Beginning in the CY 2025 performance period/2027 MIPS payment year, each MVP Participant must select an MVP and any outcomes-based administrative claims measure on which the MVP Participant intends to be scored.

* * * * *

(c) * * *

(3) * * *

(i) For the CY 2023 and 2024 performance periods/2025 through 2026 MIPS payment years:

(A) Two medium-weighted improvement activities.

(B) One high-weighted improvement activity.

(C) Participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice, as described at § 414.1380(b)(3)(ii).

(ii) Beginning in the CY 2025 performance period/2027 MIPS payment year:

(A) One improvement activity.

(B) Participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice, as described at § 414.1380(b)(3)(ii).

* * * * *

(4) * * *

(i) * * *

(A) An MVP Participant that is a subgroup is required to submit its affiliated group's data for the Promoting Interoperability performance category.

* * * * *

(d) * * *

(3) * * *

(i) * * *

(A) *Population health measures.* Except as provided in paragraph (d)(3)(i)(A)(*1*) of this section, for the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, each selected population health measure that does not have a benchmark or meet the case minimum requirement is excluded from the MVP participant's total measure achievement points and total available measure achievement points. Beginning in the CY 2025 performance period/2027 MIPS payment year, except as provided in paragraph (d)(3)(i)(A)(*1*), the highest score of all applicable and available population health measures will be used. If no population health measure has a benchmark or meet the case minimum requirement, each such measure is excluded from the MVP participant's total measure achievement points and total available measure achievement points.

(*1*) For the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, a subgroup is scored on each selected population health measure based on its affiliated group score, if available. Beginning in the CY 2025 performance period/2027 MIPS payment year, a subgroup is scored on the highest scoring of all available population health measures based on its affiliated group score, if available. If the subgroup's affiliated group score is not available, each such measure is excluded from the subgroup's total measure achievement points and total available measure achievement points.

* * * * *

(ii) *Cost performance category.* The cost performance category score is calculated for an MVP Participant using the methodology at § 414.1380(b)(2) and the cost measures included in the MVP that they select and report.

(A) A subgroup is scored on each cost measure included in the MVP that it selects and reports based on its affiliated group score for each such measure, if available. If the subgroup's affiliated group score is not available for a measure, the measure is excluded from the subgroup's total measure achievement points and total available measure achievement points, as described under § 414.1380(b)(2).

* * * * *

(iii) *Improvement activities performance category.* In the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, the improvement activities performance category score is calculated based on the submission of high- and medium-weighted improvement activities. MVP Participants will receive 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325 or for participation in a

certified or recognized patient-centered medical home (PCMH) or comparable specialty practice, as described at § 414.1380(b)(3)(ii). Beginning in the CY 2025 performance period/2027 MIPS payment year, MVP Participants will receive 40 points for each improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325 or for participation in a certified or recognized PCMH or comparable specialty practice, as described at § 414.1380(b)(3)(ii).

* * * * *

■ 41. Section 414.1367 is amended by revising paragraph (c)(1) introductory text and adding paragraph (c)(1)(iii) to read as follows:

§ 414.1367 APM performance pathway.

* * * * *

(c) * * *

(1) *Quality.* Except as provided in paragraphs (c)(1)(i) and (ii) of this section, the quality performance category score is calculated for a MIPS eligible clinician, group, or APM Entity group in accordance with § 414.1380(b)(1) based on the quality measure set applicable to the MIPS eligible clinician, group, or APM Entity group under paragraph (c)(1)(iii) of this section and established by CMS through rulemaking for a MIPS payment year.

* * * * *

(iii)(A) For performance periods beginning prior to CY 2025 and MIPS payment years beginning prior to 2027, a MIPS eligible clinician, group, or APM Entity group must report the APM Performance Pathway quality measure set.

(B) Beginning with the CY 2025 performance period/2027 MIPS payment year, a MIPS eligible clinician, group, or APM Entity group may choose to report either the APM Performance Pathway quality measure set or the APP Plus quality measure set.

* * * * *

■ 42. Section 414.1380 is amended by —

■ a. Revising paragraph (b)(1)(ii) introductory text;
■ b. Adding paragraphs (b)(1)(ii)(E) and (F);
■ c. Revising paragraph (b)(1)(iv)(B);
■ d. Adding paragraph (b)(1)(iv)(C);
■ e. Revising paragraph (b)(1)(vii) introductory text;
■ f. Adding paragraph (b)(1)(vii)(C);
■ g. Revising paragraph (b)(2) introductory text;
■ h. Adding paragraphs (b)(2)(i)(A) and (B) and (b)(2)(v)(B);
■ i. Revising paragraph (b)(3) introductory text; and
■ j. Adding paragraphs (c)(2)(i)(A)(*10*) and (c)(2)(i)(C)(*12*).

The revisions and additions read as follows:

§ 414.1380 Scoring.

* * * * *

(b) * * *

(1) * * *

(ii) *Benchmarks.* Except as provided in paragraphs (b)(1)(ii)(B) through (F) of this section, benchmarks will be based on performance by collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

* * * * *

(E) Beginning with the CY 2025 performance period/2027 MIPS payment year, CMS will publish a list in the **Federal Register** of topped out measures determined to be impacted by limited measure choice. Measures included on the list are scored from 1 to 10 measure achievement points according to defined topped out measure benchmarks calculated from performance data in the baseline period in which a performance rate in the 97th percentile corresponds to 7.5 measure achievement points.

(F) Beginning in the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQM collection type use flat benchmarks for their first two performance periods in MIPS.

* * * * *

(iv) * * *

(B) Beginning with the 2021 MIPS payment year, except as provided for in paragraph (b)(1)(iv)(C) of this section, each measure (except for measures in the CMS Web Interface) for which the benchmark for the applicable collection type is identified as topped out for 2 or more consecutive years receives no more than 7 measure achievement points in the second consecutive year it is identified as topped out, and beyond.

(C) Beginning with the CY 2025 performance period/2027 MIPS payment year, measures impacted by limited measure choice as specified in paragraph (b)(1)(ii)(E) of this section are not subject to the 7 measure achievement point cap specified in paragraph (b)(1)(iv)(B) of this section.

* * * * *

(vii) *Quality performance category score.* A MIPS eligible clinician's quality performance category score is the sum of all the measure achievement points assigned for the measures required for the quality performance category criteria plus the measure bonus points in paragraph (b)(1)(v) of this section and Complex Organization Adjustment in paragraph (b)(1)(vii)(C) of this section. The sum is divided by the sum of total available measure achievement points. The improvement percent score in paragraph (b)(1)(vi) of this section is added to that result. The quality performance category score cannot exceed 100 percentage points.

* * * * *

(C) Beginning in the CY 2025 performance period/2027 MIPS payment year, a Virtual Group and an APM Entity receives one measure achievement point for each eCQM submitted that meets the case minimum requirement at paragraph (b)(1)(iii) of this section and the data completeness requirement at § 414.1340. Each measure may not exceed 10 measure achievement points. The total adjustment to the Virtual Group or APM Entity's quality performance category score under this paragraph (b)(1)(vii)(C) may not exceed 10 percent of the total available measure achievement points.

(2) *Cost performance category.* For each cost measure attributed to a MIPS eligible clinician, the clinician receives one to ten achievement points based on the clinician's performance on the measure during the performance period compared to the measure's benchmark. Achievement points are awarded based on which benchmark range the MIPS eligible clinician's performance on the measure is in. CMS assigns partial points based on where the MIPS eligible clinician's performance falls between the top and bottom of the benchmark ranges.

(i) * * *

(A) For the 2019 through 2025 MIPS payment years, CMS determines cost measure benchmark ranges based on linear percentile distributions.

(B) Beginning with the 2026 MIPS payment year, for each cost measure, CMS determines 10 benchmark ranges based on the median cost of all MIPS eligible clinicians attributed the measure, plus or minus standard deviations. CMS awards achievement points based on which benchmark range a MIPS eligible clinician's average cost for a cost measure corresponds. Additionally, CMS awards achievement points equivalent to 10 percent of the performance threshold for a MIPS eligible clinician whose average cost attributed under a cost measure is equal to the median cost for all MIPS eligible clinicians attributed the measure.

* * * * *

(v) * * *

(B) Beginning with the 2027 MIPS payment year, if data used to calculate a score for a cost measure are impacted by significant changes or errors affecting the performance period, such that

calculating the cost measure score would lead to misleading or inaccurate results, then the affected cost measure is excluded from the MIPS eligible clinician's or group's cost performance category score. For purposes of this paragraph (b)(2)(v)(B), ''significant changes or errors'' are changes or errors external to the care provided, and that CMS determines may lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance. Significant changes or errors include, but are not limited to, rapid or unprecedented changes to service utilization, the inadvertent omission of codes or inclusion of codes, or changes to clinical guidelines or measure specifications. CMS will empirically assess the affected cost measure to determine the extent to which the changes or errors impact the calculation of a cost measure score such that calculating the cost measure score would lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance.

(3) *Improvement activities performance category.* Subject to paragraphs (b)(3)(i) and (ii) of this section, the improvement activities performance category score equals the total points for all submitted improvement activities divided by 40 points, multiplied by 100 percent. In the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, MIPS eligible clinicians (except for non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs) receive 10 points for each medium-weighted improvement activity and 20 points for each high-weighted improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325. Non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs receive 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325. Beginning in the CY 2025 performance period/2027 MIPS payment year, MIPS eligible clinicians (except for non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs) receive 20 points for each improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325. Non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs receive 40 points for each improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325.

* * * * *

(c) * * *

(2) * * *

(i) * * *

(A) * * *

(*10*) Beginning with the 2026 MIPS payment year, for the quality and improvement activities performance categories, CMS determines, based on documentation provided to the agency on or before November 1st of the year preceding the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because the MIPS eligible clinician delegated submission of the data to their third party intermediary, evidenced by a written agreement between the MIPS eligible clinician and third party intermediary, and the third party intermediary did not submit the data for the performance category(ies) on behalf of the MIPS eligible clinician in accordance with applicable deadlines. To determine whether to apply reweighting to the affected performance category(ies), CMS will consider: whether the MIPS eligible clinician knew or had reason to know of the issue with its third party intermediary's submission of the clinician's data for the performance category(ies); whether the MIPS eligible clinician took reasonable efforts to correct the issue; and whether the issue between the MIPS eligible clinician and their third party intermediary caused no data to be submitted for the performance category(ies) in accordance with applicable deadlines.

* * * * *

(C) * * *

(*12*) Beginning with the 2026 MIPS payment year, CMS determines, based on documentation provided to the agency on or before November 1st of the year preceding the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because the MIPS eligible clinician delegated submission of the data to their third party intermediary, evidenced by a written agreement between the MIPS eligible clinician and third party intermediary, and the third party intermediary did not submit the data for the performance category on behalf of the MIPS eligible clinician in accordance with applicable deadlines. To determine whether to apply reweighting to the Promoting Interoperability performance category, CMS will consider: whether the MIPS eligible clinician knew or had reason to know of the issue with its third party intermediary's submission of the clinician's data for the performance category; whether the MIPS eligible clinician took reasonable efforts to correct the issue; and whether the issue between the MIPS eligible clinician and their third party intermediary caused no data to be submitted for the performance category in accordance with applicable deadlines.

* * * * *

■ 43. Section 414.1405 is amended by adding paragraph (b)(10) and revising paragraph (g) to read as follows:

§ 414.1405 Payment.

* * * * *

(b) * * *

(10) Pursuant to the methodology established at paragraph (g)(2) of this section:

(i) The performance threshold for the 2027 MIPS payment year is 75 points. The prior period used to determine the performance threshold is the 2019 MIPS payment year.

(ii) [Reserved]

* * * * *

(g) *Performance threshold methodology.* (1) For each of the 2024, 2025, and 2026 MIPS payment years, the performance threshold is the mean of the final scores for all MIPS eligible clinicians from a prior period as specified under paragraph (b)(9) of this section.

(2) For each of the 2027, 2028, and 2029 MIPS payment years, the performance threshold is the mean of the final scores for all MIPS eligible clinicians from a prior period as specified under paragraph (b)(10) of this section.

■ 44. Section 414.1430 is amended by—

■ a. Revising paragraph (a)(1)(v);

■ b. Adding paragraph (a)(1)(vi);

■ c. Revising paragraph (a)(2)(v);

■ d. Adding paragraph (a)(2)(vi);

■ e. Revising paragraph (a)(3)(v);

■ f. Adding paragraph (a)(3)(vi);

■ g. Revising paragraph (a)(4)(v);

■ h. Adding paragraph (a)(4)(vi); and

■ i. Revising paragraphs (b)(1)(i)(A) and (B), (b)(2)(i)(A) and (B), (b)(3)(i)(A) and (B), and (b)(4)(i)(A) and (B).

The revisions and additions read as follows:

§ 414.1430 Qualifying APM participant determination: QP and partial QP thresholds.

(a) * * *

(1) * * *
(v) 2026: 50 percent.
(vi) 2027 and later: 75 percent.
(2) * * *
(v) 2026: 40 percent.
(vi) 2027 and later: 50 percent.
(3) * * *
(v) 2026: 35 percent.
(vi) 2027 and later: 50 percent.
(4) * * *
(v) 2026: 25 percent.
(vi) 2027 and later: 35 percent.
(b) * * *
(1) * * *
(i) * * *
(A) 2021 through 2026: 50 percent.
(B) 2027 and later: 75 percent.
* * * * *
(2) * * *
(i) * * *
(A) 2021 through 2026: 40 percent.
(B) 2027 and later: 50 percent.
* * * * *
(3) * * *
(i) * * *
(A) 2021 through 2026: 35 percent.
(B) 2027 and later: 50 percent.
* * * * *
(4) * * *
(i) * * *
(A) 2021 through 2026: 25 percent.
(B) 2027 and later: 35 percent.
* * * * *

■ 45. Section 414.1450 is amended by revising paragraph (a)(1)(i) and the first sentence of paragraph (b)(1) to read as follows:

§ 414.1450 APM incentive payment.

(a) * * *
(1) * * *
(i) For payment years 2019 through 2026, CMS makes a lump sum payment to QPs in the amount described in paragraph (b) of this section in the manner described in paragraphs (d) and (e) of this section.
* * * * *
(b) * * *
(1) For payment years 2019 through 2024, the amount of the APM Incentive Payment is equal to 5 percent, with respect to payment year 2025, 3.5 percent, or with respect to payment year 2026, 1.88 percent of the estimated aggregate payments for covered professional services as defined in section 1848(k)(3)(A) of the Act furnished during the calendar year immediately preceding the payment year. * * *
* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 46. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 47. Section 423.160 is amended by revising paragraph (a)(5) introductory text to read as follows:

§ 423.160 Standards for electronic prescribing.

(a) * * *
(5) Beginning on January 1, 2021, prescribers must, except in the circumstances described in paragraphs (a)(5)(i) through (iii) of this section, conduct prescribing for at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically using the applicable standards in paragraph (b) of this section, subject to the exemption in paragraph (a)(3)(iii) of this section. Prescriptions written for a beneficiary in a long-term care facility will not be included in determining compliance until January 1, 2028. Compliance actions against prescribers who do not meet the compliance threshold based on prescriptions written for a beneficiary in a long-term care facility will commence on or after January 1, 2028. Compliance actions against prescribers who do not meet the compliance threshold based on other prescriptions will commence on or after January 1, 2023. Prescribers will be exempt from this requirement in the following situations:
* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 48. The authority citation for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 49. Section 424.24 is amended by revising paragraphs (c) heading, (c)(1)(i), and (c)(3)(ii) and adding paragraph (c)(5) to read as follows:

§ 424.24 Requirements for medical and other health services furnished by providers under Medicare Part B.

* * * * *
(c) *Outpatient physical therapy, occupational therapy, and speech-language pathology services—*
(1) * * *
(i) The individual needs, or needed, physical therapy, occupational therapy, or speech-language pathology services.
* * * * *
(3) * * *
(ii) If the plan of treatment is established by a physical therapist, occupational therapist, or speech-language pathologist, the certification must be signed by a physician or by a nurse practitioner, clinical nurse specialist, or physician assistant who has knowledge of the case, except as specified in paragraph (c)(5) of this section.
* * * * *
(5) *Treatment plan.* If the plan of treatment is established by a physical therapist, occupational therapist, or speech-language pathologist, and there is a written order or referral from the individual's physician, nurse practitioner (NP), physician assistant (PA), or clinical nurse specialist (CNS) in the patient's record and the therapist has documented evidence that the plan of care has been delivered to the physician, NP, PA, or CNS within 30 days of completion of the initial evaluation, the certification does not need to be signed by a physician, NP, CNS, or PA who has knowledge of the case. If there is no written order or referral from the individual's physician, NP, CNS, or PA, in the patient's record, the therapist must obtain the signature of the physician, NP, PA, or CNS on the plan of treatment in accordance with paragraph (c)(3) of this section. No references to an order or referral in this subsection shall be construed to require an order or referral for outpatient physical therapy, occupational therapy, or speech-language pathology services.
* * * * *

■ 50. Section 424.205 is amended by revising paragraphs (c)(10), (f)(1)(ii), (f)(2)(i), and (f)(5) to read as follows:

§ 424.205 Requirements for Medicare Diabetes Prevention Program suppliers.

* * * * *
(c) * * *
(10) Except as allowed under paragraph (d)(8) of this section, the MDPP supplier must offer an MDPP beneficiary no fewer than all of the following:
(i) 16 in-person or distance learning core sessions no more frequently than weekly for the first 6 months of the MDPP services period, which begins on the date of attendance at the first such core session.
(ii) 1 in-person or distance learning core maintenance session each month during months 7 through 12 (6 months total) of the MDPP services period.
* * * * *
(f) * * *
(1) * * *
(ii) Basic beneficiary information for each MDPP beneficiary in attendance, including but not limited to beneficiary name, Medicare Beneficiary Identifier (MBI), and age.
* * * * *
(2) * * *
(i) Documentation of the type of session (in-person or distance learning).
* * * * *

(5) The MDPP supplier's records must include an attestation from the MDPP supplier that, as applicable, the MDPP beneficiary for which it is submitting a claim—

(i) Has achieved the required minimum 5-percent weight loss as measured in accordance with § 410.79(e)(3)(iii) of this chapter during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(1) of this chapter.

(ii) Has achieved the required minimum 5-percent weight loss as measured in-person during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(1) of this chapter.

(iii) Has achieved at least a 9-percent weight loss percentage as measured in accordance with § 410.79(e)(3)(iii) of this chapter during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(2) of this chapter.

(iv) Has achieved at least a 9-percent weight loss percentage as measured in-person during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(2) of this chapter.

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 51. The authority citation for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

■ 52. Section 425.100 is amended by adding paragraph (e) to read as follows:

§ 425.100 General.

* * * * *

(e) An ACO is eligible to receive prepaid shared savings if it meets the criteria under § 425.640(b).

■ 53. Section 425.110 is amended by revising paragraph (b)(2) to read as follows:

§ 425.110 Number of ACO professionals and beneficiaries.

* * * * *

(b) * * *

(2) For performance years starting before January 1, 2025, if the ACO's assigned population is not at least 5,000 by the end of the performance year specified by CMS in its request for a corrective action plan (CAP), CMS terminates the participation agreement and the ACO is not eligible to share in savings for that performance year.

* * * * *

■ 54. Section 425.202 is amended by revising paragraph (a)(3) to read as follows:

§ 425.202 Application procedures.

(a) * * *

(3) An ACO that seeks to participate in the Shared Savings Program must agree that CMS can share a copy of their application with the Antitrust Agencies.

* * * * *

■ 55. Section 425.204 is amended by—

■ a. Revising paragraphs (f)(1) and (f)(3) introductory text;

■ b. In paragraphs (f)(3)(iv), (f)(4)(iv)(A), and (f)(6)(ii) introductory text, removing the phrase ''any shared losses incurred'' and adding in its place the phrase ''any shared losses incurred and prepaid shared savings determined to be owed'';

■ c. In paragraphs (f)(5) and (f)(6)(iv)(A), removing the phrase ''shared losses owed'' and adding in its place the phrase ''shared losses owed or prepaid shared savings determined to be owed'';

■ d. In paragraph (f)(6)(iii), removing the phrase ''shared losses'' and adding in its place the phrase ''shared losses or prepaid shared savings determined to be owed''; and

■ e. In paragraph (f)(6)(iv)(C), removing the phrase ''owe any shared losses'' and adding in its place the phrase ''owe any shared losses or prepaid shared savings''.

The revisions read as follows:

§ 425.204 Content of the application.

* * * * *

(f) * * *

(1) An ACO must have the ability to repay all shared losses for which it may be liable under a two-sided model and any prepaid shared savings determined to be owed.

* * * * *

(3) An ACO that will participate under a two-sided model of the Shared Savings Program must submit for CMS approval documentation that it is capable of repaying shared losses that it may incur during its agreement period, including details supporting the adequacy of the repayment mechanism. If the ACO will receive prepaid shared savings, the repayment mechanism must also support repayment of prepaid shared savings in accordance with § 425.640.

* * * * *

■ 56. Section 425.224 is amended by revising paragraph (a)(3) to read as follows:

§ 425.224 Application procedures for renewing ACOs and re-entering ACOs.

(a) * * *

(3) An ACO that seeks to enter a new participation agreement under the Shared Savings Program must agree that CMS can share a copy of its application with the Antitrust Agencies.

* * * * *

■ 57. Section 425.304 is amended by adding paragraph (d) to read as follows:

§ 425.304 Beneficiary incentives.

* * * * *

(d) *Application of the CMS-sponsored model patient incentives safe harbor.* CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (§ 1001.952(ii)(2) of this title) is available to protect remuneration furnished in the prepaid shared savings option of the Shared Savings Program in the form of direct beneficiary services that meets all safe harbor requirements set forth in § 1001.952(ii) of this title.

■ 58. Section 425.308 is amended by adding paragraph (b)(10) to read as follows:

§ 425.308 Public reporting and transparency.

* * * * *

(b) * * *

(10) Information updated annually about the ACO's use of prepaid shared savings under § 425.640, for each performance year, including the following:

(i) Total amount of any prepaid shared savings received from CMS.

(ii) The ACO's spend plan.

(iii) An itemization of how prepaid shared savings were spent during the year, including expenditure categories, the dollar amounts spent on the various categories, information about which groups of beneficiaries received direct beneficiary services that were purchased with prepaid shared savings and investments that were made in the ACO with prepaid shared savings, how these direct beneficiary services were provided to beneficiaries and how the direct beneficiary services and investments supported the care of beneficiaries, any changes to the spend plan as submitted under § 425.640(d)(2) (if applicable), and such other information as may be specified by CMS.

* * * * *

■ 59. Section 425.312 is amended by revising paragraphs (a)(2)(iii) and (a)(2)(v)(A) to read as follows:

§ 425.312 Beneficiary notifications.

(a) * * *

(2) * * *

(iii) In the case of an ACO that has selected preliminary prospective assignment with retrospective reconciliation, by the ACO or ACO participant providing each beneficiary who received at least one primary care service during the assignment window or applicable expanded window for assignment (as defined in § 425.20) from a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in § 425.402(c), a FQHC or RHC that is part of the ACO, or an ACO professional in the ACO whom the beneficiary designated as responsible for coordinating their overall care under § 425.402(e) with a standardized written notice at least once during an agreement period in the form and manner specified by CMS. The standardized written notice must be furnished to all of these beneficiaries prior to or at the first primary care service visit during the first performance year in which the beneficiary receives a primary care service from an ACO participant.

* * * * *

(v) * * *

(A) The follow-up communication must occur no later than 180 days from the date the standardized written notice was provided.

* * * * *

■ 60. Section 425.315 is amended by revising paragraph (a)(4) and adding paragraph (b) to read as follows:

§ 425.315 Reopening determinations of ACO shared savings or shared losses to correct financial reconciliation calculations.

(a) * * *

(4) CMS has the sole discretion to determine whether to reopen a payment determination under this section.

(b) *Reopening requests.* An ACO may request a reopening in a form and manner specified by CMS and consistent with the timeframes for a reopening specified in paragraphs (a)(1)(i) and (ii) of this section.

■ 61. Section 425.316 is amended by adding paragraph (f) to read as follows:

§ 425.316 Monitoring of ACOs.

* * * * *

(f) *Monitoring ACO eligibility for and use of prepaid shared savings.* (1) CMS monitors an ACO that receives prepaid shared savings pursuant to § 425.640 to ensure ACO compliance with § 425.640(e) and to determine whether it would be appropriate to withhold or terminate an ACO's prepaid shared savings under § 425.640(h).

(2) If CMS determines that an ACO receiving prepaid shared savings is using the funds for a prohibited use under § 425.640(e)(2), fails to spend the funding in accordance with § 425.640(e)(1)(i) and (ii), or spends more than 50 percent of the estimated annual payment amount on staffing and healthcare infrastructure CMS:

(i) Will require the ACO to reallocate the funding as permitted by § 425.640(e) and submit an updated spend plan demonstrating the reallocation by a deadline specified by CMS.

(ii) May take compliance action as specified in §§ 425.216, 425.218, and 425.640(h)(1).

(3) If an ACO fails to reallocate prepaid shared savings it received as described in paragraph (f)(2)(i) of this section by a deadline specified by CMS, the ACO must repay all prepaid shared savings it received and may be subject to compliance action as specified in §§ 425.216 and 425.218. CMS will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

■ 62. Section 425.400 is amended by revising paragraph (c)(1)(viii) introductory text and adding paragraph (c)(1)(ix) to read as follows:

§ 425.400 General.

* * * * *

(c) * * *

(1) * * *

(viii) For the performance year starting on January 1, 2024, as follows:

* * * * *

(ix) For the performance year starting on January 1, 2025, and subsequent performance years as follows:

(A) CPT codes:

(*1*) 96160 and 96161 (codes for administration of health risk assessment).

(*2*) 96202 and 96203 (codes for caregiver behavior management training).

(*3*) 97550, 97551, and 97552 (codes for caregiver training services).

(*4*) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(*5*) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a skilled nursing facility (SNF)).

(*6*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*7*) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home).

(*8*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(ix)).

(*9*) 99406 and 99407 (codes for smoking and tobacco-use cessation counseling services).

(*10*) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(*11*) 99424, 99425, 99426, and 99427 (codes for principal care management services).

(*12*) 99437, 99487, 99489, 99490 and 99491 (codes for chronic care management).

(*13*) 99439 (code for non-complex chronic care management).

(*14*) 99446, 99447, 99448, 99449, 99451, 99452 (codes for interprofessional consultation services).

(*15*) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(*16*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(*17*) 99495 and 99496 (codes for transitional care management services).

(*18*) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(*19*) 9X091 (code for virtual check-in).

(B) HCPCS codes:

(*1*) G0019 and G0022 (codes for community health integration services).

(*2*) G0023 and G0024 (codes for principal illness navigation services).

(*3*) G0101 (code for cervical or vaginal cancer screening).

(*4*) G0136 (code for social determinants of health risk assessment services).

(*5*) G0317, G0318, and G2212 (codes for prolonged office or other outpatient visit for the evaluation and management of a patient).

(*6*) G0402 (code for the Welcome to Medicare visit).

(*7*) G0438 and G0439 (codes for the annual wellness visits).

(*8*) G0442 (code for alcohol misuse screening service).

(*9*) G0443 (code for alcohol misuse counseling service).

(*10*) G0444 (code for annual depression screening service).

(*11*) G0463 (code for services furnished in electing teaching amendment (ETA) hospitals).

(*12*) G0506 (code for chronic care management).

(*13*) G2010 (code for the remote evaluation of patient video/images).

(*14*) G2012 and G2252 (codes for virtual check-in).

(*15*) G2058 (code for non-complex chronic care management).

(*16*) G2064 and G2065 (codes for principal care management services).

(*17*) G2086, G2087, and G2088 (codes for office-based opioid use disorder services).

(*18*) G2211 (code for visit complexity inherent to evaluation and management services add-on).

(*19*) G2214 (code for psychiatric collaborative care model).

(*20*) G3002 and G3003 (codes for chronic pain management).

(*21*) GCDRA and GCDRM (codes for cardiovascular risk assessment and risk management services).

(*22*) GCTB1 and GCTB2 (codes for individual behavior management/modification caregiver training services).

(*23*) GCTD1, GCTD2, and GCTD3 (codes for direct care caregiver training services).

(*24*) GFCI1 (code for post-discharge telephonic follow-up contacts intervention).

(*25*) GPCM1, GPCM2, and GPCM3 (codes for advanced primary care management services).

(*26*) GSPI1 (code for safety planning interventions when the base code is also a primary care service code under this paragraph (c)(1)(ix)).

(C) Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(ix)(A) of this section or a HCPCS code specified in paragraph (c)(1)(ix)(B) of this section, when the assignment window or expanded window for assignment (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

* * * * *

■ 63. Section 425.402 is amended by revising paragraph (e)(2)(ii) introductory text and adding paragraph (e)(2)(iii) to read as follows:

§ 425.402 Basic assignment methodology.

* * * * *

(e) * * *

(2) * * *

(ii) For performance years starting on January 1, 2019, through 2024:

* * * * *

(iii) For performance year 2025 and subsequent performance years:

(A) The beneficiary meets the eligibility criteria established at § 425.401(a) and must not be excluded by the criteria at § 425.401(b). The exclusion criteria at § 425.401(b) apply for purposes of determining beneficiary eligibility for alignment to an ACO based on the beneficiary's designation of an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section, regardless of the ACO's assignment methodology selection under § 425.226(a)(1).

(B) The beneficiary must have designated an ACO professional as responsible for coordinating their overall care.

(C) If a beneficiary has designated a provider or supplier outside the ACO as responsible for coordinating their overall care, the beneficiary is not added under the assignment methodology in paragraph (b) of this section to the ACO's list of assigned beneficiaries for a 12-month performance year.

(D) The beneficiary is not assigned to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on:

(*1*) Claims for primary care and/or other services related to treatment of one or more specific diseases or conditions targeted by the model; or

(*2*) Claims for services other than primary care services, and for which there has been a determination by the Secretary that waiver of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the model.

* * * * *

■ 64. Section 425.508 is amended by revising paragraph (b) and adding paragraph (c) to read as follows:

§ 425.508 Incorporating quality reporting requirements related to the Quality Payment Program.

* * * * *

(b) *For performance years beginning in 2021–2024.* ACOs must submit the quality data via the APM Performance Pathway (APP) established under § 414.1367 of this chapter to satisfactorily report on behalf of the eligible clinicians who bill under the TIN of an ACO participant for purposes of the MIPS Quality performance category of the Quality Payment Program.

(c) *For performance years beginning on or after January 1, 2025.* ACOs must submit the quality data via the APM Performance Pathway (APP) on the quality measures contained in the APP Plus quality measure set established under § 414.1367 of this chapter to satisfactorily report on behalf of the eligible clinicians who bill under the TIN of an ACO participant for purposes of the MIPS Quality performance category of the Quality Payment Program.

■ 65. Section 425.510 is amended by revising the section heading and paragraph (b) to read as follows:

§ 425.510 Application of the APM Performance Pathway (APP) quality measure set or the APP Plus quality measure set (as applicable) to Shared Savings Program ACOs for performance years beginning on or after January 1, 2021.

* * * * *

(b) *Quality reporting.* (1) For performance years beginning in 2021–2024, ACOs must report quality data on the APP quality measure set established under § 414.1367 of this chapter, according to the method of submission established by CMS.

(2) For performance years beginning on or after January 1, 2025, ACOs must report quality data on the APP Plus quality measure set established under § 414.1367 of this chapter, according to the method of submission established by CMS.

* * * * *

■ 66. Section 425.512 is amended by—

■ a. Revising paragraphs (a)(2)(iii), (a)(5)(i) introductory text, (a)(5)(i)(A) introductory text, (a)(5)(i)(B), (a)(5)(ii), (a)(5)(iii)(B), and (a)(7);

■ b. Revising and republishing paragraph (b);

■ c. In paragraph (c)(3) introductory text, removing the phrase ''via the APP'' and adding in its place the phrase ''on the APP quality measure set or the APP Plus quality measure set (as applicable)'';

■ d. In paragraph (c)(3)(iii), removing the phrase ''and subsequent performance years'' after ''For performance year 2024''; and

■ e. Adding paragraph (c)(3)(iv).

The revisions, republication, and addition read as follows:

§ 425.512 Determining the ACO quality performance standard for performance years beginning on or after January 1, 2021.

(a) * * *

(2) * * *

(iii) For performance year 2025 and subsequent performance years, if the ACO reports the APP Plus quality measure set and meets the data completeness requirement at § 414.1340 of this subchapter on all eCQMs/Medicare CQMs, and the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter, for the applicable performance year.

* * * * *

(5) * * *

(i) Except as specified in paragraphs (a)(2) and (7) of this section, CMS designates the quality performance standard as:

(A) For performance year 2024, the ACO reporting quality data on the APP

quality measure set established under § 414.1367 of this subchapter, according to the method of submission established by CMS and—

* * * * *

(B) For performance year 2025 and subsequent performance years, the ACO reporting quality data on the APP Plus quality measure set established under § 414.1367 of this subchapter, according to the method of submission established by CMS and—

(*1*) Achieving a health equity adjusted quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring; or

(*2*) If the ACO reports all of the eCQMs in the APP Plus quality measure set applicable for a performance year, meeting the data completeness requirement at § 414.1340 of this subchapter for all eCQMs, and achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP Plus quality measure set and a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining measures in the APP Plus quality measure set.

(ii) CMS designates an alternative quality performance standard for an ACO that does not meet the criteria described in paragraph (a)(2) or (a)(5)(i) of this section as the following:

(A) For performance year 2024, the ACO reports quality data on the APP quality measure set established under § 414.1367 of this subchapter according to the method of submission established by CMS and achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP quality measure set.

(B) For performance year 2025 and subsequent performance years, the ACO reports quality data on the APP Plus quality measure set established under § 414.1367 of this subchapter according to the method of submission established by CMS and achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP Plus quality measure set.

(iii) * * *

(B) For performance year 2025 and subsequent performance years, the ACO does not report any of the eCQMs/Medicare CQMs in the APP Plus quality measure set and does not administer a CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter).

* * * * *

(7) *Facility-based scoring.* CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year when—

(i) For performance year 2024, if an ACO reports all of the required measures, meeting the data completeness requirement at § 414.1340 of this subchapter for each measure in the APP quality measure set and receiving a MIPS Quality performance category score as described at § 414.1380(b)(1) of this subchapter and the ACO meets either of the following:

(A) The ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score are reduced under § 414.1380(b)(1)(vii)(A) of this subchapter.

(B) At least one of the eCQMs/MIPS CQMs/Medicare CQMs does not have a benchmark as described at § 414.1380(b)(1)(i)(A) of this subchapter.

(ii) For performance year 2025 and subsequent performance years, if an ACO reports all of the required measures in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for each measure in the APP Plus quality measure set, and receiving a MIPS Quality performance category score as described at § 414.1380(b)(1) of this subchapter, for the relevant performance year, and the ACO meets either of the following:

(A) The ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score are reduced under § 414.1380(b)(1)(vii)(A) of this subchapter.

(B) At least one of the eCQMs/Medicare CQMs does not have a benchmark as described at § 414.1380(b)(1)(i)(A) of this subchapter.

(b) *Calculation of ACO's health equity adjusted quality performance score for performance year 2023 and subsequent performance years*—(1) *For performance year 2023.* For an ACO that reports the three eCQMs/MIPS CQMs in the APP quality measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for all three eCQMs/MIPS CQMs, and administers the CAHPS for MIPS survey, CMS calculates the ACO's health equity adjusted quality performance score as the sum of the ACO's MIPS Quality performance category score for all measures in the APP quality measure set and the ACO's health equity adjustment bonus points calculated in accordance with paragraph (b)(4) of this section. The sum of these values may not exceed 100 percent.

(2) *For performance year 2024.* For an ACO that reports the three eCQMs/MIPS CQMs/Medicare CQMs in the APP quality measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for all three eCQMs/MIPS CQMs/Medicare CQMs, and administers the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), CMS calculates the ACO's health equity adjusted quality performance score as the sum of the ACO's MIPS Quality performance category score for all measures in the APP quality measure set and the ACO's health equity adjustment bonus points calculated in accordance with paragraph (b)(4) of this section. The sum of these values may not exceed 100 percent.

(3) *For performance year 2025 and subsequent performance years.* For an ACO that reports all of the eCQMs/Medicare CQMs in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for all of the eCQMs/Medicare CQMs, and administers the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), CMS calculates the ACO's health equity adjusted quality performance score as the sum of the ACO's MIPS Quality performance category score for all measures in the APP Plus quality measure set and the ACO's health equity adjustment bonus points calculated in accordance with paragraph (b)(4) of this section. The sum of these values may not exceed 100 percent.

(4) *Calculation of ACO's health equity adjustment bonus points.* CMS calculates the ACO's health equity adjustment bonus points as follows:

(i) For each measure in the APP quality measure set, CMS groups an ACO's performance into the top, middle, or bottom third of ACO measure performers by reporting mechanism.

(ii) CMS assigns values to the ACO for its performance on each measure as follows:

(A) Values of four, two, or zero for each measure for which the ACO's performance places it in the top, middle, or bottom third of ACO measure performers, respectively.

(B) Values of zero for each measure that CMS does not evaluate because the measure is unscored or the ACO does not meet the case minimum or the minimum sample size for the measure.

(iii) CMS sums the values assigned to the ACO according to paragraph (b)(4)(ii) of this section, to calculate the ACO's measure performance scaler.

(iv) CMS calculates an underserved multiplier for the ACO.

(A)(*1*) CMS determines the proportion ranging from zero to one of the ACO's assigned beneficiary population for the performance year that is considered underserved based on the highest of either of the following:

(*i*) The proportion of the ACO's assigned beneficiaries residing in a census block group with an Area Deprivation Index (ADI) national percentile rank of at least 85. An ACO's assigned beneficiaries without an available numeric ADI national percentile rank are excluded from the calculation of the proportion of the ACO's assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85.

(*ii*) The proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D low-income subsidy (LIS); or are dually eligible for Medicare and Medicaid.

(*2*) CMS calculates the proportions specified in paragraph (b)(4)(iv)(A)(*1*)(*ii*) of this section as follows:

(*i*) For performance year 2023, the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS or are dually eligible for Medicare and Medicaid divided by the total number of the ACO's assigned beneficiaries' person years.

(*ii*) For performance year 2024 and subsequent performance years, the proportion of the ACO's assigned beneficiaries with any months enrolled in LIS or dually eligible for Medicare and Medicaid divided by the total number of the ACO's assigned beneficiaries.

(B) If the proportion determined in accordance with paragraph (b)(4)(iv)(A) of this section is lower than 20 percent, the ACO is ineligible for health equity adjustment bonus points.

(v) Except as specified in paragraph (b)(4)(iv)(B) of this section, CMS calculates the ACO's health equity adjustment bonus points as the product of the measure performance scaler determined under paragraph (b)(4)(iii) of this section and the underserved multiplier determined under paragraph (b)(4)(iv) of this section. If the product of these values is greater than 10, the value of the ACO's health equity adjustment bonus points is set equal to 10.

(5) *Use of ACO's health equity adjusted quality performance score.* The ACO's health equity adjusted quality performance score, determined in accordance with paragraphs (b)(1) through (4) of this section, is used as follows:

(i) In determining whether the ACO meets the quality performance standard as specified under paragraphs (a)(4)(i)(A), (a)(5)(i)(A)(*1*), (a)(5)(i)(B), and (a)(7) of this section.

(ii) In determining the final sharing rate for calculating shared savings payments under the BASIC track in accordance with § 425.605(d), and under the ENHANCED track in accordance with § 425.610(d), for an ACO that meets the alternative quality performance standard by meeting the criteria specified in paragraph (a)(4)(ii) or (a)(5)(ii) of this section.

(iii) In determining the shared loss rate for calculating shared losses under the ENHANCED track in accordance with § 425.610(f), for an ACO that meets the quality performance standard established in paragraphs (a)(2), (a)(4)(i), and (a)(5)(i) of this section or the alternative quality performance standard established in paragraph (a)(4)(ii) or (a)(5)(ii) of this section.

(iv) In determining the quality performance score for an ACO affected by extreme and uncontrollable circumstances as described in paragraphs (c)(3)(ii) through (iv) of this section.

(c) * * *

(3) * * *

(iv) For performance year 2025 and subsequent performance years, if the ACO reports the APP Plus quality measure set and meets the data completeness requirement at § 414.1340 of this subchapter and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter, CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

* * * * *

■ 67. Section 425.601 is amended by revising paragraph (a)(9) introductory text and adding paragraphs (a)(9)(iii) and (iv) to read as follows:

§ 425.601 Establishing, adjusting, and updating the benchmark for agreement periods beginning on or after July 1, 2019, and before January 1, 2024.

(a) * * *

(9) For the second and each subsequent performance year during the term of the agreement period, the ACO's benchmark is adjusted for the following, as applicable: For the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), for a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), for a change to the beneficiary assignment methodology specified in subpart E of this part, for changes in values used in benchmark calculations as a result of issuance of a revised initial determination under § 425.315, and for changes in values used in benchmark calculations as a result of the performance year being affected by significant, anomalous, and highly suspect billing under § 425.672. To adjust the benchmark, CMS does the following:

* * * * *

(iii) Recalculates benchmark year expenditures to account for the impact of improper payments, for the benchmark year corresponding to a performance year for which CMS issued a revised initial determination under § 425.315. In recalculating expenditures for the benchmark year, CMS applies the calculation methodology applied in recalculating expenditures for the corresponding performance year in accordance with § 425.674.

(iv) Recalculates expenditures used in Shared Savings Program benchmark calculations under this section, to exclude the same HCPCS or CPT codes identified as displaying significant, anomalous, and highly suspect billing patterns in calculation of performance year expenditures, in accordance with § 425.672.

* * * * *

■ 68. Section 425.605 is amended by revising paragraph (a)(1)(ii)(C) to read as follows:

§ 425.605 Calculation of shared savings and losses under the BASIC track.

(a) * * *

(1) * * *

(ii) * * *

(C) The aggregate growth in demographic risk scores for purposes of paragraph (a)(1)(ii)(A) of this section and the aggregate growth in prospective hierarchical condition category (HCC) risk scores for purposes of paragraph (a)(1)(ii)(B) of this section is calculated by taking a weighted average of the growth in demographic risk scores or

prospective HCC risk scores, as applicable, across the populations described in paragraph (a)(2) of this section. When calculating the weighted average growth in demographic risk scores or prospective HCC risk scores, as applicable, the weight applied to the growth in risk scores (expressed as a ratio of the ACO's performance year risk score to the ACO's BY3 risk score) for each Medicare enrollment type is equal to the product of the ACO's historical benchmark expenditures, adjusted in accordance with § 425.652(a)(8), for that enrollment type and the ACO's performance year assigned beneficiary person years for that enrollment type.

* * * * *

■ 69. Section 425.610 is amended by revising paragraph (a)(2)(ii)(C) to read as follows:

§ 425.610 Calculation of shared savings and losses under the ENHANCED track.

(a) * * *

(2) * * *

(ii) * * *

(C) The aggregate growth in demographic risk scores for purposes of paragraph (a)(2)(ii)(A) of this section and the aggregate growth in prospective HCC risk scores for purposes of paragraph (a)(2)(ii)(B) of this section is calculated by taking a weighted average of the growth in demographic risk scores or prospective HCC risk scores, as applicable, across the populations described in paragraph (a)(3) of this section. When calculating the weighted average growth in demographic risk scores or prospective HCC risk scores, as applicable, the weight applied to the growth in risk scores (expressed as a ratio of the ACO's performance year risk score to the ACO's BY3 risk score) for each Medicare enrollment type is equal to the product of the ACO's historical benchmark expenditures, adjusted in accordance with § 425.652(a)(8), for that enrollment type and the ACO's performance year assigned beneficiary person years for that enrollment type.

* * * * *

■ 70. Section 425.630 is amended by—

■ a. In paragraph (g)(3), removing the phrase ''paragraphs (g)(4) of this section'' and adding in its place the phrase ''paragraphs (g)(4) through (6) of this section'';

■ b. Redesignating paragraph (g)(5) as paragraph (g)(7);

■ c. Adding new paragraph (g)(5) and paragraph (g)(6);

■ d. In paragraph (h)(1)(ii), removing ''or'' at the end of the paragraph;

■ e. In paragraph (h)(1)(iii), removing the period at the end of paragraph and adding ''; or'' in its place; and

■ f. Adding paragraph (h)(1)(iv).

The additions read as follows:

§ 425.630 Option to receive advance investment payments.

* * * * *

(g) * * *

(5) If an ACO notifies CMS that it no longer wants to participate in the advance investment payment option but does want to continue its participation in the Shared Savings Program, the ACO must repay all outstanding advance investment payments it received. CMS will provide written notice to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

(6) If CMS terminates the participation agreement of an ACO that has an outstanding balance of advance investment payments owed to CMS, the ACO must repay any outstanding advance investment payments it received. CMS will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

* * * * *

(h) * * *

(1) * * *

(iv) Voluntarily terminates payments of advance investment payments but continues its participation in the Shared Savings Program.

* * * * *

■ 71. Section 425.640 is added to read as follows:

§ 425.640 Option to receive prepaid shared savings.

(a) *Purpose.* Prepaid shared savings provide an additional cash flow option to ACOs with a history of earning shared savings that will encourage their investment in activities that reduce costs for the Medicare program and beneficiaries and improve the quality of care provided to their assigned beneficiaries.

(b) *Eligibility.* An ACO is eligible to receive prepaid shared savings in an agreement period as specified in this section if CMS determines that all of the following criteria are met:

(1) The ACO is a renewing ACO as defined under § 425.20 entering an agreement period beginning on January 1, 2026, or in subsequent years.

(2) The ACO must have received a shared savings payment for the most recent performance year that:

(i) Occurred prior to the agreement period for which the ACO has applied to receive prepaid shared savings; and

(ii) CMS has conducted financial reconciliation.

(3) The ACO must have a positive prior savings adjustment for the agreement period for which the ACO has applied to receive prepaid shared savings as calculated pursuant to § 425.658.

(4) The ACO does not have any outstanding shared losses or advance investment payments that have not yet been repaid to CMS after reconciliation for the most recent performance year for which CMS completed financial reconciliation.

(5) If the ACO received prepaid shared savings in the current agreement period or a prior agreement period, the ACO must have fully repaid the amount of prepaid shared savings received through the most recent performance year for which CMS has completed financial reconciliation.

(6) The ACO is participating in Levels C through E of the BASIC track or the ENHANCED track during the agreement period in which it would receive prepaid shared savings.

(7) The ACO has in place an adequate repayment mechanism in accordance with § 425.204(f) that can be used to recoup outstanding prepaid shared savings.

(8) During the agreement period immediately preceding the agreement period in which the ACO would receive prepaid shared savings, the ACO:

(i) Met the quality performance standard as specified under § 425.512; and

(ii) Has not been determined by CMS to have avoided at-risk beneficiaries as specified under § 425.316(b)(2).

(c) *Application procedure.* To obtain a determination regarding whether an ACO may receive prepaid shared savings, the ACO must submit to CMS a complete supplemental application with its application to renew for a new agreement period in the Shared Savings Program (submitted pursuant to § 425.202) in the form and manner and by a deadline specified by CMS.

(d) *Application contents and review*—(1) *General.* An ACO must submit to CMS supplemental application information sufficient for CMS to determine whether the ACO is eligible to receive prepaid shared savings. In addition, the ACO must submit a proposed spend plan as part of the supplemental application information.

(2) *Spend plan.* The ACO's spend plan must:

(i) Describe how an ACO receiving prepaid shared savings will spend the payments during the first performance year in which it will receive prepaid shared savings. The spend plan must be updated annually for each performance year of the agreement period during which the ACO receives prepaid shared savings.

(ii) Identify the categories of items and services that will be purchased and investments that will be made in the ACO with prepaid shared savings (consistent with the allowable uses under paragraph (e) of this section), the dollar amounts to be spent on such categories, information about which groups of beneficiaries the ACO expects to receive direct beneficiary services that will be purchased with prepaid shared savings, how direct beneficiary services will be distributed to beneficiaries and how such services support the care of beneficiaries, descriptions of the investments that will be made in the ACO with prepaid shared savings, and such other information as may be specified by CMS.

(iii) Include an attestation that the ACO will not discriminate on the basis of race, color, religion, sex, national origin, disability, or age with respect to their use of prepaid shared savings.

(iv) Include the ACO's communication strategy for notifying CMS and any impacted beneficiaries if an ACO will no longer be providing any direct beneficiary services that had previously been provided by the ACO using prepaid shared savings.

(3) *CMS review.* CMS will review the supplemental application information to determine whether an ACO meets the eligibility criteria and other requirements necessary to receive prepaid shared savings and will approve or deny the ACO's prepaid shared savings application accordingly. CMS may review an ACO's spend plan at any time and require the ACO to modify its spend plan to comply with the requirements of this paragraph (d) and paragraph (e) of this section.

(e) *Use and management of prepaid shared savings*—(1) *Allowable uses.* An ACO must use prepaid shared savings to improve the quality and efficiency of items and services furnished to beneficiaries by investing in staffing, healthcare infrastructure, and direct beneficiary services. Expenditures of prepaid shared savings must comply with paragraph (e)(2) of this section, the beneficiary incentive provision at § 425.304(a), (b), and (d), and all other applicable laws and regulations.

(i) An ACO may spend up to 50 percent of its estimated annual prepaid shared savings on staffing and healthcare infrastructure in each performance year.

(ii) An ACO may spend up to 100 percent, but not less than 50 percent, of its estimated annual prepaid shared savings on direct beneficiary services in each performance year.

(2) *Prohibited uses.* An ACO may not use prepaid shared savings for any expense other than those allowed under paragraph (e)(1) of this section. Prohibited uses include the following—

(i) Management company or parent company profit;

(ii) Performance bonuses;

(iii) Provision of medical services covered by Medicare;

(iv) Cash or cash equivalent payments to patients;

(v) Items or activities unrelated to ACO operations or care of beneficiaries; and

(vi) In the case of an ACO participating in Levels C through E of the BASIC track or the ENHANCED track, the repayment of any shared losses incurred as specified in a written notice in accordance with § 425.605(e)(2) or § 425.610(h)(2), respectively.

(3) *Duration for spending payments.* An ACO must spend all prepaid shared savings in the agreement period in which they are received. An ACO must repay to CMS any unspent funds remaining at the end of each agreement period. Any unspent funds received for a performance year must be reallocated in the spend plan for the ACO's next performance year. When reallocated in the spend plan for the next performance year, the total unspent funds in each category must be reallocated within their originally indicated category specified in accordance with paragraph (d)(2) of this section. If an ACO fails to spend a majority of the prepaid shared savings they receive in a performance year, CMS may withhold future quarterly payments until the ACO spends the funding they have already received and reports this spending to CMS through an updated spend plan.

(f) *Payment & payment methodology.* An ACO determined eligible pursuant to paragraph (b) of this section receives quarterly prepaid shared savings payments equal to the maximum quarterly payment amount calculated pursuant to the methodology specified in paragraphs (f)(2) through (4) of this section unless the ACO elects to receive a lesser amount pursuant to paragraph (f)(6) of this section. CMS notifies in writing each ACO of its determination of the amount of prepaid shared savings and the notice will inform the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of this part. If CMS does not make any prepaid shared savings payment, the notice will specify the reason(s) why and inform the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I.

(1) *Frequency of payments.* An ACO will receive quarterly prepaid shared savings payments for the entirety of the ACO's agreement period unless the payment is withheld or terminated pursuant to paragraph (h) of this section. If an ACO's quarterly payment is withheld or terminated pursuant to paragraph (h), the ACO will not receive additional or catch-up payments if quarterly prepaid shared savings payments are later resumed.

(2) *Calculating the prepaid shared savings multiplier.* (i) Calculate total per capita savings or losses for each performance year that constitutes BY1 and BY2 of the agreement period in which the ACO receives prepaid shared savings. Per capita savings or losses will be set to zero for a performance year if the ACO was not reconciled for the performance year.

(ii) Take the simple average of the per capita savings or losses calculated in paragraph (f)(2)(i) of this section, including values of zero, if applicable.

(iii) Apply a proration factor to account for any upward growth in the ACO's assigned population in BY1 and BY2 of the agreement period in which the ACO receives prepaid shared savings as compared to the size of the assigned population when the ACO was reconciled for the corresponding performance years in its prior agreement period.

(iv) Adjust the pro-rated average per capita amount computed in paragraph (f)(2)(iii) of this section by multiplying by 50 percent.

(v) The prepaid shared savings multiplier is the lesser of the following:

(A) Two-thirds of the pro-rated, adjusted average per capita amount computed in paragraph (f)(2)(iv) of this section.

(B) 5 percent of national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY2 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY2 using data from the CMS Office of the Actuary and expressed as a single value by taking a person-year weighted average of the Medicare enrollment type-specific values.

(3) *Recalculation of the prepaid shared savings multiplier during an agreement period.* For the first performance year during the term of the agreement period in which the ACO receives prepaid shared savings, the ACO's prepaid shared savings multiplier is recalculated for changes in per capita shared savings or losses for the performance years used in the

calculation of the prepaid shared savings multiplier as a result of issuance of a revised initial determination under § 425.315. For the second and each subsequent performance year during the term of the agreement period in which the ACO receives prepaid shared savings, the ACO's prepaid shared savings multiplier is recalculated for the following, as applicable: For the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), for a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), for a change to the beneficiary assignment methodology specified in subpart E of this part, and for changes in per capita shared savings or losses for the performance years used in the calculation of the prepaid shared savings multiplier as a result of issuance of a revised initial determination under § 425.315. To recalculate the prepaid shared savings multiplier, CMS does the following:

(i) Takes into account changes to the ACO's savings or losses for a performance year for either of the 2 years that constitute BY1 and BY2 of the agreement period for which the ACO receives prepaid shared savings under paragraph (f)(2)(i) of this section, including values of zero, if applicable, as a result of issuance of a revised initial determination under § 425.315, when calculating the simple average of the per capita savings or losses calculated in paragraph (f)(2)(ii) of this section.

(ii) Redetermines the proration factor used in calculating the prepaid shared savings multiplier under paragraph (f)(2)(iii) of this section to account for changes in the ACO's assigned beneficiary population in the benchmark years of the ACO's agreement period in which the ACO receives prepaid shared savings due to the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), or changes to the beneficiary assignment methodology under subpart E of this part.

(4) *Calculating the maximum quarterly payment amount.* For each quarter for each performance year, the maximum quarterly prepaid shared savings amount is equal to the product of one-fourth of the prepaid shared savings multiplier calculated in paragraph (f)(2)(v) of this section or recalculated according to paragraph (f)(3) of this section and the ACO's performance year assigned beneficiary person years calculated from the ACO's most recent assignment list.

(5) *Estimated annual payment amount calculation methodology.* For the purposes of determining the amount of prepaid shared savings permitted to be allocated to the uses specified in paragraph (e) of this section during each performance year, the estimated annual prepaid shared savings amount can be calculated by multiplying the first quarterly payment amount the ACO receives in each performance year by four. If an ACO's maximum quarterly payments decrease over the performance year, the ACO will not be subject to compliance action solely because it spent more than 50 percent of the actual annual amount of prepaid shared savings it received during that PY on staffing and healthcare infrastructure, as long as it did not spend more than 50 percent of the originally estimated annual maximum prepaid shared savings amount on staffing and healthcare infrastructure.

(6) *ACO selection of quarterly payment amount.* An ACO may request a smaller quarterly payment amount from CMS in a form and manner and by a deadline specified by CMS.

(g) *Recoupment and recovery of prepaid shared savings; notice of bankruptcy.* (1) CMS will recoup prepaid shared savings made to an ACO from any shared savings the ACO earns until CMS has recouped in full the amount of prepaid shared savings made to the ACO. CMS will carry forward any remaining balance owed to subsequent performance year(s) in which the ACO achieves shared savings.

(2) If the amount of shared savings earned by the ACO is revised upward by CMS for any reason, CMS will reduce the redetermined amount of shared savings by the amount of prepaid shared savings made to the ACO as of the date of the redetermination. If the amount of shared savings earned by the ACO is revised downward by CMS for any reason, the ACO will not receive a refund of any portion of the prepaid shared savings previously recouped or otherwise repaid, and any prepaid shared savings that are now outstanding due to the revision in earned shared savings must be repaid to CMS upon request.

(3) If an ACO has an outstanding balance of prepaid shared savings after the calculation of shared savings or losses for the final performance year of an agreement period in which an ACO receives prepaid shared savings, the ACO must repay any outstanding amount of prepaid shared savings it received in full upon request from CMS. CMS will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of notification. If the ACO fails to repay any outstanding amount of prepaid shared savings within 90 days of that written notification, CMS will recoup any outstanding balance of prepaid shared savings from the ACO's repayment mechanism established under § 425.204(f). CMS may also recover any outstanding amount of prepaid shared savings owed by recouping from any future shared savings the ACO may be eligible to receive in a subsequent agreement period.

(4) Except as provided in paragraph (g)(4)(ii) of this section, if an ACO or CMS terminates the ACOs participation agreement during the agreement period in which it received prepaid shared savings, the ACO must repay all outstanding prepaid shared savings it received in full upon request from CMS.

(i) CMS will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of notification. If the ACO fails to repay within 90 days, CMS will recoup any outstanding balance from the ACO's repayment mechanism established under § 425.204(f).

(ii) If the ACO terminates its current participation agreement under § 425.220 and immediately enters a new agreement period to continue its participation in the program, CMS may recover the amount owed by recouping from any future shared savings the ACO may be eligible to receive in subsequent agreement periods.

(5)(i) If an ACO has filed a bankruptcy petition, whether voluntary or involuntary, the ACO must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment for the agreement period has been made by either CMS or the ACO and all administrative or judicial review proceedings relating to any payments under the Shared Savings Program have been fully and finally resolved.

(ii) The notice of bankruptcy must be sent by certified mail no later than 5 days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number). The notice to CMS must be addressed to the CMS Office of Financial Management at 7500 Security Boulevard, Mailstop C3–01–24, Baltimore, MD 21244 or such other address as may be specified on the CMS website for purposes of receiving such notices.

(h) *Withholding or termination of prepaid shared savings*—(1) *General.*

Except as provided in paragraph (h)(2) of this section, CMS may withhold or terminate an ACO's prepaid shared savings during an agreement period if—

(i) The ACO fails to comply with the requirements of this section;

(ii) The ACO meets any of the grounds for ACO termination set forth in § 425.218(b);

(iii) The ACO fails to earn sufficient shared savings in a performance year to repay the prepaid shared savings they received during that performance year;

(iv) CMS determines that the ACO is not expected to earn shared savings in a performance year during the agreement period in which the ACO received prepaid shared savings based on a rolling 12-month window of beneficiary claims data or year to date beneficiary claims data;

(v) The ACO falls below 5,000 assigned beneficiaries;

(vi) The ACO fails to spend the majority of prepaid shared savings they receive in a performance year; or

(vii) The ACO requests that CMS withhold a future quarterly prepaid shared savings payment.

(2) *Eligibility sanction.* CMS must terminate an ACO's prepaid shared savings if—

(i) The ACO fails to maintain an adequate repayment mechanism in accordance with § 425.204(f); or

(ii) The ACO fails to meet the quality performance standard as specified under § 425.512 or is subject to a pre-termination action after CMS determined the ACO avoided at-risk beneficiaries as specified under § 425.316(b)(2).

(3) *No additional payments.* If CMS withholds or terminates a quarterly payment pursuant to this paragraph (h), the ACO will not receive additional or catch-up payments if quarterly payments of prepaid shared savings are later resumed.

(4) *No pre-termination actions.* CMS may immediately terminate an ACO's prepaid shared savings under paragraphs (h)(1) and (2) of this section without taking any of the pre-termination actions set forth in § 425.216.

(i) *Reporting information on prepaid shared savings.* The ACO must report information on its receipt of and use of prepaid shared savings, as follows:

(1) The ACO must publicly report information about the ACO's use of prepaid shared savings for each performance year, in accordance with § 425.308(b)(10).

(2) In a form and manner and by a deadline specified by CMS, the ACO must report to CMS the same information it is required to publicly report under § 425.308(b)(10).

§ 425.650 [Amended]

■ 72. Section 425.650 is amended in paragraph (a) by removing the reference ''425.660'' and adding in its place the reference ''425.662''.

■ 73. Section 425.652 is amended by—

■ a. Revising paragraph (a)(8) and paragraph (a)(9) introductory text;

■ b. Redesignating paragraphs (a)(9)(v) and (vi) as paragraphs (a)(9)(vi) and (vii), respectively;

■ c. Adding new paragraph (a)(9)(v);

■ d. Revising newly redesignated paragraph (a)(9)(vi); and

■ e. Adding paragraphs (a)(9)(viii) and (ix).

The revisions and additions read as follows:

§ 425.652 Establishing, adjusting, and updating the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years.

(a) * * *

(8) Adjusts the historical benchmark, if applicable:

(i) For agreement periods beginning on January 1, 2024, except as provided in paragraph (a)(8)(i)(C) of this section, CMS adjusts the historical benchmark based on the ACO's regional service area expenditures (as specified under § 425.656), or for savings generated by the ACO, if any, in the 3 most recent years prior to the start of the agreement period (as specified under § 425.658). CMS does all of the following to determine the adjustment, if any, applied to the historical benchmark:

(A) Computes the regional adjustment in accordance with § 425.656 and the prior savings adjustment in accordance with § 425.658.

(B) If an ACO is not eligible to receive a prior savings adjustment under § 425.658(b)(3)(i), and the regional adjustment, expressed as a single value as described in § 425.656(d), is positive, the ACO will receive an adjustment to its benchmark equal to the positive regional adjustment amount. The adjustment will be calculated as described in § 425.656(c) and applied separately to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(C) If an ACO is not eligible to receive a prior savings adjustment under § 425.658(b)(3)(i), and the regional adjustment, expressed as a single value as described in § 425.656(d), is negative or zero, the ACO will not receive an adjustment to its benchmark.

(D) If an ACO is eligible to receive a prior savings adjustment and the regional adjustment, expressed as a single value as described in § 425.656(d), is positive, the ACO will receive an adjustment to its benchmark equal to the higher of the following:

(*1*) The positive regional adjustment amount. The adjustment will be calculated as described in § 425.656(c) and applied separately to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(*2*) The prior savings adjustment. The adjustment will be calculated as described in § 425.658(c) and applied as a flat dollar amount to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(E) If an ACO is eligible to receive a prior savings adjustment and the regional adjustment, expressed as a single value as described in § 425.656(d), is negative or zero, the ACO will receive an adjustment to its benchmark equal to the prior savings adjustment. The adjustment will be calculated as described in § 425.658(c) and applied as a flat dollar amount to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(ii) For agreement periods beginning on January 1, 2025, and in subsequent years, except as provided in paragraph (a)(8)(ii)(B)(*2*) of this section, CMS adjusts the historical benchmark based on the ACO's regional service area expenditures (as specified under § 425.656), for savings generated by the ACO, if any, in the 3 most recent years prior to the start of the agreement period (as specified under § 425.658), or to account for the ACO serving higher proportions of underserved beneficiaries (as specified in § 425.662). CMS does all of the following to determine the adjustment, if any, applied to the historical benchmark:

(A) Computes the regional adjustment in accordance with § 425.656, the prior savings adjustment in accordance with § 425.658, and the health equity benchmark adjustment (HEBA) in accordance with § 425.662.

(B) Compares the regional adjustment, expressed as a single value as described in § 425.656(d), the per capita prior savings adjustment determined in § 425.658(c), if any, and the HEBA

determined in § 425.662(b), if any, to determine the adjustment applied to the historical benchmark.

(*1*) The ACO will receive the highest of the positive adjustments for which it is eligible. The adjustment will be calculated as described in § 425.656(c), § 425.658(c), or § 425.662(b), respectively, and applied separately to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(*2*) If an ACO is not eligible to receive a prior savings adjustment under § 425.658(b)(3)(i) or the HEBA under § 425.662(b)(3), and the regional adjustment, expressed as a single value as described in § 425.656(d), is negative or zero, the ACO will not receive an adjustment to its benchmark.

(9) For the first performance year during the term of the agreement period, the ACO's benchmark is adjusted for the following, as applicable: For changes in values used in benchmark calculations in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315, and for changes in values used in benchmark calculations as a result of the performance year being affected by significant, anomalous, and highly suspect billing under § 425.672. For the second and each subsequent performance year during the term of the agreement period, the ACO's benchmark is adjusted for the following, as applicable: For the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), for a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), for a change to the beneficiary assignment methodology specified in subpart E of this part, for a change in the CMS–HCC risk adjustment methodology used to calculate prospective HCC risk scores under § 425.659, for changes in values used in benchmark calculations in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315, and for changes in values used in benchmark calculations as a result of the performance year being affected by significant, anomalous, and highly suspect billing under § 425.672. To adjust the benchmark, CMS does the following:

* * * * *

(v) Redetermines the HEBA scaler used in calculating the HEBA under § 425.662(b)(2) to account for changes in the ACO's regional adjustment or prior savings adjustment in accordance with paragraphs (a)(9)(ii) through (iv) of this section.

(vi) In accordance with paragraph (a)(8) of this section, CMS redetermines the adjustment to the historical benchmark based on the redetermined regional adjustment (as specified under § 425.656), the prior savings adjustment (as specified under § 425.658), or the HEBA (as specified under § 425.662) if applicable.

* * * * *

(viii) Recalculates benchmark year expenditures to account for the impact of improper payments, for the benchmark year corresponding to a performance year for which CMS issued a revised initial determination under § 425.315. In recalculating expenditures for the benchmark year, CMS applies the calculation methodology applied in recalculating expenditures for the corresponding performance year in accordance with § 425.674.

(ix) Recalculates expenditures used in Shared Savings Program benchmark calculations under this section, and as applicable under §§ 425.654 through 425.662, to exclude the same HCPCS or CPT codes identified as displaying significant, anomalous, and highly suspect billing patterns in calculation of performance year expenditures, in accordance with § 425.672.

* * * * *

■ 74. Section 425.655 is amended by revising paragraph (d)(2) to read as follows:

§ 425.655 Calculating the regional risk score growth cap adjustment factor.

* * * * *

(d) * * *

(2) Determines the aggregate growth in regional risk scores by calculating a weighted average of the growth in regional prospective HCC risk scores or demographic risk scores, as applicable, across the populations described in paragraph (d)(1) of this section. When calculating the weighted average growth in prospective HCC risk scores or demographic risk scores, as applicable, the weight applied to the growth in risk scores for each Medicare enrollment type is equal to the product of the ACO's historical benchmark expenditures, adjusted in accordance with § 425.652(a)(8), for that enrollment type and the ACO's performance year assigned beneficiary person years for that enrollment type.

* * * * *

■ 75. Section 425.658 by revising paragraph (d) to read as follows:

§ 425.658 Calculating the prior savings adjustment to the historical benchmark.

* * * * *

(d) *Applicability of the prior savings adjustment.* CMS compares the per capita prior savings adjustment determined in paragraph (c)(1) of this section with the regional adjustment, expressed as a single value as described in § 425.656(d), and the HEBA as determined in § 425.662(b), if any, to determine the adjustment, if any, that will be applied to the ACO's benchmark in accordance with § 425.652(a)(8).

* * * * *

■ 76. Section 425.662 is added to read as follows:

§ 425.662 Calculating the health equity adjustment to the historical benchmark.

(a) *General.* For agreement periods beginning on January 1, 2025, and in subsequent years, CMS calculates a health equity adjustment to the historical benchmark (HEBA) to account for ACOs serving higher proportions of underserved beneficiaries.

(b) *Calculation of the health equity benchmark adjustment.* To calculate the adjustment described in paragraph (a) of this section, CMS does all of the following:

(1) Calculates the weighted average of the ACO's third benchmark year (BY3) national per capita expenditure amounts across the following populations of beneficiaries, where the weights are the ACO's BY3 proportion of assigned beneficiaries for that enrollment type:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Calculates the HEBA scaler as the difference between 5 percent of the national per capita expenditure amount, expressed as single value as calculated in paragraph (b)(1) of this section, and the higher of: the regional adjustment, expressed as a single value as described in § 425.656(d); the per capita prior savings adjustment determined in § 425.658(c); or no adjustment, in the case where the regional adjustment is negative and the ACO is not eligible for the prior savings adjustment under § 425.658(b)(3)(i).

(3) Determines the ACO's eligibility for the HEBA based on the proportion of the ACO's assigned beneficiaries for the performance year who are enrolled in the Medicare Part D low-income subsidy (LIS) or dually eligible for Medicare and Medicaid. An ACO is

only eligible for the HEBA if this proportion is greater than or equal to 20 percent. An ACO with a proportion less than 20 percent is ineligible to receive a HEBA.

(4) Calculates the HEBA. If the ACO is eligible for the HEBA as determined in paragraph (b)(3) of this section, the HEBA is equal to the product of the HEBA scaler calculated in paragraph (b)(2) of this section and the proportion of the ACO's assigned beneficiaries for the performance year who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid.

(c) *Applicability of the HEBA.* CMS compares the HEBA determined in paragraph (b)(4) of this section with the regional adjustment, expressed as a single value as described in § 425.656(d), and the per capita prior savings adjustment determined in § 425.658(c), if any, to determine the adjustment, if any, that will be applied to the ACO's benchmark in accordance with § 425.652(a)(8)(ii).

§§ 425.664 through 425.669 [Added and Reserved]

■ 77. Sections 425.664 through 425.669 are added and reserved.

■ 78. Section 425.672 is added to read as follows:

§ 425.672 Adjustments to mitigate the impact of significant, anomalous, and highly suspect billing activity on Shared Savings Program financial calculations involving calendar year 2024 or subsequent calendar years.

(a) *General.* This section describes adjustments CMS may make to Shared Savings Program calculations to mitigate the impact of significant, anomalous, and highly suspect billing activity occurring in calendar year 2024 or subsequent calendar years.

(b) *Significant, anomalous, and highly suspect billing activity for a HCPCS or CPT code impacting Shared Savings Program calculations.* CMS, at its sole discretion, may determine that the billing of one or more specified HCPCS or CPT codes represents significant, anomalous, and highly suspect billing activity for a calendar year that warrants adjustment to calculations made under this part.

(c) *Applicability of adjustments to performance year and benchmark year calculations.* Notwithstanding any other provision in this part, CMS adjusts the following Shared Savings Program calculations, as applicable, to exclude all Medicare Parts A and B fee-for-service payment amounts on claims for the specified claim types associated with a HCPCS or CPT code identified pursuant to paragraph (b) of this section for the periods identified in paragraph (d) of this section:

(1) Calculation of Medicare Parts A and B fee-for-service expenditures for an ACO's assigned beneficiaries for all purposes including the following: Establishing, adjusting, updating, and resetting the ACO's historical benchmark and determining performance year expenditures.

(2) Calculation of fee-for-service expenditures for assignable beneficiaries as used in determining county-level fee-for-service expenditures and national Medicare fee-for-service expenditures, including the following calculations:

(i) Determining average county fee-for-service expenditures based on expenditures for the assignable population of beneficiaries in each county in the ACO's regional service area according to §§ 425.601(c) and 425.654(a) for purposes of calculating the ACO's regional fee-for-service expenditures.

(ii) Determining the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries for purposes of the following:

(A) Truncating assigned beneficiary expenditures used in calculating benchmark expenditures under §§ 425.601(a)(4) and 425.652(a)(4), and performance year expenditures under §§ 425.605(a)(3) and 425.610(a)(4).

(B) Truncating expenditures for assignable beneficiaries in each county for purposes of determining county fee-for-service expenditures according to §§ 425.601(c)(3) and 425.654(a)(3).

(C) Truncating expenditures for assignable beneficiaries for purposes of determining truncated national per capita fee-for service expenditures for purposes of calculating the ACPT according to § 425.660(b)(3).

(iii) Determining truncated national per capita fee-for-service Medicare expenditures for assignable beneficiaries for purposes of calculating the ACPT according to § 425.660(b)(3).

(iv) Determining national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program for assignable beneficiaries for purposes of capping the regional adjustment to the ACO's historical benchmark according to §§ 425.601(a)(8)(ii)(C) and 425.656(c)(3), capping the prior savings adjustment according to § 425.658(c)(1)(ii), capping the prepaid shared savings multiplier according to § 425.640(f)(2)(v), and calculating the HEBA scaler according to § 425.662(b)(2).

(v) Determining national growth rates that are used as part of the blended growth rates used to trend forward BY1 and BY2 expenditures to BY3 according to §§ 425.601(a)(5)(ii) and 425.652(a)(5)(ii) and as part of the blended growth rates used to update the benchmark according to §§ 425.601(b)(2) and 425.652(b)(2)(i).

(3) Calculation of Medicare Parts A and B fee-for-service revenue of ACO participants for purposes of calculating the ACO's loss recoupment limit under the BASIC track as specified in § 425.605(d).

(4) Calculation of total Medicare Parts A and B fee-for-service revenue of ACO participants and total Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries for purposes of identifying whether an ACO is a high revenue ACO or low revenue ACO, as defined under § 425.20, determining an ACO's eligibility to receive advance investment payments according to § 425.630, and determining whether an ACO qualifies for a shared savings payment under § 425.605(h).

(5) Calculation or recalculation of the amount of the ACO's repayment mechanism arrangement according to § 425.204(f)(4).

(d) *Periods of adjustment.* CMS adjusts the Shared Savings Program calculations identified in paragraph (c) of this section for significant, anomalous, and highly suspect billing activity identified for calendar year 2024 or subsequent calendar years as follows:

(1) The calendar year for which the significant, anomalous, and highly suspect billing activity was identified pursuant to paragraph (b) of this section, when it is either a performance year or a benchmark year.

(2) The 3 most recent years prior to the start of the ACO's agreement period used in establishing the historical benchmark, when such a benchmark is used to reconcile the ACO for a performance year adjusted in accordance with paragraph (d)(1) of this section.

(e) *Adjustments for growth rates used in calculating the ACPT.* In addition to adjustments described in paragraph (c) of this section, CMS makes adjustments for payments associated with a HCPCS or CPT code identified pursuant to paragraph (b) of this section for any calendar year corresponding to BY3 in projecting per capita growth in Parts A and B fee-for-service expenditures, according to § 425.660(b)(1), for purposes of calculating the ACPT for agreement periods beginning on January 1, 2024, and in subsequent years.

■ 79. Section 425.674 is added to read as follows:

§ 425.674 Accounting for the impact of improper payments on Shared Savings Program financial calculations.

(a) *General rule.* Upon the reopening of an initial determination pursuant to § 425.315(a)(4), CMS will use the methodology specified in this section to account for the impact of improper payments when:

(1) Determining savings or losses for the relevant performance year in accordance with § 425.315 in order to issue a revised initial determination.

(2) Adjusting the benchmark by recalculating benchmark year expenditures under §§ 425.601(a)(9)(iii) and 425.652(a)(9)(viii) in the event that CMS recalculates a payment determination and issues a revised initial determination for the corresponding performance year in a prior agreement period, in accordance with paragraph (a)(1) of this section.

(b) *Improper payment.* For the purpose of this section, improper payment includes:

(1) An amount associated with a demanded overpayment determination.

(2) An amount identified in a settlement agreement or judgment, pursuant to conduct by individuals or entities performing functions or services related to an ACO's activities, less any penalties or damages.

(c) *Accounting for improper payments.* To adjust Medicare Parts A and B fee-for-service expenditures for improper payments CMS does the following:

(1) Identify each Shared Savings Program expenditure calculation for a performance year or benchmark year, as calculated according to the standard methodology described in this subpart and expressed as a per capita dollar amount, that will be adjusted for the impact of improper payments.

(2) Determine each specific population of Medicare fee-for-service beneficiaries used to calculate the expenditure amount identified in paragraph (c)(1) of this section. The populations relevant for a specific expenditure calculation may include:

(i) The population of beneficiaries assigned to the ACO for calculating the ACO's performance year or benchmark year expenditures.

(ii) The population of assignable beneficiaries in each county in the ACO's regional service area for calculating county-level expenditures.

(iii) The national population of assignable beneficiaries for calculating national assignable expenditures.

(iv) The national population of Medicare fee-for-service beneficiaries for calculating national expenditures.

(3) Determine the per capita amount of improper payments for the performance year or benchmark year included in the per capita Medicare Parts A and B fee-for-service expenditure amount for a population identified in paragraph (c)(2) of this section in accordance with paragraph (d) of this section for all providers or suppliers with identified improper payments.

(4) Subtract the per capita amount determined in paragraph (c)(3) of this section from the expenditure calculation identified in paragraph (c)(1) of this section for the population identified in paragraph (c)(2) of this section for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(5) If applicable, CMS will do the following to adjust regional expenditures for improper payments:

(i) Adjust county-level fee-for-service expenditures determined under paragraph (c)(4) of this section, for each county in the ACO's regional service area, for severity and case mix of assignable beneficiaries in the county using prospective HCC risk scores. This calculation is made for each of the populations of beneficiaries identified in paragraphs (c)(4)(i) through (iv) of this section.

(ii) Weight the risk adjusted county-level fee-for-service expenditures determined under paragraph (c)(5)(i) of this section according to the ACO's proportion of assigned beneficiaries in the county, determined in accordance with § 425.601(d)(1), § 425.603(f)(1), or § 425.654(b)(1), as applicable, for each of the populations of beneficiaries identified in paragraphs (c)(4)(i) through (iv) of this section.

(iii) Aggregate the values determined in paragraph (c)(5)(ii) of this section for each of the populations of beneficiaries identified in paragraphs (c)(4)(i) through (iv) of this section across all counties within the ACO's regional service area.

(d) *Determining the per capita amount of improper payments.* CMS may use one or more of the following approaches to determine the per capita amount that will be used to adjust expenditure calculations identified in paragraph (c)(1) of this section:

(1) Calculate aggregate improper payments attributable to a population identified in paragraph (c)(2) of this section for each provider or supplier that had improper payments.

(i) For improper payments associated with specific claims, CMS will do the following:

(A) For improper payments to a provider or supplier that correspond to payment amounts on claims or line items that were used in a Shared Savings Program calculation identified in paragraph (c)(1) of this section, and subsequently adjusted after the 3-month claims run out period, CMS will sum the improper payment amounts across all such claims or line items with dates of service during the period used to calculate performance year or benchmark year expenditures for the population identified in paragraph (c)(2) of this section.

(B) In the event CMS determines it is necessary to account for the impact of improper payments on Shared Savings Program financial calculations by adjusting the payment amounts for a specific HCPCS or CPT code billed by the provider or supplier for the population identified in paragraph (c)(2) of this section, CMS will do the following—

(*1*) Identify the applicable claims or line items with dates of service during the period used to calculate performance year or benchmark year expenditures processed before the end of the applicable 3-month claims run out period;

(*2*) Sum the claim or line item payment amounts, on the claims or line items identified in paragraph (d)(1)(i)(B)(*1*) of this section; and

(*3*) If applicable, multiply the sum calculated in paragraph (d)(1)(i)(B)(*2*) of this section by a scaling factor to compute the payment differential between the HCPCS or CPT code that was improperly billed and a CMS-identified alternate code.

(ii) For aggregate improper payment amounts that are not linked to specific claims or line items, CMS will calculate the amount attributable to the population identified in paragraph (c)(2) of this section by applying a proration factor to the aggregate improper payment amount identified for that provider or supplier. CMS calculates the proration factor as follows:

(A) The denominator of the proration factor is total Medicare Parts A and B claim or line item payment amounts to the provider or supplier for all fee-for-service beneficiaries on claims of specified claim types for the time period associated with the aggregate improper payment amount identified for the provider or supplier that were made before the end of the applicable 3-month claims run out period.

(B) The numerator of the proration factor is the portion of the total from the

denominator, in paragraph (d)(1)(ii)(A) of this section, that CMS determines is attributable to the population identified in paragraph (c)(2) of this section with dates of service during the period used to calculate expenditures for the applicable performance year or benchmark year.

(2) Sum the amounts calculated pursuant to paragraph (d)(1) of this section attributable to a population identified in paragraph (c)(2) of this section across all providers or suppliers that had identified improper payments.

(3) Take the lesser of the following two values—

(i) The sum from paragraph (d)(2) of this section; or

(ii) Total Medicare Parts A and B claim or line item payment amounts to all providers or suppliers that had improper payments for the population identified in paragraph (c)(2) of this section on claims of specified claim types with dates of service within the performance year or benchmark year made before the end of the applicable 3-month claims run out period.

(4) Express the lesser-of amount from paragraph (d)(3) of this section as a per capita value by dividing by the total beneficiary person years in the population identified in paragraph (c)(2) of this section for the applicable performance year or the benchmark year.

■ 80. Part 427 is added to read as follows:

PART 427—MEDICARE PART B DRUG INFLATION REBATE PROGRAM

Subpart A—General Provisions

Sec.
427.10 Basis and scope.
427.20 Definitions.

Subpart B—Determination of Part B Rebatable Drugs

427.100 Definitions.
427.101 Identification of Part B rebatable drugs.

Subpart C—Coinsurance Adjustment and Adjusted Medicare Payment for Part B Rebatable Drugs With Price Increases Faster Than Inflation

427.200 Definitions.
427.201 Computation of beneficiary coinsurance and adjusted Medicare Payment for Part B rebatable drugs with price increases faster than inflation.

Subpart D—Determination of the Rebate Amount for Part B Rebatable Drugs

427.300 Definitions.
427.301 Calculation of the total Part B rebate amount to be paid by manufacturers.
427.302 Calculation of the per unit Part B drug rebate amount.
427.303 Determination of total number of billing units.
427.304 Adjustments for changes to billing and payment codes.

Subpart E—Reducing the Rebate Amount for Part B Rebatable Drugs in Shortage and When There Is a Severe Supply Chain Disruption

427.400 Definitions.
427.401 Reducing the rebate amount for Part B rebatable drugs currently in shortage.
427.402 Reducing the rebate amount for certain Part B rebatable drugs when there is a severe supply chain disruption.

Subpart F—Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments

427.500 Definitions.
427.501 Rebate Reports and reconciliation.
427.502 Rebate Reports for applicable calendar quarters in calendar years 2023 and 2024.
427.503 Suggestion of Error.
427.504 Manufacturer access to Rebate Reports.
427.505 Deadline and process for payment of rebate amount.

Subpart G—Enforcement of Manufacturer Payment of Rebate Amounts

427.600 Civil money penalty notice and appeals procedures.

Authority: 42 U.S.C. 1395w–3a(i), 1302, and 1395hh.

Subpart A—General Provisions

§ 427.10 Basis and scope.

(a) *Basis.* This part implements section 1847A(i) of the Social Security Act (''the Act'').

(b) *Scope.* This part sets forth the requirements of the Medicare Part B Drug Inflation Rebate Program, which requires, for each calendar quarter, manufacturers to pay rebates for certain single source drugs and biological products with prices that increase faster than the rate of inflation.

(c) *Severability.* Were any provision of this part to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, such provisions would be severable from this part and the invalidity or unenforceability would not affect the remainder thereof or any other part of this subchapter or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances.

§ 427.20 Definitions.

As used in this part, the following definitions apply:

Allowed charges means the amount that is inclusive of the beneficiary coinsurance and Medicare payment for the covered Part B item or service.

Applicable calendar quarter means a calendar quarter (January 1 to March 31, April 1 to June 30, July 1 to September 30, or October 1 to December 31) in which an inflation rebate is applied, starting with January 1, 2023.

Applicable threshold means the amount calculated in accordance with § 427.101(c)(2).

Average sales price (ASP) means the manufacturer's price for a quarter for a drug represented by a particular 11-digit National Drug Code (NDC–11) calculated in accordance with § 414.804 of this chapter.

Benchmark period Consumer Price Index for All Urban Consumers (CPI–U) means the CPI–U identified in § 427.302(e).

Billing and payment code means the specific code used to classify and report a drug or biological for purposes of Medicare Part B payment. A Healthcare Common Procedure Coding System (HCPCS) code, as established by CMS, is an example of a billing and payment code used to describe a drug or biological and for which CMS publishes a payment amount.

Billing unit means the identifiable quantity of a drug or biological product associated with a billing and payment code (for example, a HCPCS code), as established by CMS.

Biosimilar biological product has the meaning set forth in section 1847A(c)(6)(H) of the Act.

CPI–U means the monthly Consumer Price Index for All Urban Consumers (United States city average) index level for all items from the Bureau of Labor Statistics.

Food and Drug Administration (FDA) application means, for the purposes of calculating the Part B rebate amount, a New Drug Application (NDA) or Biologics License Application (BLA) approved by the FDA.

Final action claim means a non-rejected claim for which a Medicare payment has been made, and for which all disputes and adjustments have been resolved.

First marketed date means the earliest date of first sale of any NDC–11 within a billing and payment code among all products and package sizes under the same FDA application. The first marketed date will be identified using ASP data reported by NDC–11 to CMS by a manufacturer as required under sections 1927(b)(3)(A)(iii)(I) and 1847A(f)(2) of the Act, if available.

Grouped billing and payment code, for the purposes of Part B rebate calculations, means a billing and payment code, such as a HCPCS code, other than a Not Otherwise Classified (NOC) code, that typically contains multiple drug products approved under multiple NDAs or BLAs and may be

inclusive of, but are not limited to, multiple source billing codes.

Inflation-adjusted payment amount means the amount calculated in § 427.302(g).

Manufacturer has the meaning set forth in section 1847A(c)(6)(A) of the Act.

National Drug Code (NDC) means the unique identifying prescription drug product number that is listed with FDA identifying the product and package size and type.

Not Otherwise Classified (NOC) code means a billing and payment code, including an unclassified, unspecified, or unlisted code, for drugs and biological products for which no specific billing and payment code is assigned.

Part B rebatable drug means, subject to the exclusions described in § 427.101(b), a single source drug or biological product, including a biosimilar biological product but excluding a qualifying biosimilar biological product, for which payment is made under Part B.

Payment amount benchmark quarter means the calendar quarter identified in § 427.302(c).

Payment amount in the payment amount benchmark quarter means the amount identified in § 427.302(d).

Rebate period CPI–U means the CPI–U identified in § 427.302(f).

Single source drug or biological product has the meaning set forth in section 1847A(c)(6)(D) of the Act.

Specified amount refers to the amount identified in § 427.302(b).

Subsequently approved drug means a drug first approved or licensed by the FDA after December 1, 2020.

Unit means, with respect to a Part B rebatable drug, with respect to each National Drug Code (including package size) associated with a drug or biological, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids as reported under section 1847A(b)(2)(B) of the Act.

Subpart B—Determination of Part B Rebatable Drugs

§ 427.100 Definitions.

As used in this subpart, the following definitions apply:

EUA Declaration refers to the March 27, 2020, Emergency Use Authorization (EUA) Declaration for Drugs and Biological Products under section 564 of the Food, Drug, and Cosmetic (FD&C) Act.

Individual who uses such a drug or biological means a unique Medicare Part B beneficiary who was furnished the Part B drug or biological that was covered under Part B during the applicable calendar quarter, identified using final action claims data with dates of service during the calendar year described in § 427.101(b)(6) and with allowed charges greater than zero.

§ 427.101 Identification of Part B rebatable drugs.

(a) *Determination of Part B rebatable drugs.* (1) For each applicable calendar quarter, CMS will:

(i) Identify single source drugs or biological products, including biosimilar biological products, covered under Part B; and

(ii) Identify the applicable billing and payment code for each drug or biological product identified in paragraph (a)(1)(i) of this section.

(2) For a drug or biological product identified under paragraph (a)(1) of this section, CMS will determine whether the drug or biological product meets the exclusion criteria described in paragraph (b) or (c) of this section as of the first day of the applicable calendar quarter.

(3) To determine whether a drug or biological product is a Part B rebatable drug under this section, CMS will use the most recent available data submitted to CMS by manufacturers pursuant to section 1927(b)(3)(A)(iii) of the Act or section 1847A(f)(2), as applicable, and other available data, including but not limited to information available at FDA.gov and information in drug pricing compendia, as applicable.

(b) *Excluded product categories.* The following categories of products are not considered Part B rebatable drugs:

(1) *Qualifying biosimilar biological products.* Biological products as defined under section 1847A(b)(8)(B)(iii) of the Act.

(2) *Products with historically excepted grouped billing and payment codes.* Single source drugs or biological products that were within the same billing and payment code as of October 1, 2003, and which, as required under section 1847A(c)(6)(C)(ii) of the Act, are treated as multiple source drugs.

(3) *Products billed under a NOC code.* A drug or biological product billed under a NOC code.

(4) *Radiopharmaceutical drugs and biological products.* A separately payable radiopharmaceutical drug or biological product not paid under section 1847A of the Act.

(5) *Skin substitutes.* A product included within the suite of cellular- and tissue-based products that aid wound healing.

(6) *Drugs with average total allowed charges under the applicable threshold.* Drugs and biological products for which the Medicare Part B average total allowed charges for a year per individual that uses such drug or biological are below the applicable threshold, as described in paragraph (c) of this section.

(7) *Certain vaccines and other products.* The following products:

(i) The vaccines described in section 1861(s)(10) of the Act, which includes the influenza, pneumococcal, hepatitis B, and COVID–19 vaccines.

(ii) Monoclonal antibodies used for treatment or post-exposure prophylaxis of COVID–19 that are covered and paid for under section 1861(s)(10) of the Act. This exclusion will apply to applicable quarters until the end of the calendar year in which the EUA Declaration ends.

(iii) Monoclonal antibodies that are used for pre-exposure prophylaxis of COVID–19 that are covered and paid for under section 1861(s)(10) of the Act. This exclusion will apply to applicable calendar quarters even after the year in which the EUA Declaration ends, as long as after the EUA Declaration is terminated, these products have an FDA-approved application or license.

(8) *Generic drugs.* Part B drugs approved under an Abbreviated New Drug Application (ANDA) submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

(c) *Drugs and biological products with average total allowed charges below the applicable threshold.* For each applicable calendar quarter, CMS will identify drugs and biological products with Part B average total allowed charges for a year per individual that uses such a drug or biological product that are below the applicable threshold in accordance with the calculations described in this section. Such drugs and biological products are not considered Part B rebatable drugs and will be excluded from the identification of Part B rebatable drugs in paragraph (a) of this section.

(1) *Average total allowed charges for a year per individual.* For each drug or biological that is identified in accordance with paragraph (a) of this section, CMS will calculate average total allowed charges for a year per individual as follows:

(i) For single source drugs and biological products assigned to only one billing and payment code, CMS will sum the allowed charges from final action claims greater than $0 and divide the summed amount by the number of

individuals who use such a drug or biological with allowed charges for this billing and payment code.

(ii) For single source drugs and biological products assigned to more than one billing and payment code, CMS will sum the allowed charges from final action claims greater than $0 for all billing and payment codes and divide the summed amount by the number of individuals who use such a drug or biological with allowed charges for these billing and payment codes.

(iii) For single source drugs and biological products previously crosswalked to a grouped billing and payment code:

(A) If crosswalked to a grouped billing and payment code during the full year, CMS will calculate the average total allowed charges per individual per year for the drug using allowed charges and the number of individuals who used the drug or biological product based on claims for the previously grouped billing and payment code during the year.

(B) If crosswalked to a grouped billing and payment code and later assigned to a unique billing and payment code for part of the year, CMS will calculate average total allowed charges per individual per year by:

(*1*) Summing the total allowed charges billed under the unique billing and payment code for the drug with dates of service on or after the Medicare effective date for this unique billing and payment code and identifying the individuals on those claims.

(*2*) Summing the total allowed charges on claims billed under the previously grouped billing and payment code and identifying individuals with claims prior to the unique billing and payment code's effective date.

(*3*) Summing the total allowed charges as determined in paragraphs (c)(1)(iii)(B)(*1*) and (*2*) of this section and dividing by the total number of individuals, de-duplicated for individuals identified under paragraphs (c)(1)(iii)(B)(*1*) and (*2*).

(2) *Applicable threshold.* CMS will calculate the applicable threshold for an applicable calendar quarter as follows:

(i) For applicable calendar quarters in 2023, the applicable threshold is equal to $100.

(ii) For applicable calendar quarters in 2024, the applicable threshold is equal to $100 increased by the percentage increase in the CPI–U for the 12-month period ending with June of 2023.

(iii) For applicable calendar quarters in each subsequent calendar year, the applicable threshold is equal to the unrounded applicable threshold calculated for the prior calendar year increased by the percentage increase in the CPI–U for the 12-month period ending with June of the previous year.

(iv) If the resulting amount under paragraphs (c)(2)(i) through (iii) of this section is not a multiple of $10, CMS will round that amount to the nearest multiple of $10.

(3) *Application of the* applicable *threshold at the billing and payment code level.* For each applicable calendar quarter, CMS will apply the exclusion of drugs and biological products identified in paragraph (c)(1) of this section, with average total allowed charges for a year per individual less than the applicable threshold described in paragraph (c)(2) of this section, to applicable billing and payment codes as follows:

(i) For single source drugs or biological products assigned to a unique billing and payment code, CMS will exclude the assigned billing and payment code for an applicable calendar quarter if the average total allowed charges for a year per individual are less than the applicable threshold.

(ii) For a single source drug or biological product that is assigned to more than one billing and payment code during a year, CMS will exclude all such assigned billing and payment codes for an applicable calendar quarter.

(4) *Definition of year.* For purposes of the calculations described in this section, a year is defined as the 4 consecutive calendar quarters beginning 6 calendar quarters before the applicable calendar quarter. CMS will use final action claims from the Medicare fee-for-service claims repository where separate payment was allowed for the applicable billing and payment code for dates of service within a year to calculate Part B average total allowed charges for that year.

Subpart C—Coinsurance Adjustment and Adjusted Medicare Payment for Part B Rebatable Drugs With Price Increases Faster Than Inflation

§ 427.200 Definitions.

As used in this subpart, *inflation-adjusted beneficiary coinsurance* means the coinsurance adjustment as calculated in accordance with this subpart.

§ 427.201 Computation of beneficiary coinsurance and adjusted Medicare payment for Part B rebatable drugs with price increases faster than inflation.

(a) *Methodology.* CMS must use the methodology set forth in this section to calculate the inflation-adjusted beneficiary coinsurance and associated adjusted Medicare payment percentage for Part B rebatable drugs as set forth in §§ 410.152(m), 419.41(e), and 489.30(b)(6) of this chapter.

(b) *Calculation of inflation-adjusted beneficiary coinsurance.* To calculate the inflation-adjusted beneficiary coinsurance for Part B rebatable drugs with respect to a calendar quarter, CMS compares the payment amount, as described in paragraph (b)(3) of this section, to the inflation-adjusted payment amount for the applicable calendar quarter.

(1) If the payment amount exceeds the inflation-adjusted payment amount, the inflation-adjusted beneficiary coinsurance is calculated by multiplying the inflation-adjusted payment amount by 0.20.

(2) If the inflation-adjusted payment amount does not exceed the payment amount, the adjustment to the beneficiary coinsurance described in paragraph (b)(1) of this section is not applied.

(3) CMS will use the published payment amount in quarterly pricing files published by CMS as the payment amount in this determination.

(c) *Exclusions.* Any drug that is excluded from Part B rebatable drugs in accordance with § 427.101(b) is not subject to inflation-adjusted beneficiary coinsurance.

Subpart D—Determination of the Rebate Amount for Part B Rebatable Drugs

§ 427.300 Definitions.

As used in this subpart, the following definitions apply:

340B Program is the program under section 340B of the Public Health Service (PHS) Act.

Refundable single-dose container or *single-use package drug* has the meaning set forth in § 414.902 of this chapter.

§ 427.301 Calculation of the total Part B rebate amount to be paid by manufacturers.

(a) *Total rebate.* Subject to paragraph (b) of this section, the total rebate amount to be paid for a Part B rebatable drug, as identified under § 427.101, for an applicable calendar quarter is equal to the product of the per unit Part B rebate amount of such drug, as determined under § 427.302, and the billing units of the Part B rebatable drug furnished during the applicable calendar quarter, as identified in accordance with § 427.303. The rebate amount may be reduced in accordance with subpart E of this part or adjusted in accordance with subpart F of this part.

(b) *Apportionment of the Part B rebate amount.* CMS will identify billing and

payment codes for which multiple manufacturers report ASP, in accordance with sections 1927(b)(3) and 1847A(f) of the Act, for NDCs assigned to the billing and payment code. CMS will calculate the rebate amount owed by each manufacturer by:

(1) Determining the total billing units sold for each NDC assigned to the billing and payment code, by multiplying the number of units reported by a manufacturer in ASP data submissions at the NDC–11 package level by the number of billing units per NDC–11 reporting unit.

(2) Summing the individual manufacturer's total billing units sold during the applicable calendar quarter (for all NDCs of the manufacturer assigned to the billing and payment code).

(3) Summing all manufacturers' total billing units sold during the applicable calendar quarter for all NDCs of the Part B rebatable drug assigned to the billing and payment code.

(4) Dividing the resulting amount from paragraph (b)(2) of this section by the resulting amount from paragraph (b)(3) of this section.

(5) Multiplying the resulting amount from paragraph (b)(4) of this section by the total rebate amount as determined under paragraph (a) of this section.

§ 427.302 Calculation of the per unit Part B drug rebate amount.

(a) *Formula for calculating the per unit Part B rebate amount.* CMS will calculate the per unit Part B rebate amount for a Part B rebatable drug and applicable calendar quarter by determining the amount by which the specified amount, as calculated in accordance with paragraph (b) of this section, exceeds the inflation-adjusted payment amount, as calculated in accordance with paragraph (g) of this section.

(b) *Identification of the specified amount for the applicable calendar quarter.* For each applicable calendar quarter, subject to paragraph (b)(2) of this section, the specified amount is equal to the amount determined in accordance with section 1847A(i)(3)(A)(ii)(I)(aa) or (bb) of the Act, as applicable, for the calendar quarter.

(1) The first applicable calendar quarter for a Part B rebatable drug will be the earliest applicable calendar quarter that follows the payment amount benchmark quarter identified in paragraphs (c)(1) through (5) of this section.

(2) If all NDCs in the billing and payment code have neither manufacturer-reported ASP nor Wholesale Acquisition Cost (WAC) price data available for the applicable calendar quarter, CMS will use WAC price data from other public sources, if available, to calculate 106 percent of WAC, which will serve as the specified amount.

(c) *Identification of the payment amount benchmark quarter.* For each Part B rebatable drug, CMS will identify the applicable payment amount benchmark quarter using the earliest first marketed date of any NDC ever marketed under any FDA application under which any NDCs that have ever been assigned to the billing and payment code as of the applicable calendar quarter have been marketed, as set forth in paragraphs (c)(1) through (3) of this section, as applicable, subject to paragraphs (c)(4) and (5) of this section:

(1) For a Part B rebatable drug first approved or licensed by the FDA on or before December 1, 2020, and with a first marketed date on or before December 1, 2020, the payment amount benchmark quarter is the calendar quarter beginning July 1, 2021.

(2) For a Part B rebatable drug first approved or licensed by the FDA after December 1, 2020, the payment amount benchmark quarter is the third full calendar quarter after a drug's first marketed date.

(3) For a Part B rebatable drug first approved or licensed by the FDA on or before December 1, 2020, but with a first marketed date after December 1, 2020, the payment amount benchmark quarter is the third full calendar quarter after a drug's first marketed date.

(4) Notwithstanding paragraph (c)(3) of this section, for a Part B rebatable drug that was billed under a NOC code during the calendar quarter beginning July 1, 2021, or the third full calendar quarter after such drug's first marketed date, whichever is later, the payment amount benchmark quarter is the third full calendar quarter after the Part B rebatable drug is assigned a billing and payment code other than a NOC code.

(5) For a Part B rebatable drug that is a selected drug (as defined in section 1192(c) of the Act) with respect to a price applicability period (as defined in section 1191(b)(2) of the Act), in the case such Part B rebatable drug is no longer considered to be a selected drug, for each applicable quarter beginning after the price applicability period with respect to such drug, the payment amount benchmark quarter is the calendar quarter beginning January 1 of the last year during such price applicability period with respect to such selected drug.

(d) *Identification of the payment amount in the payment amount benchmark quarter.* CMS will identify the payment amount in the payment amount benchmark quarter using the published payment limit for the billing and payment code for the applicable payment amount benchmark quarter identified in accordance with paragraph (c) of this section.

(1) For a Part B rebatable drug, subject to paragraphs (d)(1)(i) and (ii) of this section and except as provided in paragraph (d)(2) of this section, CMS will identify the payment amount in the payment amount benchmark quarter using the published payment limit for the billing and payment code for the applicable payment amount benchmark quarter determined in accordance with section 1847A of the Act.

(i) If a published payment limit is not available for the applicable payment amount benchmark quarter, CMS will use the lower of 106 percent of manufacturer-reported ASP or 106 percent of manufacturer-reported WAC.

(ii) If neither a published payment limit nor manufacturer-reported ASP or WAC data are available, CMS will use WAC data from other public sources to calculate 106 percent of WAC, which, solely for the purposes of this section, CMS will consider to be the payment amount for the payment amount benchmark quarter.

(2) For a Part B rebatable drug previously billed under a grouped billing and payment code during the payment amount benchmark quarter and later billed under a unique billing and payment code, CMS will use the grouped billing and payment code payment limit as the payment amount in the payment amount benchmark quarter.

(e) *Identification of the benchmark period CPI–U.* For each Part B rebatable drug, CMS will identify the applicable benchmark period CPI–U at the billing and payment code level as set forth in paragraphs (e)(1) and (2) of this section, subject to paragraphs (e)(3) through (5) of this section:

(1) For a Part B rebatable drug first approved or licensed by the FDA on or before December 1, 2020, and with a first marketed date on or before December 1, 2020, the benchmark period CPI–U is the CPI–U for January 2021.

(2) For a Part B rebatable drug first approved or licensed by the FDA after December 1, 2020, the benchmark period CPI–U is the CPI–U for the first month of the first full calendar quarter after a drug's first marketed date.

(3) Notwithstanding paragraph (e)(2) of this section, for a Part B rebatable drug first approved or licensed by FDA on or before December 1, 2020, and with

a first marketed date after December 1, 2020, the benchmark period CPI–U is the CPI–U for the first month of the third full calendar quarter after a drug's first marketed date.

(4) Notwithstanding paragraph (e)(3) of this section, for a Part B rebatable drug that was billed under a NOC code during the calendar quarter beginning July 1, 2021, or the third full calendar quarter after such drug's first marketed date, whichever is later, the benchmark period CPI–U is the CPI–U for the first month of the third full calendar quarter after the Part B rebatable drug is assigned a billing and payment code other than a NOC code.

(5) Notwithstanding paragraph (e)(4) of this section, for a Part B rebatable drug that is a selected drug (as defined in section 1192(c) of the Act) with respect to a price applicability period (as defined in section 1191(b)(2) of the Act), in the case such Part B rebatable drug is no longer considered to be a selected drug, the benchmark period CPI–U is the CPI–U for the July of the year preceding the last year during such price applicability period.

(f) *Identification of the rebate period CPI–U.* For each Part B rebatable drug by billing and payment code, CMS will identify and use the greater of the benchmark period CPI–U index level or the CPI–U index level for the first month of the calendar quarter that is two calendar quarters before the applicable calendar quarter in which the Part B rebatable drug is furnished.

(g) *Determination of inflation-adjusted payment amount.* For each applicable calendar quarter and for each Part B rebatable drug by billing and payment code, CMS will calculate the inflation-adjusted payment amount by dividing the rebate period CPI–U by the benchmark period CPI–U and then multiplying the quotient by the payment amount in the payment amount benchmark quarter, determined in accordance with paragraph (d) of this section.

§ 427.303 Determination of total number of billing units.

(a) *General.* For each Part B rebatable drug, CMS will determine the total number of billing units of the billing and payment code subject to a rebate in the applicable calendar quarter using final action Medicare fee-for-service claims for which Medicare payment was allowed and greater than zero.

(b) *Total billing units.* Using final action claims in the Medicare fee-for-service claims repository, at least 3 months after the end of the applicable calendar quarter, CMS will determine the total number of billing units for a Part B rebatable drug in an applicable calendar quarter by identifying separately payable claim lines for such billing and payment code for dates of service in that applicable calendar quarter and excluding the following billing units in claim lines as applicable:

(1) *Billing units of drugs acquired through the 340B Program.* CMS will exclude billing units acquired under the 340B Program as identified through—

(i) Separately payable billing units in claim lines for professional claims with dates of service during 2023 and 2024 from suppliers that are associated with covered entities listed by the Health Resources and Services Administration (HRSA) 340B Office of Pharmacy Affairs Information System as participating in the 340B Program. CMS will use National Provider Identifiers and/or Medicare Provider Numbers to identify these suppliers and the claims submitted with such identifiers;

(ii) Separately payable billing units in claim lines for institutional claims that are billed with the ''JG'' or ''TB'' modifiers for claims with dates of service through December 31, 2024; and

(iii) Separately payable billing units in claim lines billed with the ''TB'' modifier for claims with dates of service on or after January 1, 2025.

(2) *Billing units with a rebate under section 1927 of the Social Security Act.* Subject to paragraph (b)(2)(i) of this section, CMS will exclude billing units from claims with dates of service during a month within an applicable calendar quarter if the units are furnished to a dually eligible Medicare beneficiary who has Medicaid coverage that may provide cost-sharing assistance.

(i) CMS will not exclude billing units from claims when the Medicare beneficiary has Medicaid coverage that does not include cost-sharing assistance, including Specified Low-Income Medicare Beneficiaries (SLMB), Qualified Disabled and Working Individuals (QDWI), and Qualifying Individuals (QI) beneficiaries.

(ii) [Reserved]

(3) *Billing units that are packaged into the payment amount for an item or service and are not separately payable.* CMS will exclude billing units that are packaged into the payment amount for an item or service and are not separately payable.

(4) *Billing units when a drug is no longer a Part B rebatable drug.* In situations where a Part B rebatable drug that is a single source drug becomes a multiple source drug during an applicable calendar quarter, CMS will:

(i) Determine if such drug has become a multiple source drug by reviewing FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (commonly known as the Orange Book) for a drug that is that is rated as therapeutically equivalent to such drug; and,

(ii) If a therapeutically equivalent drug is identified in accordance with paragraph (b)(4)(i) of this section, determine if the therapeutically equivalent drug was sold or marketed during the applicable calendar quarter; and

(iii) Exclude billing units of such drug furnished on and after the first day of the calendar month in which the therapeutically equivalent drug was first sold or marketed during the applicable calendar quarter.

(5) *Billing units subject to discarded drug refunds.* CMS will exclude billing units of discarded refundable single-dose container or single-use package drugs for which a refund has been paid in accordance with § 414.940 of this chapter from the calculation of rebate amounts. For applicable calendar quarters beginning on or after January 1, 2024, these billing units will be excluded as part of the reconciliation process described at § 427.501(d).

§ 427.304 Adjustments for changes to billing and payment codes.

(a) *Changes in billing unit dose description.* If there has been a change to the dose description for a Part B rebatable drug (causing a new billing and payment code to be assigned), CMS will calculate a conversion factor based on the ratio of the billing unit dose description for the current billing and payment code to the billing unit dose description for the prior billing and payment code. CMS will apply the conversion factor to the payment amount in the payment amount benchmark quarter, as described in § 427.302(d), before applying the percentage by which the rebate period CPI–U for the calendar quarter exceeds the benchmark period CPI–U.

(b) *Instances when a new billing and payment code is assigned.* If a new billing and payment code is assigned for a Part B rebatable drug, CMS will use the payment amount in the payment amount benchmark quarter, the payment amount benchmark quarter, and the benchmark quarter CPI–U of the prior billing and payment code to calculate the per unit Part B rebate amount under § 427.302.

(c) *Documentation.* CMS will maintain a crosswalk reflecting the changes in billing and payment codes and dose descriptions as applicable.

Subpart E—Reducing the Rebate Amount for Part B Rebatable Drugs in Shortage and When There Is a Severe Supply Chain Disruption

§ 427.400 Definitions.

As used in this subpart, the following definitions apply:

Currently in shortage means that at least one NDC–10 assigned to the billing and payment code of a Part B rebatable drug with the status ''currently in shortage'' is on a shortage list maintained by the FDA under section 506E of the FD&C Act.

Drug shortage or *shortage* means a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug (see section 506C(h)(2) of the FD&C Act).

Natural disaster means any natural catastrophe, including, but not limited to any of the following: hurricane, tornado, storm, high water, wind-driven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, snowstorm, or drought, or regardless of cause, any fire, flood, or explosion.

Other unique or unexpected event means any exogenous, unpredictable event outside of a manufacturer's control, including, but not limited to, a geopolitical disruption, pandemic, or act of terror.

Plasma-derived product means a licensed biological product that is derived from human whole blood or plasma, as indicated on the approved product labeling.

Severe supply chain disruption means a change in production or distribution that is reasonably likely to lead to a significant reduction in the U.S. supply of a Part B rebatable biosimilar biological product by a manufacturer and significantly affects the ability of the manufacturer of the biosimilar biological product to fill orders or meet expected demand for its product in the United States for at least 90 days. This definition does not include interruptions in manufacturing due to matters such as routine maintenance, manufacturing quality issues, or insignificant changes made in the manufacturing process for the drug.

§ 427.401 Reducing the rebate amount for Part B rebatable drugs currently in shortage.

(a) *General.* As required under section 1847A(i)(3)(G)(i) of the Act, CMS will reduce the total rebate amount calculated under § 427.301(a), if any is owed, for a Part B rebatable drug that is currently in shortage, as defined in § 427.400, at any point during the applicable calendar quarter.

(b) *Calculation of the reduced rebate amount.* (1) For each applicable calendar quarter beginning on or after January 1, 2023, the reduced total rebate amount for a Part B rebatable drug currently in shortage will be calculated using the following formula:

Equation 1 to Paragraph (b)(1)

Reduced Total Rebate Amount = the total rebate amount multiplied by (1 *minus* applicable percent reduction) multiplied by (percentage of time drug was currently in shortage during the applicable calendar quarter) added to the total rebate amount multiplied by (1 *minus* percentage of time drug was currently in shortage during the applicable calendar quarter)

(2) For purposes of paragraph (b)(1) of this section, the applicable percent reduction is:

(i) For a Part B rebatable drug that is a plasma-derived product:

(A) 75 percent for the first 4 consecutive applicable calendar quarters such drug is currently in shortage.

(B) 50 percent for the second 4 consecutive applicable calendar quarters such drug is currently in shortage.

(C) 25 percent for each subsequent applicable calendar quarter such drug is currently in shortage.

(ii) For a Part B rebatable drug that is not a plasma-derived product:

(A) 25 percent for the first 4 consecutive applicable calendar quarters such drug is currently in shortage.

(B) 10 percent for the second 4 consecutive applicable calendar quarters such drug is currently in shortage.

(C) 2 percent for each subsequent applicable calendar quarter such drug is currently in shortage.

(3) For purposes of paragraph (b)(1) of this section, the percentage of time the drug is currently in shortage during the applicable calendar quarter is equal to the number of days such drug is currently in shortage in an applicable calendar quarter, divided by the total number of days in the applicable calendar quarter.

(c) *Application of reduction.* CMS will apply a reduction of the rebate amount as determined under paragraph (b) of this section to all the NDCs under the relevant billing and payment code.

§ 427.402 Reducing the rebate amount for certain Part B rebatable drugs when there is a severe supply chain disruption.

(a) *General.* As required under section 1847A(i)(3)(G)(ii) of the Act, CMS will reduce the total rebate amount calculated under § 427.301(a), if any is owed, for a Part B rebatable biosimilar biological product when CMS determines there is a severe supply chain disruption during the applicable calendar quarter such as that caused by a natural disaster or other unique or unexpected event.

(b) *Calculation of the reduced rebate amount*—(1) *Initial reduction.* If CMS determines the criteria described in paragraph (c)(4) of this section are met, then CMS will reduce the total rebate amount owed by the manufacturer for a Part B rebatable biosimilar biological product by 75 percent for the quarter in which the event occurred and the 3 subsequent applicable calendar quarters.

(2) *Extension of reduction.* If CMS determines a severe supply chain disruption continues into a fifth applicable calendar quarter as described in paragraph (c)(5) of this section, then CMS will reduce the total rebate amount owed by the manufacturer for a Part B rebatable biosimilar biological product by 75 percent for that fifth quarter and an additional 3 consecutive applicable calendar quarters.

(3) *Application of reduction.* If CMS determines there is a severe supply chain disruption for an NDC–11 assigned to a billing and payment code, CMS will apply any reduction of the rebate amount as described in paragraphs (b)(1) and (2) of this section to all the NDCs under the relevant billing and payment code.

(4) *Limitation on rebate reductions.* CMS will not apply multiple rebate reductions for the same Part B rebatable drug and applicable calendar quarter.

(i) If a manufacturer believes there are multiple events causing severe supply chain disruptions during the same 4 applicable calendar quarters for the same Part B rebatable biosimilar biological product and submits multiple rebate reduction requests for the same product, CMS will grant no more than 1 rebate reduction under paragraph (b)(1) or (2) of this section for that product for those consecutive applicable calendar quarters.

(ii) If CMS grants a rebate reduction request under this section, and the Part B rebatable biosimilar biological product subject to the reduction is currently in shortage during the same four applicable calendar quarters as the ones for which the severe supply chain disruption reduction request was granted, CMS will reduce the rebate amount as described in paragraph (b)(1) of this section and will not grant a reduction under § 427.401 during those applicable calendar quarters.

(iii) If a Part B rebatable biosimilar biological product that is currently in shortage experiences a severe supply chain disruption, CMS will reduce the rebate amount as described in paragraph (b)(1) of this section and will not grant a reduction under § 427.401 during those applicable calendar quarters.

(c) *Eligibility for a rebate reduction*—(1) *Eligible drug.* Subject to paragraph (b)(3) of this section, eligibility for a rebate reduction under this section is limited to Part B rebatable biosimilar biological products for which a manufacturer submits a rebate reduction request under this section.

(2) *Timing.* For a natural disaster or other unique or unexpected event occurring on or after August 2, 2024, that the manufacturer believes caused a severe supply chain disruption, the manufacturer must submit the rebate reduction request within 60 calendar days from the first day that the natural disaster or other unique or unexpected event occurred or began in order to receive consideration for a reduction in the rebate amount owed in accordance with paragraph (b)(1) of this section.

(3) *Required elements of a rebate reduction request.* To receive consideration for a reduction in the rebate amount owed in accordance with paragraph (b)(1) of this section, the manufacturer must submit to CMS information and supporting documentation to substantiate the evaluation criteria described in paragraph (c)(4) of this section. Such information and supporting documentation include the following:

(i) Evidence that the severe supply chain disruption directly affects the manufacturer itself, a supplier of an ingredient or packaging, a contract manufacturer, or a method of shipping or distribution that the manufacturer uses to make or distribute the Part B rebatable biosimilar biological product(s), such as a change in the production or distribution of the Part B rebatable biosimilar biological product(s) that is reasonably likely to lead to a significant reduction in the U.S. supply of product and significantly affects the manufacturer's ability to fill orders or meet expected demand for the Part B rebatable biosimilar biological product(s) for at least 90 days;

(ii) Information about when the manufacturer expects supply of the Part B rebatable biosimilar biological product(s) to meet expected demand;

(iii) Evidence that the natural disaster or other unique or unexpected event caused the severe supply chain disruption, including when the natural disaster or other unique or unexpected event occurred or began occurring, and the expected or actual duration of the severe supply chain disruption; and

(iv) Evidence of the manufacturer's physical presence related to manufacturing the Part B rebatable biosimilar biological product(s) in a geographic area where a natural disaster or other unique or unexpected event occurred. If the manufacturer is not physically present in a geographic area where a natural disaster or other unique or unexpected event occurred, but believes there is a severe supply chain disruption caused by a natural disaster or other unique or unexpected event that affects the manufacturer's Part B rebatable biosimilar biological product(s), the information and supporting documentation may include evidence of the impact of the natural disaster or other unique or unexpected event on the supply chain of the Part B rebatable drug or biosimilar, on a supplier of an ingredient or packaging, or method of shipping or distribution that the manufacturer uses.

(4) *Evaluation criteria.* In accordance with paragraph (b)(1) of this section, CMS will grant a reduction in the rebate amount owed if a manufacturer submits to CMS a request in writing for an eligible drug, in accordance with the timing specified in paragraph (c)(2) of this section, demonstrating that:

(i) A severe supply chain disruption has occurred during the applicable calendar quarter;

(ii) The severe supply chain disruption directly affects the manufacturer itself, a contract manufacturer, a supplier of an ingredient or packaging, or a method of shipping or distribution that the manufacturer uses in a significant capacity to make or distribute the Part B rebatable biosimilar biological product; and

(iii) The severe supply chain disruption was caused by a natural disaster or other unique or unexpected event.

(5) *Rebate reduction extensions.* If CMS determines that a Part B rebatable biosimilar biological product that received a reduction of the rebate amount under paragraph (b)(1) of this section continues to be affected by a severe supply chain disruption, CMS will grant a single extension of the reduction for 4 additional consecutive applicable calendar quarters and reduce the rebate amount owed in accordance with paragraph (b)(2) of this section.

(i) To receive consideration for a rebate reduction extension, a manufacturer must submit a request with updated or new information and supporting documentation on why the Part B rebatable biosimilar biological product continues to be affected by the severe supply chain disruption during the fifth through eighth applicable calendar quarters.

(ii) A manufacturer must submit the rebate reduction extension request at least 60 calendar days before the start of the fifth applicable calendar quarter to receive consideration for a reduction in the rebate amount owed, if any, in accordance with paragraph (b)(2) of this section.

(6) *Decision to grant or deny a request.* CMS will review rebate reduction requests and rebate reduction extension requests within 60 calendar days of receipt of all documentation, if feasible, beginning with the applicable calendar quarter that begins on October 1, 2024.

(i) CMS will deny a rebate reduction request that does not meet the criteria in paragraph (c)(4) of this section or that is incomplete or untimely based on the requirements of this paragraph (c).

(ii) CMS will deny a rebate reduction extension request that does not meet the criteria in paragraph (c)(5) of this section, that is incomplete or untimely based on the requirements of paragraph (c)(5), or if a reduction under paragraph (b)(1) of this section was not provided for such biosimilar biological product.

(iii) CMS' decisions to deny a request are final and will not be subject to an appeals process.

(7) *Public disclosure of information.* CMS will keep confidential, to the extent allowable under law, any requests for a rebate reduction, including supporting documentation. Information provided as part of a request for a rebate reduction that the submitter indicates is a trade secret or confidential commercial or financial information will be protected from disclosure if CMS determines the information meets the requirements set forth under Exemptions 3 and/or 4 in 5 U.S.C. 552.

Subpart F—Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments

§ 427.500 Definitions.

As used in this subpart, *date of receipt* is the calendar day following the day on which a report of a rebate amount (as set forth in §§ 427.501(b) through (d) and 427.502(c)) is made available to the manufacturer of a Part B rebatable drug by CMS.

§ 427.501 Rebate Reports and reconciliation.

(a) *General.* This section applies to Part B rebatable drugs for all applicable calendar quarters except as otherwise

set forth in § 427.502 regarding the applicable calendar quarters in calendar years 2023 and 2024.

(b) *Preliminary Rebate Report.* A Preliminary Rebate Report will be provided to each manufacturer of a Part B rebatable drug at least 1 month prior to the issuance of the Rebate Report as set forth in paragraph (c) of this section for an applicable calendar quarter.

(1) The Preliminary Rebate Report for each Part B rebatable drug will include the following information:

(i) The NDC(s) and billing and payment codes for the Part B rebatable drug as defined under § 427.20.

(ii) Total number of billing units as specified in § 427.303.

(iii) Payment amount in the payment amount benchmark quarter as specified in § 427.302(d).

(iv) Applicable calendar quarter specified amount as specified in § 427.302(b).

(v) Applicable benchmark period and rebate period CPI–Us as specified in § 427.302(e) and (f).

(vi) Inflation-adjusted payment amount as specified in § 427.302(g).

(vii) The amount, if any, by which the specified amount as described in § 427.302(b) exceeds the inflation-adjusted payment amount as described in § 427.302(g) for the Part B rebatable drug for the applicable calendar quarter as determined under § 427.302.

(viii) Any applied reductions as described in §§ 427.401 and 427.402.

(ix) Rebate amount due as specified in § 427.301(a).

(2) [Reserved]

(c) *Rebate Report.* A Rebate Report will be provided to each manufacturer of a Part B rebatable drug no later than 6 months after the end of each applicable calendar quarter.

(1) The Rebate Report will include the information specified in paragraph (b)(1) of this section, with the inclusion of any revisions to such information resulting from CMS' review of a Suggestion of Error as set forth in § 427.503, if applicable, and any CMS-determined recalculations from paragraph (d)(2) of this section.

(2) The Rebate Report is the invoice of a manufacturer's rebate amount due as calculated in § 427.301, if any, for a Part B rebatable drug for an applicable calendar quarter.

(d) *Reconciliation of the rebate amount.* CMS will perform reconciliation of a rebate amount provided in a Rebate Report specified in paragraph (c) of this section for an applicable calendar quarter in the following circumstances:

(1) *Regular reconciliation.* Except as otherwise described in § 427.502, CMS will perform one regular reconciliation of the rebate amount within 12 months of the date of receipt of the Rebate Report specified in paragraph (c) of this section for each applicable calendar quarter in order to include revisions to the information used to calculate the rebate amount as specified in paragraph (b)(1) of this section.

(i) *Preliminary reconciliation.* At least 1 month prior to the issuance of a report with the reconciled rebate amount specified in paragraph (d)(1)(ii) of this section, CMS will conduct a preliminary reconciliation of a rebate amount for an applicable calendar quarter specified in paragraph (d)(3) of this section based on the information specified in this paragraph (b)(1)(i) and paragraphs (d)(1)(ii) through (ix) of this section and provide the information specified in this paragraph (b)(1)(i) and paragraphs (d)(1)(ii) through (ix) to the manufacturer of a Part B rebatable drug for the applicable calendar quarter, if applicable:

(A) Updated total number of rebatable units, as specified in § 427.303.

(B) Payment amount in the payment amount benchmark quarter, as specified in § 427.302(d) if any inputs are restated within the reconciliation run-out period.

(C) Applicable calendar quarter specified amount as specified in § 427.302(b), if any inputs are restated within the reconciliation run-out period.

(D) The excess amount by which the specified amount exceeds the inflation-adjusted payment amount as specified in § 427.302, if any inputs are restated within the reconciliation run-out period.

(E) Reconciled total rebate amount as specified in § 427.301(a).

(F) The difference between the total rebate amount due as specified on the Rebate Report set forth in paragraph (c) of this section and the reconciled rebate amount as set forth in this paragraph (d)(1)(i).

(ii) *Report with reconciled rebate amount.* With the inclusion of any additional revisions to such information resulting from CMS' review of a Suggestion of Error as set forth in § 427.503, if applicable, a report with the reconciled rebate amount will be provided to each manufacturer of a Part B rebatable drug within 12 months after the issuance of the Rebate Report described in paragraph (c) of this section.

(2) *CMS identification of error and manufacturer misreporting.* CMS may recalculate a rebate amount and provide the manufacturer of a Part B rebatable drug a report with a reconciled rebate amount when:

(i) CMS identifies an agency error in the information specified in paragraphs (c) and (d)(1) of this section, including reporting system or coding errors, not later than 3 years from the date of receipt by a manufacturer of a reconciled rebate amount for the applicable calendar quarter; or

(ii) CMS determines at any time that the information used by CMS to calculate the rebate amount was inaccurate due to manufacturer misreporting.

(3) *Impact of reconciliation on rebate amount.* A reconciliation as set forth in this paragraph (d) could result in an increase, decrease, or no change to the rebate amount as calculated in § 427.301 owed by a manufacturer for the applicable calendar quarter for the Part B rebatable drug.

(i) A report with a reconciled rebate amount that is an increase to the rebate amount is the invoice for such additional amount due on the manufacturer's rebate amount as set forth in § 427.301 for a Part B rebatable drug for an applicable calendar quarter.

(ii) [Reserved]

(4) *Drugs included in a reconciliation.* A drug covered under Part B that does not meet the requirements of a rebatable drug specified in subpart B for an applicable period will not be included in a reconciliation under this paragraph (d).

§ 427.502 Rebate Reports for applicable calendar quarters in calendar years 2023 and 2024.

(a) *Transition rule for reporting.* Section 1847A(i)(1)(C) of the Act allows CMS to delay the timeframe for reporting the information and rebate amount described in § 427.501(c) for applicable calendar quarters in calendar years 2023 and 2024 until not later than September 30, 2025.

(b) *Rebate Report information for applicable calendar quarters in calendar years 2023 and 2024.* The Rebate Reports for applicable calendar quarters in calendar years 2023 and 2024 will include the information described in § 427.501(b)(1).

(c) *Rebate Report procedures for applicable calendar quarters in calendar years 2023 and 2024.* Rebate amounts for the applicable calendar quarters in calendar year 2023 and 2024 will be reported as follows:

(1) The four applicable calendar quarters in calendar year 2023 will be consolidated into a single report and manufacturers will receive a single Preliminary Rebate Report followed by a single Rebate Report.

(i) Discarded drug units for which a refund has been paid will be removed from the total number of billing units in the single Preliminary Rebate Report for the applicable calendar quarters in calendar year 2023.

(ii) For this single Preliminary Rebate Report for the applicable calendar quarters in calendar year 2023, the Suggestion of Error period as described in § 427.503 will be 30 calendar days.

(iii) No regular reconciliation of the rebate amount as described in § 427.501(d)(1) will be conducted for the rebate amount in the single Rebate Report for the applicable calendar quarters in calendar year 2023.

(2) The four applicable calendar quarters in calendar year 2024 will be consolidated into a single report and manufacturers will receive a single Preliminary Rebate Report followed by a single Rebate Report.

(i) For this single Preliminary Rebate Report for the applicable calendar quarters in calendar year 2024, the Suggestion of Error period as described in § 427.503 will be 30 calendar days.

(ii) Nine months after issuance of the single Rebate Report, CMS will perform one regular reconciliation for the applicable calendar quarters in calendar year 2024 in order to include revisions to the information used, specified in § 427.501(b)(1), to calculate the rebate amount. Such reconciliation will be as described in § 427.501(d) inclusive of a preliminary reconciliation and a report with the reconciled rebate amount.

(iii) The Suggestion of Error period for the preliminary reconciliation for the applicable calendar quarters in calendar year 2024 will be 10 calendar days.

§ 427.503 Suggestion of Error.

(a) *General.* The manufacturer of a Part B rebatable drug may submit a Suggestion of Error about the information in their Preliminary Rebate Report and the report detailing the preliminary reconciliation of the rebate amount to CMS, for its discretionary consideration, if the manufacturer believes that there is a mathematical error or errors to be corrected before the Rebate Report or a subsequent reconciliation of the rebate amount, as applicable, is finalized.

(1) Section 1847A(i)(8) of the Act precludes administrative or judicial review on the determination of units as set forth in § 427.303, the determination of whether a drug is a Part B rebatable drug as set forth in§ 427.101, and the calculation of the rebate amount as set forth in § 427.301, inclusive of any reconciled rebate amount.

(2) [Reserved]

(b) *Process of submission.* Subject to the scope and timing requirements specified in paragraphs (a) and (c) of this section, manufacturers may submit the Suggestion of Error and provide supporting documentation (if applicable).

(c) *Timing.* Except as specified in § 427.502 for applicable calendar quarters in calendar year 2023 and 2024, a manufacturer must submit its Suggestion of Error for the applicable calendar quarter within 10 calendar days from the date of receipt of a Preliminary Rebate Report or a preliminary reconciliation of a rebate amount using the method and process established by CMS in paragraph (b) of this section.

(d) *Notice.* (1) CMS will include any revisions to the calculation of the rebate amount, if determined necessary by CMS based on the Suggestion of Error submitted under this section prior to issuance of the Rebate Report as set forth in § 427.501(c) or § 427.502(c) as well as any report of reconciled rebate amount as set forth in § 427.501(d) or § 427.502(c)(2)(ii).

(2) CMS will notify the manufacturer whether CMS revised its calculation of the rebate amount based on the Suggestion of Error.

§ 427.504 Manufacturer access to Rebate Reports.

(a) *General.* CMS will establish a method and process for a manufacturer of the Part B rebatable drug to:

(1) Access the manufacturer's Rebate Report as set forth in §§ 427.501 and 427.502, including any report of reconciled rebate amount as set forth in §§ 427.501(d) and 427.502(c)(2)(ii);

(2) Submit a Suggestion of Error as set forth in §§ 427.502(c)(1)(ii) and (c)(2)(i) and 427.503; and

(3) Pay a rebate amount as set forth in § 427.505.

(b) [Reserved]

§ 427.505 Deadline and process for payment of rebate amount.

(a) *Rebate amounts owed by a manufacturer.* For a rebate amount owed by a manufacturer, payment is due no later than 11:59 p.m. Pacific Time (PT) on the 30th calendar day after the date of receipt of information regarding the rebate amount on—

(1) A Rebate Report specified in § 427.501(c) or § 427.502(c)(1) or (2); or

(2) A report of a reconciled rebate amount specified in § 427.501(d) or § 427.502(c)(2)(ii).

(b) *Failure to pay a rebate amount.* Failure to pay a rebate amount due timely and in full may result in an enforcement action as described in subpart G of this part.

(c) *Refund to the manufacturer.* If a reconciled rebate amount for an applicable calendar quarter as specified in § 427.501(d) or § 427.502(c)(2)(ii) is less than what the manufacturer paid for that applicable calendar quarter, CMS will initiate the process to provide a refund equal to the excess amount paid within 60 days of the date of receipt of the report with such reconciled rebate amount.

Subpart G—Enforcement of Manufacturer Payment of Rebate Amounts

§ 427.600 Civil money penalty notice and appeals procedures.

(a) *General.* CMS may impose a civil money penalty on a manufacturer that fails to pay the rebate amount set forth in § 427.301(a) on a Part B rebatable drug identified at § 427.101, by the payment deadline as set forth in § 427.505(a) for such drug for such applicable calendar quarter.

(b) *Determination of the civil money penalty amount.* CMS may impose a civil money penalty for each failure by a manufacturer to provide an inflation rebate for an applicable calendar quarter equal to 125 percent of the rebate amount determined in § 427.301(a).

(1) The civil money penalty is in addition to the rebate amount due.

(2) If a reconciled rebate amount as set forth in § 427.501(d) or § 427.502(c)(2)(ii) results in an increase to the rebate amount due, a separate civil money penalty may be imposed for the failure by a manufacturer to provide an inflation rebate for the applicable quarter for the increase to the rebate amount due.

(c) *Notice of imposition of civil money penalties.* If CMS makes a determination to impose a civil money penalty described in paragraph (b) of this section, CMS will send a written notice of its decision to impose a civil money penalty to include the following:

(1) A description of the basis for the determination.

(2) The basis for the penalty.

(3) The amount of the penalty.

(4) The date the penalty is due.

(5) The manufacturer's right to a hearing as specified in paragraph (e)(3) of this section.

(6) Information about where to file the request for a hearing.

(d) *Collection.* (1) A manufacturer must pay the civil money penalty in full within 60 calendar days after the date of the notice of imposition of a civil money penalty from CMS under paragraph (c) of this section.

(2) In the event a manufacturer requests a hearing, pursuant to 42 CFR

part 423, subpart T, the manufacturer must pay the amount in full within 60 calendar days after the date of a final decision by the Departmental Appeal Board, to uphold, in whole or in part, the civil money penalty.

(3) If the 60th calendar day described in paragraphs (d)(1) and (2) of this section is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(e) *Appeal procedures for civil money penalties.* Section 1128A(c)(2) of the Act provides that CMS may not collect a civil money penalty until the affected party has had notice and the opportunity for a hearing.

(1) Manufacturers may appeal the following determinations:

(i) A CMS determination that the rebate amount was not paid by the applicable payment deadline as described in § 427.505.

(ii) The calculation of the amount of the civil money penalty.

(2) The notice provided to a manufacturer if CMS decides to impose a civil money penalty is paragraph (c) of this section.

(3) A manufacturer has a right to a hearing following a decision by CMS to impose a civil money penalty following the administrative appeal process and procedures established in 42 CFR part 423, subpart T.

(f) *Other applicable provisions.* The provisions of section 1128A of the Act (except subsections (a) and (b) of section 1128A of the Act) apply to civil money penalties under this section to the same extent that they apply to a civil money penalty or procedures under section 1128A of the Act.

(g) *Bankruptcy.* In the event that a manufacturer declares bankruptcy, as described in title 11 of the United States Code, and as a result of the bankruptcy, fails to pay either the full rebate amount owed or the total sum of civil money penalties imposed, the Government reserves the right to file a proof of claim with the bankruptcy court to recover the unpaid amount of the rebates and civil money penalties owed by the manufacturer.

■ 81. Part 428 is added to read as follows:

PART 428—MEDICARE PART D DRUG INFLATION REBATE PROGRAM

Subpart A—General Provisions

Sec.

428.10 Basis and scope.
428.20 Definitions.

Subpart B—Determination of Part D Rebatable Drugs

428.100 Definitions.
428.101 Identification of Part D rebatable drugs.

Subpart C—Determination of the Rebate Amount for Part D Rebatable Drugs

428.200 Definitions.
428.201 Calculation of the total rebate amount to be paid by manufacturers.
428.202 Calculation of the per unit Part D drug rebate amount.
428.203 Determination of the total number of units dispensed under Part D.
428.204 Treatment of new formulations of Part D rebatable drugs.

Subpart D—Reducing the Rebate Amount for Part D Rebatable Drugs in Shortage and When There is a Severe Supply Chain Disruption or Likely Shortage

428.300 Definitions.
428.301 Reducing the rebate amount for Part D rebatable drugs currently in shortage.
428.302 Reducing the rebate amount for certain Part D rebatable drugs when there is a severe supply chain disruption.
428.303 Reducing the rebate amount for generic Part D rebatable drugs likely to be in shortage.

Subpart E—Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments

428.400 Definitions.
428.401 Rebate Reports and reconciliation.
428.402 Rebate Reports for applicable periods beginning October 1, 2022, and October 1, 2023.
428.403 Suggestion of Error.
428.404 Manufacturer access to Rebate Reports.
428.405 Deadline and process for payment of rebate amount.

Subpart F—Enforcement of Manufacturer Payment of Rebate Amounts

428.500 Civil money penalty notice and appeals procedures.

Authority: 42 U.S.C. 1395w–114b, 1302, and 1395hh.

Subpart A—General Provisions

§ 428.10 Basis and scope.

(a) *Basis.* This part implements section 1860D–14B of the Social Security Act (''the Act'').

(b) *Scope.* This part sets forth the requirements of the Medicare Part D Drug Inflation Rebate Program, which requires, for each 12-month applicable period, manufacturers to pay rebates for certain drugs and biological products with prices that increase faster than the rate of inflation.

(c) *Severability.* Were any provision of this part to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, such provisions would be severable from this part and the invalidity or unenforceability would not affect the remainder thereof or any other part of this subchapter or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances.

§ 428.20 Definitions.

As used in this part, the following definitions apply:

Annual manufacturer price (AnMP) refers to the amount calculated in § 428.202(b).

Applicable period means a 12-month period beginning with October 1 of a year (beginning with October 1, 2022).

Applicable period Consumer Price Index for All Urban Consumers (CPI–U) means, with respect to an applicable period, the CPI–U for the first month of such applicable period (that is, October).

Applicable threshold means the amount calculated in accordance with § 428.101(b)(2).

Average manufacturer price (AMP) means the average price paid to the manufacturer for the drug by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer, calculated in accordance with § 447.504 of this chapter.

Benchmark period CPI–U means the CPI–U identified in § 428.202(e).

Benchmark period manufacturer price refers to the amount calculated in § 428.202(d).

Covered Part D Drug has the meaning set forth in section 1860D–2(e) of the Act and § 423.100 of this chapter.

CPI–U means the monthly Consumer Price Index for All Urban Consumers (United States city average) index level for all items from the Bureau of Labor Statistics.

First marketed date means the date that a manufacturer is required to report for a Part D rebatable drug as its ''market date'' under section 1927(b)(3)(A)(v) of the Act.

Inflation-adjusted payment amount means the amount calculated in § 428.202(f).

Manufacturer has the meaning set forth in section 1927(k)(5) of the Act.

National Drug Code (NDC) means the unique identifying prescription drug product number that is listed with FDA identifying the product and package size and type.

Part D rebatable drug means, subject to the exclusion described in § 428.101(b), a drug or biological that is a covered Part D drug that, as of the first day of the applicable period, is:

(1) A drug approved under a New Drug Application (NDA) under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act;

(2) A generic drug approved under an Abbreviated New Drug Application

(ANDA) under section 505(j) of the FD&C Act (''section 505(j) ANDA''), in the case where:

(i) The reference listed drug approved under an NDA under section 505(c) of the FD&C Act, including any authorized generic drug as defined in section 505(t)(3) of the FD&C Act, is not being marketed, as identified in the Food and Drug Administration's (FDA) NDC Directory;

(ii) There is no other drug approved under section 505(j) of the FD&C Act that is rated as therapeutically equivalent in FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (commonly known as the Orange Book), and that is being marketed, as identified in FDA's NDC Directory;

(iii) The manufacturer is not a ''first applicant'' during the ''180-day exclusivity period,'' as those terms are defined in section 505(j)(5)(B)(iv) of the FD&C Act; and

(iv) The manufacturer is not a ''first approved applicant'' for a competitive generic therapy, as that term is defined in section 505(j)(5)(B)(v) of the FD&C Act; or

(3) A biological licensed under section 351 of the Public Health Service (PHS) Act, including a biosimilar.

Payment amount benchmark period means the period identified in § 428.202(c).

Subsequently approved drug means a Part D rebatable drug first approved or licensed by the FDA after October 1, 2021.

Unit means, with respect to a Part D rebatable drug, the lowest dispensable amount (such as a capsule or tablet, milligram of molecules, or grams) of the Part D rebatable drug, as reported under section 1927 of the Act.

Subpart B—Determination of Part D Rebatable Drugs

§ 428.100 Definitions.

As used in this subpart, the following definitions apply:

Individual who uses such a drug or biological means a unique Medicare Part D beneficiary who was dispensed the Part D drug or biological that was covered by their Part D plan sponsor during the applicable period, identified using Prescription Drug Event (PDE) data with dates of service during the applicable period and with gross covered prescription drug costs greater than zero.

Gross covered prescription drug costs has the meaning set forth in § 423.308 of this chapter.

§ 428.101 Identification of Part D rebatable drugs.

(a) *Determination of Part D rebatable drugs.* (1) For each applicable period, CMS will use PDE data to identify all covered Part D drugs.

(2) CMS will match the covered Part D drugs identified in the PDE data with application numbers using FDA sources to determine whether each covered Part D drug is a drug or biological approved under an NDA under section 505(c) of the FD&C Act, approved under an ANDA under section 505(j) of the FD&C Act, or licensed under a Biologics License Application (BLA) under section 351 of the PHS Act, as of the first day of the applicable period.

(3) For a covered Part D drug identified in the PDE that is approved under an ANDA under section 505(j) of the FD&C Act, CMS will determine whether such drug meets the criteria in section 1860D–14B(g)(1)(C)(ii) of the Act as of the first day of the applicable period as follows:

(i) To determine whether the reference listed drug or an authorized generic of the reference listed drug is being marketed, as required under section 1860D–14B(g)(1)(C)(ii)(I) of the Act, CMS will use FDA's NDC Directory, including historical information from NDC Directory files such as discontinued, delisted, and expired listings, provided by the FDA or published on the FDA website.

(ii) To determine whether another drug has been approved under an ANDA that is therapeutically equivalent to the Part D rebatable drug identified in this paragraph (a)(3), CMS will use FDA's Orange Book. To determine if this therapeutically equivalent drug is being marketed, as required under section 1860D–14B(g)(1)(C)(ii)(II) of the Act, CMS will use FDA's NDC Directory, including historical information from NDC Directory files, such as discontinued, delisted, and expired listings, provided by the FDA or published on the FDA website.

(iii) To determine whether the manufacturer of the drug identified in this paragraph (a)(3) is a first applicant during the 180-day exclusivity period, or whether the manufacturer of this drug is a first approved applicant for a competitive generic drug therapy, CMS will refer to publicly available FDA sources such as the Orange Book and may consult with FDA for technical assistance as needed.

(b) *Drugs and biologicals with average annual total cost below the applicable threshold.* For each applicable period, CMS will identify drugs and biologicals with average annual total costs under Part D for such applicable period, per individual who uses such drug or biological, that are below the applicable threshold in accordance with the steps described in this paragraph (b). Such drugs and biologicals are not considered Part D rebatable drugs and will be excluded from the identification of Part D rebatable drugs in paragraph (a) of this section.

(1) *Average annual total cost.* For each drug or biological that is identified in accordance with paragraph (a) of this section, CMS will calculate average annual total costs under Part D per individual who uses such drug or biological by dividing the gross covered prescription drug costs for the drug or biological by the number of individuals who use such drug or biological in the applicable period.

(2) *Applicable threshold.* CMS will calculate the applicable threshold for an applicable period as follows:

(i) For the applicable period beginning October 1, 2022, the applicable threshold is equal to $100.

(ii) For the applicable period beginning October 1, 2023, the applicable threshold is equal to $100 increased by the percentage increase in CPI–U for the 12-month period beginning October 1, 2023.

(iii) For subsequent applicable periods, the applicable threshold is equal to the applicable threshold for the prior applicable period increased by the percentage increase in the CPI–U for the 12-month period beginning with October of the previous period.

(iv) If the resulting amount under paragraph (b)(2)(ii) or (iii) of this section is not a multiple of $10, CMS will round that amount to the nearest multiple of $10.

Subpart C—Determination of the Rebate Amount for Part D Rebatable Drugs

§ 428.200 Definitions.

As used in this subpart, the following definitions apply:

340B Program is the program under section 340B of the PHS Act.

Line extension has the meaning set forth in § 447.502 of this chapter.

New formulation has the meaning set forth in § 447.502 of this chapter.

Oral solid dosage form has the meaning set forth in § 447.502 of this chapter.

§ 428.201 Calculation of the total rebate amount to be paid by manufacturers.

(a) *Total rebate.* (1) Subject to paragraph (b) of this section, the total rebate amount to be paid by a manufacturer for a Part D rebatable drug, as identified under § 428.101, for an applicable period is equal to:

(i) The product of the per unit Part D rebate amount of such drug, as determined under § 428.202(a), and the total number of units dispensed of such drug under Part D, as determined under § 428.203; or

(ii) In the case of a Part D rebatable drug that is a line extension of a Part D rebatable drug that is an oral solid dosage form, the amount specified in § 428.204.

(2) The rebate amount may be reduced in accordance with subpart D of this part or adjusted in accordance with subpart E of this part.

(b) *Drugs and biologicals excluded from Part D rebate calculations.* CMS will exclude from the Part D drug inflation rebate calculations described in this subpart—

(1) Drugs and biologicals that meet the definition of a Part D rebatable drug but whose manufacturers do not have an agreement in effect with the HHS Secretary under section 1927 of the Act at any point during the applicable period, as determined by CMS through consultation with Medicaid Drug Rebate Program staff and review of the Medicaid Drug Programs system.

(2) Drugs and biologicals that meet the definition of a Part D rebatable drug but, for the entire duration of the applicable period, are excluded from the definition of covered outpatient drugs as defined in section 1927(k)(2)–(4) of the Act and § 447.502 of this chapter, as determined by CMS through consultation with Medicaid Drug Rebate Program staff and review of the Medicaid Drug Programs system.

§ 428.202 Calculation of the per unit Part D drug rebate amount.

(a) *Formula for calculating the per unit Part D rebate amount.* CMS will calculate the per unit Part D drug inflation rebate amount for a Part D rebatable drug and applicable period by determining the amount by which the AnMP for the Part D rebatable drug, as calculated in accordance with paragraph (b) of this section, exceeds the inflation-adjusted payment amount, as calculated in accordance with paragraph (f) of this section.

(b) *Calculation of the AnMP for the applicable period.* Subject to paragraph (g) of this section, CMS will calculate the AnMP for a Part D rebatable drug using the AMP reported by a manufacturer under sections 1927(b)(3)(A)(i) and (ii) of the Act for each calendar quarter of the applicable period and units reported by a manufacturer under section 1927(b)(3)(A)(iv) of the Act for each month of the applicable period.

(1) CMS will calculate the AnMP for a Part D rebatable drug as the sum of the following:

(i) The product of—

(A) The AMP for the Part D rebatable drug reported for the calendar quarter beginning October of the applicable period; and

(B) The sum of the monthly units reported for the calendar quarter beginning October of the applicable period divided by the sum of the monthly units reported for the 4 calendar quarters in the applicable period.

(ii) The product of—

(A) The AMP for the Part D rebatable drug reported for the calendar quarter beginning January of the applicable period; and

(B) The sum of the monthly units reported for the calendar quarter beginning January of the applicable period divided by the sum of the monthly units reported for the 4 calendar quarters in the applicable period.

(iii) The product of—

(A) The AMP for the Part D rebatable drug reported for the calendar quarter beginning April of the applicable period; and

(B) The sum of the monthly units reported for the calendar quarter beginning April of the applicable period divided by the sum of the monthly units reported for the 4 calendar quarters in the applicable period.

(iv) The product of—

(A) The AMP for the Part D rebatable drug reported for the calendar quarter beginning July of the applicable period; and

(B) The sum of the monthly units reported for the calendar quarter beginning July of the applicable period divided by the sum of the monthly units reported for the 4 calendar quarters in the applicable period.

(2) The first applicable period for a Part D rebatable drug will be the earliest applicable period that follows the payment amount benchmark period identified in paragraphs (c)(1) through (4) of this section.

(c) *Identification of the payment amount benchmark period.* For each Part D rebatable drug, CMS will identify the payment amount benchmark period using the date of FDA approval or licensure or the first marketed date as set forth in paragraphs (c)(1) and (2) of this section, subject to paragraphs (c)(3) through (5) of this section:

(1) For a Part D rebatable drug first approved or licensed by the FDA on or before October 1, 2021, the payment amount benchmark period is the period beginning on January 1, 2021, and ending on September 30, 2021;

(2) For a subsequently approved drug, the payment amount benchmark period is the first calendar year beginning after the drug's first marketed date;

(3) Notwithstanding paragraph (c)(2) of this section, for a Part D rebatable drug first approved or licensed by the FDA on or before October 1, 2021, for which there are no quarters during the period beginning on January 1, 2021, and ending on September 30, 2021, for which AMP has been reported under section 1927(b)(3) of the Act, the payment amount benchmark period is the first calendar year no earlier than calendar year 2021 in which such drug has at least 1 quarter of AMP reported;

(4) Notwithstanding paragraph (c)(3) of this section, for a subsequently approved drug for which there are no quarters during the first calendar year beginning after the drug's first marketed date for which AMP has been reported under section 1927(b)(3) of the Act, the payment amount benchmark period is the first calendar year in which such drug has at least 1 quarter of AMP reported; and

(5) Notwithstanding paragraph (c)(4) of this section, for a Part D rebatable drug that is a selected drug (as defined in section 1192(c) of the Act) with respect to a price applicability period (as defined in section 1191(b)(2) of the Act), in the case such Part D rebatable drug is no longer considered to be a selected drug, for each applicable period beginning after the price applicability period with respect to such drug, the payment amount benchmark period is the last calendar year of such price applicability period with respect to such selected drug.

(d) *Calculation of benchmark period manufacturer price.* Subject to paragraph (g) of this section, CMS will calculate the benchmark period manufacturer price for a Part D rebatable drug using the AMP reported by a manufacturer under sections 1927(b)(3)(A)(i) and (ii) of the Act for each calendar quarter of the payment amount benchmark period and the monthly units reported by a manufacturer under section 1927(b)(3)(A)(iv) of the Act during the payment amount benchmark period.

(1) For a Part D rebatable drug with a payment amount benchmark period identified under paragraph (c)(1) of this section, CMS will calculate the benchmark period manufacturer price as the sum of the following:

(i) The product of—

(A) The AMP reported for the calendar quarter beginning January 2021; and

(B) The sum of the monthly units reported for the calendar quarter beginning January 2021 divided by the sum of the monthly units reported for the 3 quarters of the payment amount benchmark period.

(ii) The product of—

(A) The AMP reported for the calendar quarter beginning April 2021; and

(B) The sum of the monthly units reported for the calendar quarter beginning April 2021 divided by the sum of the monthly units reported for the 3 quarters of the payment amount benchmark period.

(iii) The product of—

(A) The AMP reported for the calendar quarter beginning July 2021; and

(B) The sum of the monthly units reported for the calendar quarter beginning July 2021 divided by the sum of the units reported for the 3 quarters of the payment amount benchmark period.

(2) For a Part D rebatable drug with a payment amount benchmark period identified under paragraphs (c)(2) through (5) of this section, CMS will calculate the benchmark period manufacturer price as the sum of the following:

(i) The product of—

(A) The AMP reported for the calendar quarter beginning January of the payment amount benchmark period; and

(B) The sum of the monthly units reported for the calendar quarter beginning January of the payment amount benchmark period divided by the sum of the monthly units reported for the 4 quarters of the payment amount benchmark period.

(ii) The product of—

(A) The AMP reported for the calendar quarter beginning April of the payment amount benchmark period; and

(B) The sum of the monthly units reported for the calendar quarter beginning April of the payment amount benchmark period divided by the sum of the monthly units reported for the 4 quarters of the payment amount benchmark period.

(iii) The product of—

(A) The AMP reported for the calendar quarter beginning July of the payment amount benchmark period; and

(B) The sum of the monthly units reported for the calendar quarter beginning July of the payment amount benchmark period divided by the sum of the monthly units reported for the 4 quarters of the payment amount benchmark period.

(iv) The product of—

(A) The AMP reported for the calendar quarter beginning in October of the payment amount benchmark period; and

(B) The sum of the monthly units reported for the calendar quarter beginning October of the payment amount benchmark period divided by the sum of the monthly units reported for the 4 quarters of the payment amount benchmark period.

(e) *Identification of the benchmark period CPI–U.* For each Part D rebatable drug, CMS will identify the benchmark period CPI–U as set forth in paragraphs (e)(1) and (2) of this section, subject to paragraphs (e)(3) through (5) of this section:

(1) For a Part D rebatable drug first approved or licensed by the FDA on or before October 1, 2021, the benchmark period CPI–U is the CPI–U for January 2021.

(2) For a subsequently approved drug, the benchmark period CPI–U is the CPI–U for January of the first calendar year beginning after a drug's first marketed date.

(3) Notwithstanding paragraph (e)(2) of this section, for a Part D rebatable drug first approved or licensed by the FDA on or before October 1, 2021, for which there are no quarters during the period beginning on January 1, 2021, and ending on September 30, 2021, for which AMP has been reported under section 1927(b)(3) of the Act, the benchmark period CPI–U is the CPI–U for January of the payment amount benchmark period identified under paragraph (c)(3) of this section.

(4) Notwithstanding paragraph (e)(3) of this section, for a subsequently approved drug for which there are no quarters during the first calendar year beginning after the drug's first marketed date for which AMP has been reported under section 1927(b)(3) of the Act, the benchmark period CPI–U is the CPI–U for January of the payment amount benchmark period identified under paragraph (c)(4) of this section.

(5) Notwithstanding paragraph (e)(5) of this section, for a drug that is a selected drug (as defined in section 1192(c) of the Act) with respect to a price applicability period (as defined in section 1191(b)(2) of the Act), in the case such Part D rebatable drug is no longer considered to be a selected drug, the benchmark period CPI–U is the CPI–U for January of the last calendar year of such price applicability period.

(f) *Calculation of inflation-adjusted payment amount.* For an applicable period for each Part D rebatable drug, CMS will calculate the inflation-adjusted payment amount by dividing the applicable period CPI–U by the benchmark period CPI–U and then multiplying the quotient by the benchmark period manufacturer price.

(g) *Situations in which manufacturers do not report units under section 1927(b)(3)(A)(iv) of the Act.* For the purpose of calculating the AnMP in accordance with paragraph (b) of this section and the benchmark period manufacturer price in accordance with paragraph (d) of this section—

(1) If there is 1 or more quarter(s) in the payment amount benchmark period or applicable period for which a manufacturer has not reported units under section 1927(b)(3)(A)(iv) of the Act but has reported AMP under sections 1927(b)(3)(A)(i) and (ii) of the Act, CMS will calculate the benchmark period manufacturer price or AnMP, as applicable, using data only from quarter(s) with units. Quarter(s) in the payment amount benchmark period or applicable period for which a manufacturer has not reported units under section 1927(b)(3)(A)(iv) of the Act will be excluded from the calculation.

(2) If there are no quarters of the payment amount benchmark period or applicable period for which a manufacturer has reported units under section 1927(b)(3)(A)(iv) of the Act, but the manufacturer but has reported AMP, under sections 1927(b)(3)(A)(i) and (ii) of the Act for at least 1 quarter of such period, CMS will use the average of the AMP over the calendar quarters of the payment amount benchmark period or applicable period for which AMP is reported to calculate the benchmark period manufacturer price or AnMP, respectively.

§ 428.203 Determination of the total number of units dispensed under Part D.

(a) *General.* For each Part D rebatable drug, CMS will determine the total number of units as follows:

(1) *Use of PDE data to determine total units dispensed.* To determine the total number of units of each Part D rebatable drug dispensed under Part D and covered by Part D plan sponsors during an applicable period, CMS will use the quantity dispensed reported on the PDE record for each Part D rebatable drug with gross covered prescription drug costs greater than zero.

(2) *Crosswalk to AMP units.* CMS will crosswalk the information from the PDE record to database(s) that includes the unit type (for example, each, capsule) for the Part D rebatable drug, matching on the NDC of the Part D rebatable drug. If the unit type obtained from such database does not match the AMP unit type reported by a manufacturer to the

Medicaid Drug Programs system, CMS will convert the total units reported on the PDE to the AMP units reported.

(b) *Removal of certain units.* CMS will exclude certain units from the total number of units dispensed of a Part D rebatable drug, with respect to an applicable period, as follows:

(1) *Removal of units when a generic drug is no longer a Part D rebatable drug.* To determine whether a generic drug that meets the definition of a Part D rebatable drug on the first day of an applicable period ceases to meet such definition later in the applicable period, CMS will—

(i) Review FDA's NDC Directory, including historical information from NDC Directory files such as discontinued, delisted, and expired listings provided by the FDA or published on the FDA website to determine whether the reference listed drug or an authorized generic of the reference listed drug is being marketed;

(ii) Review the most recent version of the downloadable FDA Orange Book to determine whether another drug has been approved under a section 505(j) ANDA that is therapeutically equivalent to such generic drug. If CMS determines that FDA has approved such a therapeutically equivalent drug under a section 505(j) ANDA, CMS will then: use the FDA's NDC Directory, including historical information from NDC Directory files such as discontinued, delisted, and expired listings provided by the FDA or published on the FDA website to determine the marketing status of such therapeutically equivalent drug and whether, during the applicable period, the therapeutically equivalent drug was marketed; and

(iii) Exclude from the total number of units determined under paragraph (a) of this section any units dispensed on or after the first day of the calendar month that a generic drug no longer meets the definition of a Part D rebatable drug.

(2) *Exclusion of units acquired through the 340B Program.* (i) For the applicable period beginning October 1, 2025, and subsequent applicable periods, CMS will exclude from the total number of units determined under paragraph (a) of this section units for which a manufacturer provided a discount under the 340B Program (''340B units'') as follows:

(A) For the applicable period beginning October 1, 2025, 340B units will be excluded from the total number of units dispensed for claims with a date of service on or after January 1, 2026.

(B) For the applicable period beginning October 1, 2026, and applicable periods thereafter, 340B units will be excluded from the total number of units dispensed.

(ii) To determine the total number of such units for which a manufacturer provided a discount under the 340B Program, CMS will use data reflecting the total number of units of a Part D rebatable drug for which a discount was provided under the 340B Program and that were dispensed during the applicable period.

§ 428.204 Treatment of new formulations of Part D rebatable drugs.

In the case of a Part D rebatable drug that is a line extension of a Part D rebatable drug that is an oral solid dosage form, the rebate amount for an applicable period is equal to the amount computed under § 428.201(a) for such new drug or, if greater, the alternative total rebate amount. CMS will determine the alternative total rebate amount for such new formulations according to the following:

(a) *Identification* of the *initial drug.* The initial drug that CMS will use to calculate the inflation rebate amount ratio is the initial drug identified in accordance with § 447.509(a)(4)(iii)(B) of this chapter for the last quarter of the applicable period or, if an initial drug was not identified in the last quarter, the initial drug identified for a quarter most recently in that applicable period.

(b) *Calculation of the inflation rebate amount ratio.* The inflation rebate amount ratio is equal to the per unit Part D drug inflation rebate amount for the initial drug, as calculated in § 428.202(a), divided by the AnMP for that initial drug for the applicable period.

(c) *Calculation of the alternative total rebate amount.* The alternative total rebate amount is equal to the product of all of the following:

(1) The AnMP for the applicable period, as calculated in § 428.202(b), of the Part D rebatable drug that is a line extension of a Part D rebatable drug that is an oral solid dosage form.

(2) The inflation rebate amount ratio as determined in paragraph (b) of this section.

(3) The total number of units dispensed under Part D identified in § 428.203.

Subpart D—Reducing the Rebate Amount for Part D Rebatable Drugs in Shortage and When There Is a Severe Supply Chain Disruption or Likely Shortage

§ 428.300 Definitions.

As used in this subpart, the following definitions apply:

Biosimilar has the meaning set forth in section 351(i) of the PHS Act.

Currently in shortage means that at least one NDC–10 of a Part D rebatable drug with the status ''currently in shortage'' is on a shortage list maintained by the FDA under section 506E of the FD&C Act.

Drug shortage or *shortage* means a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug (see section 506C(h)(2) of the FD&C Act).

Generic Part D rebatable drug means a generic drug approved under an ANDA under section 505(j) of the FD&C Act that meets the sole source criteria specified in § 428.101(a)(3).

Likely to be in shortage means that a generic Part D rebatable drug is likely to be described as currently in shortage during a subsequent applicable period without such rebate reduction.

Natural disaster means any natural catastrophe, including, but not limited to any of the following: hurricane, tornado, storm, high water, wind-driven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, snowstorm, or drought, or regardless of cause, any fire, flood, or explosion.

Other unique or unexpected event means any exogenous, unpredictable event outside of a manufacturer's control, including, but not limited to, a geopolitical disruption, pandemic, or act of terror.

Plasma-derived product means a licensed biological product that is derived from human whole blood or plasma, as indicated on the approved product labeling.

Severe supply chain disruption means a change in production or distribution that is reasonably likely to lead to a significant reduction in the U.S. supply of a generic Part D rebatable drug or biosimilar by a manufacturer and significantly affects the ability of the manufacturer of the generic drug or biosimilar to fill orders or meet expected demand for its product in the United States for at least 90 days. This definition does not include interruptions in manufacturing due to matters such as routine maintenance, manufacturing quality issues, or insignificant changes made in the manufacturing process for the drug.

§ 428.301 Reducing the rebate amount for Part D rebatable drugs currently in shortage.

(a) *General.* As required under section 1860D–14B(b)(1)(C)(i) of the Act, CMS will reduce the total rebate amount calculated under § 428.201(a), if any is owed, for a Part D rebatable drug that is currently in shortage, as defined in

§ 428.300, at any point during the applicable period.

(b) *Calculation of the reduced rebate amount.* (1) For each applicable period beginning on or after October 1, 2022, the reduced rebate amount for a Part D rebatable drug currently in shortage will be calculated using the following formula:

Equation 1 to Paragraph (b)(1)

Reduced *Total* Rebate Amount = the total rebate amount *multiplied by* (1 *minus* applicable percent reduction) *multiplied by* (percentage of time drug was currently in shortage during the applicable period) *added to* the total rebate amount *multiplied by* (1 *minus* percentage of time drug was currently in shortage during the applicable period)

(2) For purposes of paragraph (b)(1) of this section, the applicable percent reduction is:

(i) For a Part D rebatable drug that is a generic drug or plasma-derived product:

(A) 75 percent for the first applicable period such drug is currently in shortage.

(B) 50 percent for the second applicable period such drug is currently in shortage.

(C) 25 percent for each subsequent period such drug is currently in shortage.

(ii) For a Part D rebatable drug that is not a generic drug or plasma-derived product:

(A) 25 percent for the first applicable period such drug is currently in shortage.

(B) 10 percent for the second applicable period such drug is currently in shortage.

(C) 2 percent for each subsequent applicable period such drug is currently in shortage.

(3) For purposes of paragraph (b)(1) of this section, the percentage of time the drug is currently in shortage during the applicable period is equal to the number of days such drug is currently in shortage in an applicable period, divided by the total number of days in the applicable period.

(c) *Application of reduction.* CMS will apply a reduction of the rebate amount as determined under paragraph (b) of this section to the Part D rebatable drug at the NDC–9 level.

§ 428.302 Reducing the rebate amount for certain Part D rebatable drugs when there is a severe supply chain disruption.

(a) *General.* As required under section 1860D–14B(b)(1)(C)(ii) of the Act, CMS will reduce the total rebate amount calculated under § 428.201(a), if any is owed, for a generic Part D rebatable drug or biosimilar when CMS determines there is a severe supply chain disruption, as defined in § 428.300, during the applicable period such as that caused by a natural disaster or other unique or unexpected event.

(b) *Calculation of the reduced rebate amount*—(1) *Initial reduction.* If CMS determines the criteria described in paragraph (c)(4) of this section are met, then CMS will reduce the total rebate amount owed by the manufacturer for a generic Part D rebatable drug or biosimilar by 75 percent for an applicable period.

(2) *Extension of reduction.* If CMS determines a severe supply chain disruption continues into a second consecutive applicable period as described in paragraph (c)(5) of this section, then CMS will reduce the total rebate amount owed by the manufacturer for a generic Part D rebatable drug or biosimilar by 75 percent for that second applicable period.

(3) *Application of reduction.* If CMS determines there is a severe supply chain disruption for an NDC–11, CMS will apply any reduction of the rebate amount as described in paragraphs (b)(1) and (2) of this section to a Part D rebatable drug at the NDC–9 level.

(4) *Limitation on rebate reductions.* CMS will not apply multiple rebate reductions for the same Part D rebatable drug and applicable period.

(i) If a manufacturer believes there are multiple events causing severe supply chain disruptions during the same applicable period for the same generic Part D rebatable drug or biosimilar and submits multiple rebate reduction requests for the same drug or biosimilar, CMS will grant no more than 1 rebate reduction under paragraph (b)(1) or (2) of this section for that product for the applicable period.

(ii) If CMS grants a rebate reduction request under this section and the generic Part D rebatable drug or biosimilar subject to the reduction is currently in shortage during the same applicable period as the one for which the severe supply chain disruption reduction request was granted, CMS will reduce the rebate amount as described in paragraph (b)(1) of this section and will not grant a reduction under § 428.301 during that applicable period.

(iii) If a generic Part D rebatable drug or biosimilar that is currently in shortage experiences a severe supply chain disruption, CMS will reduce the rebate amount as described in paragraph (b)(1) of this section, and will not grant a reduction under § 428.301 during that applicable period.

(c) *Eligibility for a rebate reduction*—(1) *Eligible drug.* Subject to paragraph (b)(3) of this section, eligibility for a rebate reduction under this section is limited to Part D rebatable drugs and biosimilars for which a manufacturer submits a rebate reduction request under this section.

(2) *Timing.* For a natural disaster or other unique or unexpected event occurring on or after August 2, 2024 that the manufacturer believes caused a severe supply chain disruption, the manufacturer must submit the rebate reduction request within 60 calendar days from the first day that the natural disaster or other unique or unexpected event occurred or began to receive consideration for a reduction in the rebate amount owed in accordance with paragraph (b)(1) of this section.

(3) *Required elements of a rebate reduction request.* To receive consideration for a reduction in the rebate amount owed in accordance with paragraph (b)(1) of this section, the manufacturer must submit to CMS information and supporting documentation to substantiate the evaluation criteria described in paragraph (c)(4) of this section. Such information and supporting documentation include the following:

(i) Evidence that the severe supply chain disruption directly affects the manufacturer itself, a supplier of an ingredient or packaging, a contract manufacturer, or a method of shipping or distribution that the manufacturer uses to make or distribute the generic Part D rebatable drug(s) or biosimilar(s), such as a change in the production or distribution of the generic Part D rebatable drug(s) or biosimilar(s) that is reasonably likely to lead to a significant reduction in the U.S. supply of product and significantly affects the manufacturer's ability to fill orders or meet expected demand for the generic Part D rebatable drug(s) or biosimilar(s) for at least 90 days;

(ii) Information about when the manufacturer expects supply of the generic Part D rebatable drug(s) or biosimilar(s) to meet expected demand;

(iii) Evidence that the natural disaster or other unique or unexpected event caused the severe supply chain disruption, including when the natural disaster or other unique or unexpected event occurred or began occurring, and the expected or actual duration of the severe supply chain disruption; and

(iv) Evidence of the manufacturer's physical presence related to manufacturing the generic Part D rebatable drug(s) or biosimilar(s) in a

geographic area where a natural disaster or other unique or unexpected event occurred. If the manufacturer is not physically present in a geographic area where a natural disaster or other unique or unexpected event occurred, but believes there is a severe supply chain disruption caused by a natural disaster or other unique or unexpected event that affects the manufacturer's generic Part D rebatable drug(s) or biosimilar(s), the information and supporting documentation may include evidence of the impact of the natural disaster or other unique or unexpected event on the supply chain of the generic Part D rebatable drug or biosimilar, on a supplier of an ingredient or packaging, or method of shipping or distribution that the manufacturer uses.

(4) *Evaluation criteria.* In accordance with paragraph (b)(1) of this section, CMS will grant a reduction in the rebate amount owed if a manufacturer submits to CMS a request in writing for an eligible drug, in accordance with the timing specified in paragraph (c)(2) of this section, demonstrating that:

(i) A severe supply chain disruption has occurred during the applicable period;

(ii) The severe supply chain disruption directly affects the manufacturer itself, a contract manufacturer, a supplier of an ingredient or packaging, or a method of shipping or distribution that the manufacturer uses in a significant capacity to make or distribute the generic Part D rebatable drug or biosimilar; and

(iii) The severe supply chain disruption was caused by a natural disaster or other unique or unexpected event.

(5) *Rebate reduction extensions.* If CMS determines that a generic Part D rebatable drug or biosimilar that received a reduction of the rebate amount under paragraph (b)(1) of this section continues to be affected by the severe supply chain disruption, CMS will grant a single extension of the reduction for 1 additional consecutive applicable period and reduce the rebate amount owed in accordance with paragraph (b)(2) of this section.

(i) To receive consideration for a rebate reduction extension, a manufacturer must submit a request with updated or new information and supporting documentation on why the generic Part D rebatable drug or biosimilar continues to be affected by the severe supply chain disruption during the second applicable period.

(ii) A manufacturer must submit the rebate reduction extension request at least 60 calendar days before the start of the second consecutive applicable period to receive consideration for a reduction in the rebate amount owed, if any, in accordance with paragraph (b)(2) of this section, except for when the initial request is made less than 60 calendar days before the end of an applicable period such that the initial rebate reduction is applied to the next applicable period rather than the applicable period in which the event that caused the severe supply chain disruption occurred or began. In these cases, the rebate reduction extension request must be submitted at least 60 calendar days prior to the end of the applicable period in which the initial reduction under paragraph (b)(1) of this section is applied.

(6) *Decision to grant or deny a request.* CMS will review rebate reduction requests and rebate reduction extension requests within 60 calendar days of receipt of all documentation, if feasible, beginning with the applicable period that begins on October 1, 2024.

(i) CMS will deny a rebate reduction request that does not meet the criteria in paragraph (c)(4) of this section or that is incomplete or untimely based on the requirements of this paragraph (c).

(ii) CMS will deny a rebate reduction extension request that does not meet the criteria in paragraph (c)(5) of this section, that is incomplete or untimely based on the requirements of paragraph (c)(5) of this section, or if a reduction under paragraph (b)(1) of this section was not provided for such generic Part D rebatable drug or biosimilar.

(iii) CMS' decisions to deny a request are final and will not be subject to an appeals process.

(7) *Public disclosure of information.* CMS will keep confidential, to the extent allowable under law, any requests for a rebate reduction, including supporting documentation. Information provided as part of a request for a rebate reduction request that the submitter indicates is a trade secret or confidential commercial or financial information will be protected from disclosure if CMS determines the information meets the requirements set forth under Exemption 3 or Exemption 4 in 5 U.S.C. 552.

§ 428.303 Reducing the rebate amount for generic Part D rebatable drugs likely to be in shortage.

(a) *General.* As required under section 1860D–14B(b)(1)(C)(iii) of the Act, CMS will reduce the total rebate amount calculated under § 428.201, if any is owed, for a generic Part D rebatable drug when CMS determines that the generic Part D rebatable drug is likely to be in shortage, as defined in § 428.300.

(b) *Calculation of the reduced rebate amount*—(1) *Initial reduction.* If CMS determines the criteria described in paragraph (c)(4) of this section are met, then CMS will reduce the total rebate amount owed by the manufacturer for a generic Part D rebatable drug by 75 percent for an applicable period.

(2) *Extension of reduction.* If CMS determines the generic Part D rebatable drug is likely to be in shortage in a second applicable period as described in paragraph (c)(5) of this section, then CMS will reduce the total rebate amount owed by the manufacturer for a generic Part D rebatable drug by 75 percent for a second consecutive applicable period.

(3) *Application of reduction.* If CMS determines that an NDC–11 is likely to be in shortage, CMS will apply any reduction of the rebate amount as described in paragraphs (b)(1) and (2) of this section to the generic Part D rebatable drug at the NDC–9 level.

(4) *Limitation on rebate reductions.* If CMS grants a rebate reduction request under this section, and the generic Part D rebatable drug subject to the reduction is currently in shortage during the same applicable period as the one for which the request was granted, CMS will reduce the rebate amount as described in paragraph (b)(1) of this section and will not grant a reduction under § 428.301 during that applicable period.

(c) *Eligibility for a rebate reduction*—(1) *Eligible drug.* Subject to paragraph (b)(3) of this section, eligibility for a rebate reduction under this section is limited to generic Part D rebatable drugs for which a manufacturer submits a rebate reduction request under this section.

(2) *Timing.* The manufacturer must submit the rebate reduction request before the start of the next applicable period in which the manufacturer believes the generic Part D rebatable drug is likely to be in shortage to receive consideration for a reduction in the rebate amount owed in accordance with paragraph (b)(1) of this section.

(3) *Required elements of a rebate reduction request.* To receive consideration for a reduction in the rebate amount owed in accordance with paragraph (b)(1) of this section, the manufacturer must submit to CMS information and supporting documentation to substantiate the evaluation criteria described in paragraph (c)(4) of this section. Such information and supporting documentation include the following:

(i) Evidence that demonstrates a generic Part D rebatable drug is likely to be in shortage, including anticipated cause(s) of the shortage and information about why the manufacturer believes

the generic Part D rebatable drug is likely to be in shortage; and

(ii) Evidence of the anticipated start date and duration of the potential drug shortage, the actions the manufacturer is taking to avoid the potential drug shortage, and how the reduction of the rebate amount would reduce the likelihood of the drug appearing on an FDA shortage list.

(4) *Evaluation criteria.* In accordance with paragraph (b)(1) of this section, CMS will grant a reduction in the rebate amount owed if a manufacturer submits to CMS a request in writing for an eligible drug, in accordance with the timing specified in paragraph (c)(2) of this section, demonstrating that:

(i) The generic Part D rebatable drug is likely to be in shortage;

(ii) The manufacturer is taking actions to avoid the potential drug shortage; and

(iii) The reduction of the rebate amount would reduce the likelihood of the drug appearing on an FDA shortage list.

(5) *Rebate reduction extensions.* If CMS determines that a generic Part D rebatable drug that received a reduction of the rebate amount under paragraph (b)(1) of this section continues to be affected by the potential drug shortage, CMS will grant a single extension of the reduction for 1 additional consecutive applicable period and reduce the rebate amount owed in accordance with paragraph (b)(2) of this section.

(i) To receive consideration for a rebate reduction extension, a manufacturer must submit a request with updated or new information and supporting documentation on why the generic Part D rebatable drug continues to be affected by the potential drug shortage during the second applicable period.

(ii) A manufacturer must submit the rebate reduction extension request at least 60 calendar days before the start of the second consecutive applicable period in which the manufacturer believes the generic Part D rebatable drug is likely to be in shortage to receive consideration for a reduction in the rebate amount owed, if any, in accordance with paragraph (b)(2) of this section.

(6) *Decision to grant or deny a request.* CMS will review rebate reduction requests and rebate reduction extension requests within 60 calendar days of receipt of all documentation, if feasible, beginning with the applicable period that begins on October 1, 2024.

(i) CMS will deny a rebate reduction request that does not meet the criteria in paragraph (c)(4) of this section or that is incomplete or untimely based on the requirements of this paragraph (c).

(ii) CMS will deny a rebate reduction extension request that does not meet the criteria in paragraph (c)(5) of this section, that is incomplete or untimely based on the requirements of paragraph (c)(5) of this section, or if a reduction under paragraph (b)(1) of this section was not provided for such generic Part D rebatable drug.

(iii) CMS' decisions to deny a request are final and will not be subject to an appeals process.

(7) *Public disclosure of information.* CMS will keep confidential, to the extent allowable under law, any requests for a rebate reduction, including supporting documentation. Information provided as part of a request for a rebate reduction that the submitter indicates is a trade secret or confidential commercial or financial information will be protected from disclosure if CMS determines the information meets the requirements set forth under Exemption 3 or Exemption 4 in 5 U.S.C. 552.

Subpart E—Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments

§ 428.400 Definitions.

For the purposes of this subpart, *date of receipt* is the calendar day following the day in which a report of a rebate amount (as set forth in §§ 428.401(b), (c), and (d) and 428.402(b) and (c)) is made available to the manufacturer of a Part D rebatable drug by CMS.

§ 428.401 Rebate Reports and reconciliation.

(a) *General.* This section applies to Part D rebatable drugs for all applicable periods except as otherwise set forth in § 428.402 for the applicable periods beginning October 1, 2022, and October 1, 2023.

(b) *Preliminary Rebate Report.* A Preliminary Rebate Report will be provided to each manufacturer of a Part D rebatable drug at least 1 month prior to the issuance of the Rebate Report as set forth in paragraph (c) of this section for an applicable period.

(1) The Preliminary Rebate Report for each Part D rebatable drug will include the following information:

(i) The NDC(s) for the Part D rebatable drug as defined under § 428.20;

(ii) The total number of units dispensed under Part D for the Part D rebatable drug for the applicable period as determined under § 428.203;

(iii) The benchmark period manufacturer price as described in § 428.202(d).

(iv) The AnMP for the Part D rebatable drug for the applicable period as determined in § 428.202(b);

(v) The amount, if any, of the excess AnMP for the Part D rebatable drug for the applicable period as set forth under § 428.202(a);

(vi) The benchmark period and applicable period CPI-Us as set forth in §§ 428.202(e) and 428.20, respectively;

(vii) Inflation-adjusted payment amount as set forth in § 428.202(f);

(viii) Any applied reductions described in §§ 428.301, 428.302, and 428.303; and

(ix) Rebate amount due as set forth in § 428.201(a).

(2) If the Part D rebatable drug is a line extension, the Preliminary Rebate Report will also include the following information described in § 428.204:

(i) The NDC for the initial drug;

(ii) The inflation rebate amount ratio for the initial drug; and

(iii) The alternative total rebate amount.

(c) *Rebate Report.* A Rebate Report will be provided to each manufacturer of a Part D rebatable drug no later than 9 months after the end of each applicable period.

(1) The Rebate Report will include the information described in paragraphs (b)(1) and (2) of this section, if applicable, with the inclusion of any revisions to such information resulting from CMS' review of a Suggestion of Error as set forth in § 428.403, if applicable, and any CMS-determined recalculations from paragraph (d)(2) of this section.

(2) The Rebate Report is the invoice of a manufacturer's rebate amount due as calculated in § 428.201(a), if any, for a Part D rebatable drug for an applicable period.

(d) *Reconciliation of the rebate amount.* CMS will perform reconciliation of the rebate amount provided in a Rebate Report specified in paragraph (c) of this section for an applicable period in the following circumstances:

(1) *Regular reconciliation.* Except as otherwise described in § 428.402, CMS will perform a reconciliation of the rebate amount within 12 months of the date of receipt of the Rebate Report for an applicable period and a second reconciliation approximately 24 months thereafter to include revisions to the information used to calculate the rebate amount as specified in paragraph (c)(1) of this section.

(i) *Preliminary reconciliation.* At least 1 month prior to the issuance of a report with the reconciled rebate amount for an applicable period specified in paragraph (d)(1)(ii) of this section, CMS will conduct a preliminary reconciliation of the rebate amount for an applicable period based on the

information specified in paragraphs (d)(1)(i)(A) through (G) of this section, and CMS will provide the information specified in paragraphs (d)(1)(i)(A) through (G) to the manufacturer of a Part D rebatable drug for the applicable period, if applicable:

(A) Updated total number of rebatable units, including updates submitted by a prescription drug plan (PDP) or Medicare Advantage Prescription Drug (MA–PD) plan sponsor and updates to 340B units (as applicable to the dates of service and applicable periods specified in § 428.203(b)(2)(i)(A) and (B)), or units otherwise excluded as specified in § 428.203(b);

(B) Inflation-adjusted payment amount as specified in § 428.202(f) if any inputs are restated within the reconciliation run-out period;

(C) Updated benchmark period manufacturer price as specified in § 428.202(d);

(D) The excess amount by which the AnMP exceeds the inflation-adjusted payment amount for the applicable period as specified in § 428.202(a), using the most recent AMP (if any inputs are restated within the reconciliation run-out period);

(E) Updated data on line extension calculations, including the initial drug identified as set forth in § 447.509(a)(4)(iii)(B) of this chapter, the inflation rebate amount ratio, and the alternative total rebate amount as set forth in § 428.204 if any inputs are restated within the reconciliation run-out period;

(F) Reconciled rebate amount as specified in § 428.201(a); and

(G) The difference between the total rebate amount due as specified on the Rebate Report set forth in paragraph (c) of this section and the reconciled rebate amount as set forth in this paragraph (d)(1)(i).

(ii) *Report with a reconciled rebate amount.* With the inclusion of any additional revisions to such information resulting from CMS' review of a Suggestion of Error as set forth in § 428.403, if applicable, a report with the reconciled rebate amount will be provided to each manufacturer of a Part D rebatable drug within 12 months and 36 months after the issuance of the Rebate Report described in paragraph (c) of this section.

(2) *CMS identification of an error or manufacturer misreporting.* CMS may recalculate a rebate amount and provide the manufacturer of a Part D rebatable drug a report with a reconciled rebate amount when:

(i) CMS identifies an error in the information specified in paragraphs (c) and (d)(1) of this section, including reporting system or coding errors, not later than 5 years from the date of receipt by a manufacturer of a reconciled rebate amount for the applicable period; or

(ii) CMS determines at any time that the information used by CMS to calculate the rebate amount was inaccurate due to manufacturer misreporting.

(3) *Impact of reconciliation on rebate amount.* A reconciliation as set forth in this paragraph (d) could result in an increase, decrease, or no change to the rebate amount as calculated under § 428.201(a) owed by a manufacturer for the applicable period for the Part D rebatable drug.

(i) A report with a reconciled rebate amount that is an increase to the rebate amount is the invoice for such additional amount due on the manufacturer's rebate amount as set forth in § 428.201 for a Part D rebatable drug for an applicable period.

(ii) [Reserved]

(4) *Drugs included in a reconciliation.* A drug covered under Part D that does not meet the requirements of a rebatable drug specified in § 428.101 for an applicable period will not be included in a reconciliation under this paragraph (d).

§ 428.402 Rebate Reports for applicable periods beginning October 1, 2022, and October 1, 2023.

(a) *Transition rule for reporting.* Section 1860D–14B(a)(3) of the Act allows CMS to delay the timeframe for reporting the information and rebate amount described in § 428.401 for the applicable periods beginning October 1, 2022, and October 1, 2023, until not later than December 31, 2025.

(b) *Rebate Report information for applicable periods beginning October 1, 2022, and October 1, 2023.* The Rebate Reports for the applicable periods beginning October 1, 2022, and October 1, 2023, will include the information described in § 428.401(b)(1).

(c) *Rebate Report procedures for applicable periods beginning October 1, 2022, and October 1, 2023.* Rebate amounts for the applicable periods beginning October 1, 2022, and October 1, 2023, will be reported as follows:

(1) The Rebate Report for the applicable period beginning October 1, 2022, will be issued no later than December 31, 2025. The Preliminary Rebate Report for such applicable period will be issued at least 1 month prior to the Rebate Report.

(i) For this single Preliminary Rebate Report for the applicable period, the Suggestion of Error period as described in § 428.403 will be 30 calendar days.

(ii) The rebate amount will be reconciled 21 months after the Rebate Report specified in paragraph (b)(1) of this section is issued to include the information specified in § 428.401(d)(1)(i)(A) through (G).

(iii) The Suggestion of Error period for the reconciliation described in paragraph (b)(1)(ii) of this section will be 10 calendar days.

(2) The Rebate Report for the applicable period beginning October 1, 2023, will be issued no later than December 31, 2025. The Preliminary Rebate Report for such applicable period will be issued at least 1 month prior to the Rebate Report.

(i) For this single Preliminary Rebate Report for the applicable period, the Suggestion of Error period as described in § 428.403 will be 30 calendar days.

(ii) The rebate amount will be reconciled 9 months after the Rebate Report and 33 months after the Rebate Report specified in paragraph (b)(2) of this section is issued to include the information specified in § 428.401(d)(1)(i)(A) through (G).

§ 428.403 Suggestion of Error.

(a) *General.* Manufacturers of Part D rebatable drugs may submit a Suggestion of Error about the information in their Preliminary Rebate Report and the report detailing the preliminary reconciliation of the rebate amount to CMS, for its discretionary consideration, if the manufacturer believes that there is a mathematical error or errors to be corrected before the Rebate Report or a subsequent reconciliation, as applicable, is finalized.

(1) Section 1860D–14B(f) of the Act precludes administrative or judicial review on the determination of units as set forth in § 428.203, the determination of whether a drug is a Part D rebatable drug as set forth in § 428.101, and the calculation of the rebate amount as set forth in § 428.201(a) inclusive of any reconciled rebate amount.

(2) [Reserved]

(b) *Process of submission.* Subject to the scope and timing requirements specified in paragraphs (a) and (c) of this section, manufacturers may submit the Suggestion of Error and provide supporting documentation (if applicable).

(c) *Timing.* Except as specified in § 428.402 for the applicable periods beginning on October 1, 2022, and October 1, 2023, a manufacturer must submit its Suggestion of Error for the applicable period within 10 calendar days from the date of receipt of a Preliminary Rebate Report or a preliminary reconciliation of a rebate

amount using the method and process established by CMS in paragraph (b) of this section.

(d) *Notice.* (1) CMS will include any revisions to the calculation of the rebate amount, if determined necessary by CMS based on the Suggestion of Error submitted under this section prior to issuance of the Rebate Report as set forth in § 428.401(c) or § 428.402(c) as well as any report of a reconciled rebate amount as set forth in § 428.401(d) or § 428.402(c)(1)(ii) and (c)(2)(ii).

(2) CMS will notify the manufacturer whether CMS revised its calculation of the rebate amount based on the Suggestion of Error.

§ 428.404 Manufacturer access to Rebate Reports.

(a) *General.* CMS will establish a method and process for a manufacturer of the Part D rebatable drug to:

(1) Access the Rebate Report as set forth in §§ 428.401 and 428.402, including any report of a reconciled rebate amount as set forth in §§ 428.401 and 428.402;

(2) Submit a Suggestion of Error as set forth in §§ 428.402(c) and 428.403; and

(3) Pay a rebate amount as set forth in § 428.405.

(b) [Reserved]

§ 428.405 Deadline and process for payment of rebate amount.

(a) *Rebate amounts owed by a manufacturer.* For payment of a rebate amount owed by a manufacturer:

(1) Upon receipt of a rebate amount, payment is due no later than 11:59 p.m. Pacific Time (PT) on the 30 calendar days after the date of receipt of information regarding the rebate amount on—

(i) A Rebate Report specified in § 428.401(c) or § 428.402; or

(ii) A report of a reconciled rebate amount specified in § 428.401(d) or § 428.402.

(2) Failure to pay a rebate amount due timely and in full may result in an enforcement action as described in subpart F of this part.

(b) *Refund to the manufacturer.* If a reconciled rebate amount for an applicable period as specified in § 428.401(d) or § 428.402 is less than what the manufacturer paid for that applicable period, CMS will initiate the process to provide a refund equal to the excess amount paid within 60 days of the date of receipt of the report with such reconciled rebate amount.

Subpart F—Enforcement of Manufacturer Payment of Rebate Amounts

§ 428.500 Civil money penalty notice and appeals procedures.

(a) *General.* CMS may impose a civil money penalty on a manufacturer that fails to pay the rebate amount set forth in § 428.201(a) on a Part D rebatable drug defined at § 428.20, by the payment deadline as set forth in section § 428.405(a) for such drug for such applicable period.

(b) *Determination of the civil money penalty amount.* CMS may impose a civil money penalty for each failure by a manufacturer to provide an applicable inflation rebate equal to 125 percent of the rebate amount determined in § 428.201(a).

(1) The civil money penalty is in addition to the rebate amount due.

(2) If a reconciled rebate amount as set forth in § 428.401(d) or § 428.402(c)(1)(ii) or (c)(2)(ii) results in an increase to the rebate amount due, a separate civil money penalty may be imposed for the failure by a manufacturer to provide an inflation rebate for the applicable period for the increase to the rebate amount due.

(c) *Notice of imposition of civil money penalties.* If CMS makes a determination to impose a civil money penalty described in paragraph (b) of this section, CMS will send a written notice of its decision to impose a civil money penalty to include the following:

(1) A description of the basis for the determination.

(2) The basis for the penalty.

(3) The amount of the penalty.

(4) The date the penalty is due.

(5) The manufacturer's right to a hearing as specified in paragraph (e) of this section.

(6) Information about where to file the request for a hearing.

(d) *Collection.* (1) A manufacturer must pay the civil money penalty in full within 60 calendar days after the date of the notice of imposition of a civil money penalty from CMS under paragraph (c) of this section.

(2) In the event a manufacturer requests a hearing, pursuant to 42 CFR part 423, subpart T, the manufacturer must pay the amount in full within 60 calendar days after the date of a final decision by the Departmental Appeal Board, to uphold, in whole or in part, the civil money penalty.

(3) If the 60th calendar day described in paragraphs (d)(1) and (2) of this section is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(e) *Appeal procedures for civil money penalties.* Section 1128A(c)(2) of the Act provides that CMS may not collect a civil money penalty until the affected party has had notice and the opportunity for a hearing.

(1) Manufacturers may appeal the following determinations:

(i) A CMS determination that the rebate amount was not paid by the applicable payment deadline as described in § 428.405.

(ii) The calculation of the amount of the civil money penalty.

(2) The notice provided to a manufacturer if CMS decides to impose a civil money penalty is described in paragraph (c) of this section.

(3) A manufacturer has a right to a hearing following a decision by CMS to impose a civil money penalty following the administrative appeal process and procedures established in 42 CFR part 423, subpart T.

(f) *Other applicable provisions.* The provisions of section 1128A of the Act (except subsections (a) and (b) of section 1128A of the Act) apply to civil money penalties under this section to the same extent that they apply to a civil money penalty or procedures under section 1128A of the Act.

(g) *Bankruptcy.* In the event that a manufacturer declares bankruptcy, as described in title 11 of the United States Code, and as a result of the bankruptcy, fails to pay either the full rebate amount owed or the total sum of civil money penalties imposed, the government reserves the right to file a proof of claim with the bankruptcy court to recover the unpaid amount of the rebates and civil money penalties owed by the manufacturer.

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

■ 82. The authority citation for part 491 continues to read as follows:

Authority: 42 U.S.C. 263a and 1302.

■ 83. Section 491.9 by—
■ a. Adding paragraphs (a)(2)(i) and (ii);
■ b. Removing paragraph (c)(2)(ii);
■ c. Redesignating paragraphs (c)(2)(iii) through (vi) as paragraphs (c)(2)(ii) through (v), respectively; and
■ d. Revising newly designated paragraph (c)(2)(v).

The additions and revisions read as follows:

§ 491.9 Provision of services.

(a) * * *

(2) * * *

(i) The clinic or center must provide primary care services.

(ii) The clinic is not a rehabilitation agency or a facility primarily for the care and treatment of mental diseases.

* * * * *

(c) * * *

(2) * * *

(v) Collection of patient specimens for transmittal to a certified laboratory for culturing.

* * * * *

Xavier Becerra,

Secretary, Department of Health and Human Services.

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

Appendix 1: MIPS Quality Measures

Note: Except as otherwise noted in this proposed rule, previously finalized measures and specialty measure sets will continue to apply for the CY 2025 performance period/2027 MIPS payment year and future years. Previously finalized measures and specialty measure sets are in the CY 2017 through CY 2024 PFS final rules: 81 FR 77558 through 77816, 82 FR 53966 through 54174, 83 FR 60097 through 60285, 84 FR 63205 through 63513, 85 FR 85045 through 85369, 86 FR 65687 through 65968, 87 FR 70250 through 70633, and 88 FR 79556 through 79964. In addition, electronic clinical quality measures (eCQMs) that are endorsed by a Consensus-Based Entity (CBE) are shown in Table A of this Appendix as follows: CBE #/eCQM CBE #.

Table Group A: New MIPS Quality Measures Proposed for the CY 2025 Performance Period/2027 MIPS Payment Year and Future Years

Note: In the CY 2024 PFS final rule, measure Q494: Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level), was finalized with a 1-year delay to the CY 2025 performance period (88 FR 79556 through 79560) and does not have a new measure table in this proposed rule.

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A.1. Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients, aged 18 years and older, with a diagnosis of metastatic non-small cell lung cancer (NSCLC) or squamous cell carcinoma of head and neck (HNSCC) on first-line immune checkpoint inhibitor (ICI) therapy, who had a positive PD-L1 biomarker expression test result prior to giving ICI therapy.
Measure Steward:	Society for Immunotherapy of Cancer (SITC)
Numerator:	Patients who had a positive PD-L1 biomarker expression test result prior to the initiation of first-line immune checkpoint inhibitor therapy.
Denominator:	Patients aged 18 years and older with a diagnosis of metastatic non-small cell lung cancer (NSCLC) or squamous cell carcinoma of head and neck (HNSCC) and on first-line immune checkpoint inhibitors without chemotherapy.
Exclusions:	Patients with NSCLC with epidermal growth factor receptor (EGFR) mutations, ALK genomic tumor aberrations, or other targetable genomic abnormalities with approved first-line targeted therapy, such as NSCLC with ROS1 rearrangement, BRAF V600E mutation, NTRK 1/2/3 gene fusion, MET ex14 skipping mutation, and RET rearrangement.
Measure Type:	Process
High Priority Measure:	Yes
Collection Type:	MIPS CQM Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure.

Rationale:	We are proposing this process measure because it addresses timely biomarker testing, which impacts treatment decisions for patients with a diagnosis of metastatic non-small cell lung cancer or squamous cell carcinoma of the head and neck. In addition, this measure aligns with CMS priorities of improving patient outcomes and safety, while promoting efficacy of timely treatment. Appropriate intervention and timeliness of PD-L1 biomarker expression testing prior to initiation of first-line treatment for metastatic non-small cell lung cancer or squamous cell carcinoma of the head and neck can lead to improvements in mortality and morbidity rates.[1] Untimely biomarker testing could lend to negative clinical implications or outcomes, including delayed care and treatment and/or ineffective or incorrect prescribed therapies leading to chemotherapy toxicity, decreased quality of life, and unnecessary healthcare costs.[2] [3] Immunotherapy remains a new realm for oncology and health care clinicians; therefore, opportunities exist to improve care provided to patients receiving immune checkpoint inhibitor therapy. In 2017, a survey conducted by the Association of Community Cancer Centers (ACCC) indicated only 24 percent of respondents reported they had a deep familiarity with checkpoint inhibitors, 32 percent with monoclonal antibody therapy, and only 17 percent with combination treatment regimens.[4] This measure is predicated on two evidence-based clinical guidelines that address the measure's quality actions of a positive PD-L1 biomarker expression test prior to giving first-line immune checkpoint inhibitor therapy in the metastatic non-small cell lung cancer or squamous cell carcinoma of the head and neck population.[5] [6] The measure would enhance compliance with the clinical guidelines by incentivizing clinicians to address timely biomarker testing, positively influencing treatment decisions and improving patient outcomes. The Pre-Rulemaking Measure Review (PRMR) Clinician Recommendation Committee conditionally supported this measure and requested additional testing examining measure performance and feasibility. This measure has been fully developed and tested at the clinician level with high reliability based upon signal-to-noise scores, and adequate face validity. As a part of the MERIT submission, the measure developer reported adequate reliability testing of the individual data elements via Cohen's kappa coefficient, which substantiates the feasibility for implementation in MIPS. Testing of measure performance indicated a large gap in care for conducting timely biomarker testing, with an average performance rate of 19.6 percent, which allows significant room for improvement among clinicians treating this patient population and conducting the biomarker testing for this measure. This measure is not currently CBE endorsed. Although CBE endorsement is preferred, it is still recommended this measure be added to MIPS because it is an evidence-based measure, satisfying the requirement set forth at section 1848(q)(2)(D)(v) of the Act, stating that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. This measure aligns with the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines.[7] [8] We recognize that not all measures within MIPS are applicable or appropriate for all clinicians due to the nuances for each clinician specialization, scope of care, or regional location. However, this measure fills a gap in MIPS quality measures for treatment of patients with non-small cell lung cancer and squamous cell carcinoma of the head and neck. In addition, it would provide a specialty specific measure for the MIPS Oncology/Hematology specialty set under Table B.27a of this Appendix. Furthermore, this measure could be added to the Advancing Cancer Care MVP in the future and would fill a current quality measure inventory gap within the oncologic clinical topic. Note: Refer to the PRMR Clinician Recommendation Committee Spreadsheet of Final Recommendations to CMS and HHS at *https://p4qm.org/sites/default/files/2024-02/PRMR-Final-MUC-Recommendation-Spreadsheet%20%283%29.xlsx*.

[1] Lim, C., Tsao, M. S., Le, L. W., Shepherd, F. A., Feld, R., Burkes, R. L., Liu, G., Kamel-Reid, S., Hwang, D., Tanguay, J., da Cunha Santos, G., & Leighl, N. B. (2015). Biomarker Testing and Time to Treatment Decision in Patients with Advanced Nonsmall-cell Lung Cancer. *Annals of Oncology: Official Journal of the European Society for Medical Oncology*, *26*(7), 1415–1421. https://doi.org/10.1093/annonc/mdv208.

[2] Pai, S., Blaisdell, D., Brodie, R., Carlson, R., Finnes, H., Galioto, M., Jensen, R. E., Valuck, T., Sepulveda, A. R., & Kaufman, H. L. (2020). Defining Current Gaps in Quality Measures for Cancer Immunotherapy: Consensus Report from the Society for Immunotherapy of Cancer (SITC) 2019 Quality Summit. Journal for Immunotherapy of Cancer, 8(1), e000112. https://doi.org/10.1136/jitc-2019-000112.

[3] See footnote Lim et al., 2015.

[4] Association of Community Cancer Centers (ACCC). (2017-2018). Immuno-Oncology: Transforming the Delivery of Cancer Care in the Community [White paper]. http://www.informz.net/ACCC/data/images/Attachments/2017%20IO%20White%20Paper.pdf.

[5] Ettinger, D. S., Wood, D. E., Aisner, D. L., Akerley, W., Bauman, J. R., Bharat, A., Bruno, D. S., Chang, J. Y., Chirieac, L. R., D'Amico, T. A., DeCamp, M., Dilling, T. J., Dowell, J., Gettinger, S., Grotz, T. E., Gubens, M. A., Hegde, A., Lackner, R. P., Lanuti, M., Lin, J., … Hughes, M. (2022). Non-Small Cell Lung Cancer, Version 3.2022, NCCN Clinical Practice Guidelines in Oncology. Journal of the National Comprehensive Cancer Network: JNCCN, 20(5), 497–530. https://doi.org/10.6004/jnccn.2022.0025.

[6] Pfister, D. G., Spencer, S., Adelstein, D., Adkins, D., Anzai, Y., Brizel, D. M., Bruce, J. Y., Busse, P. M., Caudell, J. J., Cmelak, A. J., Colevas, A. D., Eisele, D. W., Fenton, M., Foote, R. L., Galloway, T., Gillison, M. L., Haddad, R. I., Hicks,

W. L., Hitchcock, Y. J., Jimeno, A., … Darlow, S. D. (2020). Head and Neck Cancers, Version 2.2020, NCCN Clinical Practice Guidelines in Oncology. Journal of the National Comprehensive Cancer Network: JNCCN, 18(7), 873–898. https://doi.org/10.6004/jnccn.2020.0031.

[7] National Comprehensive Cancer Network (2021). NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancer. https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf.

[8] National Comprehensive Cancer Network (2021). NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf.

A.2. Appropriate Germline Testing for Ovarian Cancer Patients

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients aged 18 and older diagnosed with epithelial ovarian, fallopian tube, or primary peritoneal cancer who undergo germline testing within 6 months of diagnosis.
Measure Steward:	American Society of Clinical Oncology
Numerator:	Patients who receive germline genetic testing for BRCA1 and BRCA2 (ideally within the context of a multigene panel) or who have genetic counseling completed within 6 months of diagnosis.
Denominator:	All patients, aged 18 and older, with epithelial ovarian, fallopian tube, or primary peritoneal cancer newly diagnosed between July 1st of the previous calendar year through June 30th of the current performance period with two encounters during the performance period.
Exclusions:	Patients who have germline BRCA testing completed before diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQM Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure

Category	Description
Rationale:	We are proposing this process measure because it addresses patients diagnosed with epithelial ovarian, fallopian tube, or primary peritoneal cancer who undergo germline testing within 6 months of their diagnosis to guide the most appropriate treatment. In addition, this measure addresses the CMS priority of promoting more personalized diagnostic, predictive, prognostic, and therapeutic options for the patient. According to the American Cancer Society, estimates indicate that there will be about 19,680 new cases of ovarian cancer diagnosed and an estimated 12,740 women will die of the disease, in 2024 in the U.S.[9] "Knowledge about underlying molecular alterations in ovarian cancer could allow for more personalized diagnostic, predictive, prognostic, and therapeutic strategies for the patient but also have clinical implications for her family members."[10] Despite current recommendations for all women diagnosed with ovarian cancer to receive genetic testing, only approximately 30 percent of those women undergo any genetic testing.[11] Germline mutations in BRCA1 and BRCA2 have been identified in 13 to 15 percent of women diagnosed with ovarian cancer, with somatic mutations found in an additional 7 percent of women. The high incidence of these mutations, in conjunction with the advent of therapy targeting BRCA mutations, warrants testing in all individuals diagnosed with ovarian cancer.[12] This testing serves multiple purposes, including determination of appropriate and best treatment recommendations, risk of other cancers, and need for cascade testing of family members. "Testing for germline mutations should be performed at the time of initial diagnosis. Presence of a germline mutation in a woman with advanced cancer designates her as eligible for maintenance therapy with a poly (ADP-ribose) polymerase (PARP) inhibitor (Olaparib) after response to initial chemotherapy."[13] Although the FDA recently approved frontline maintenance therapy for patients independent of mutation status following the publication of the ASCO evidence-based guidelines, emerging evidence is expected to indicate an overall survival benefit in ovarian cancer patients with germline mutations, based upon prognostic information from these patients. Germline mutations testing allows for more personalized therapeutic strategies, therefore, ovarian cancer patients with germline mutations are expected to derive greater benefit from therapy, thereby increasing the survival rate in this patient population.[14] Additionally, germline testing informs potential clinical implications for the relatives of ovarian cancer patients with germline mutations who should be offered individualized genetic risk evaluation, counseling, and genetic testing as reflected in Recommendation 1.5 in the ASCO germline testing guidelines.[15] Furthermore, NCCN evidence-based guidelines[16] indicate all patients with histologically confirmed ovarian, fallopian tube, or primary peritoneal cancer should undergo genetic risk evaluation as well as germline and somatic testing if not previously performed due to germline and/or somatic BRCA1 and BRCA2 statuses delineating future options for maintenance therapy. This measure could be added to the Advancing Cancer Care MVP in the future and would fill a current quality measure inventory gap within the oncologic clinical topic. In addition, it would provide a specialty specific measure for the MIPS Oncology/Hematology specialty set under Table B.27a of this Appendix. The PRMR Clinician Recommendation Committee conditionally supported this measure for rulemaking pending endorsement of the measure by a CBE. Although CBE endorsement is preferred, it is still recommended this measure be added to MIPS because it is an evidence-based measure, satisfying the requirement set forth at section 1848(q)(2)(D)(v) of the Act, stating that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. As mentioned above, this measure aligns with ASCO and NCCN evidence-based clinical guidelines.[17] [18] Note: Refer to the PRMR Clinician Recommendation Committee Spreadsheet of Final Recommendations to CMS and HHS at *https://p4qm.org/sites/default/files/2024-02/PRMR-Final-MUC-Recommendation-Spreadsheet%20%283%29.xlsx*.

A.3. Patient-Reported Pain Interference Following Chemotherapy among Adults with Breast Cancer

[9] American Cancer Society (ACS). (2024). Key Statistics for Ovarian Cancer. https://www.cancer.org/cancer/types/ovarian-cancer/about/key-statistics.html#:~:text=The%20American%20Cancer%20Society%20estimates%20for%20ovarian%20cancer,About%2012%2C740%20women%20will%20die%20from%20ovarian%20cancer.

[10] Konstantinopoulos, P. A., Norquist, B., Lacchetti, C., Armstrong, D., Grisham, R. N., Goodfellow, P. J., Kohn, E. C., Levine, D. A., Liu, J. F., Lu, K. H., Sparacio, D., & Annunziata, C. M. (2020). Germline and Somatic Tumor Testing in Epithelial Ovarian Cancer: ASCO Guideline. *Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology, 38(11), 1222–1245.* https://doi.org/10.1200/JCO.19.02960.

[11] See footnote Konstantinopoulos et al., 2020.

[12] See footnote Konstantinopoulos et al., 2020.

[13] See footnote Konstantinopoulos et al., 2020.

[14] See footnote Konstantinopoulos et al., 2020.

[15] See footnote Konstantinopoulos et al., 2020.

[16] NCCN. (2024). NCCN Guidelines: Detection, Prevention, and Risk Reduction. https://www.nccn.org/guidelines/category_2.

[17] See footnote Konstantinopoulos et al., 2020.

[18] See footnote NCCN, 2024.

Category	Description
CBE # / eCQM CBE #:	CBE 3718 / N/A
Quality #:	TBD
Description:	The PRO-PM will assess pain interference following chemotherapy administered with curative intent to adult female patients with breast cancer.
Measure Steward:	Purchaser Business Group on Health
Numerator:	The mean of the patient-level PROMIS Pain Interference scores at the follow-up survey.
Denominator:	Adult patients with stages I-III female breast cancer receiving an initial chemotherapy regimen.
Exclusions:	● Patients on a therapeutic clinical trial ● Patients with recurrence/disease progression ● Patients who leave the practice during the follow-up period ● Patients who died during the follow-up period
Measure Type:	Patient-Reported Outcome-based Performance Measure (PRO-PM)
High Priority Measure:	Yes
Collection Type:	MIPS CQM Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure

Category	Description
Rationale:	We are proposing this measure because it addresses a CMS high priority as a PRO-PM and fills a gap in providing the patient's experience of care related to breakthrough pain after chemotherapy for breast cancer lending to performance improvement. Common persistent symptoms following chemotherapy include pain, fatigue, and detriments to health-related quality of life. Data from this measure would provide insight into the effectiveness of minimizing the persistent symptoms following treatment(s), thereby driving quality improvement leading to practice changes and better patient outcomes. This oncology PRO-PM's conceptual development is grounded in the evidence-based premise that medical oncologists who provide the highest quality care (including medical and non-medical support services) to patients receiving curative-intent cytotoxic therapy can reduce longer-term symptom burden, thus improving a patient's transition into the cancer survivorship period.[19] [20] [21] Additionally, research suggests collecting and using patient-reported symptoms during cancer care can improve patient outcomes, such as increased survival, reduced symptom burden and improved patient experience.[22] [23] Using a standardized symptom assessment process would facilitate appropriate follow-up to ensure patient needs are addressed, while supporting and improving patient-provider communication. This measure could be added to the Advancing Cancer Care MVP in the future and would fill a current quality measure inventory gap within the oncologic clinical topic. In addition, it would provide a specialty specific measure for the MIPS Oncology/Hematology specialty set under Table B.27a of this Appendix. This would be the first outcome specialty specific oncology measure to address the patient experience of care. There is potential consideration for adding broader cancer diagnoses, such as colon and lung cancer, to this measure in the future. The PRMR Clinician Recommendation Committee conditionally supported this measure for rulemaking with the condition of implementation at the group level. This measure was endorsed by the CBE as CBE 3718. We are proposing this measure for implementation at the individual clinician level in addition to the group level. As part of the MERIT submission, testing was completed at the clinician level with a small sample size due to accessibility to data. However, the measure steward estimated that measure score reliability given an average sample size of 26 would yield a measure score reliability of 0.7. The measure was found during the MERIT submission to be feasible at the clinician level and data element testing was completed showing exact agreement values between 71.63 to 100 percent, with the lowest sensitivity variable being 'recurrence,' which would correlate to a small subset of the patient population. The requirements for quality measure scoring include a case minimum threshold; therefore, we are proposing to allow this measure for group and clinician level implementation as it is an important concept and meets all testing and development criteria for MIPS quality measures. Note: Refer to the PRMR Clinician Recommendation Committee Spreadsheet of Final Recommendations to CMS and HHS at *https://p4qm.org/sites/default/files/2024-02/PRMR-Final-MUC-Recommendation-Spreadsheet%20%283%29.xlsx*.

[19] NCCN. (2024). Clinical Practice Guidelines in Oncology, Cancer-Related Fatigue, Version 2.2024. https://www.nccn.org/guidelines/guidelines-detail?category=3&id=1424.

[20] Smith, T. G., Troeschel, A. N., Castro, K. M., Arora, N. K., Stein, K., Lipscomb, J., Brawley, O. W., McCabe, R. M., Clauser, S. B., & Ward, E. (2019). Perceptions of Patients With Breast and Colon Cancer of the Management of Cancer-Related Pain, Fatigue, and Emotional Distress in Community Oncology. Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology, 37(19), 1666–1676. https://doi.org/10.1200/JCO.18.01579.

[21] Bubis, L. D., Davis, L., Mahar, A., Barbera, L., Li, Q., Moody, L., Karanicolas, P., Sutradhar, R., & Coburn, N. G. (2018). Symptom Burden in the First Year After Cancer Diagnosis: An Analysis of Patient-Reported Outcomes. Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology, 36(11), 1103–1111. https://doi.org/10.1200/JCO.2017.76.0876.

[22] Basch, E., Deal, A. M., Kris, M. G., Scher, H. I., Hudis, C. A., Sabbatini, P., Rogak, L., Bennett, A. V., Dueck, A. C., Atkinson, T. M., Chou, J. F., Dulko, D., Sit, L., Barz, A., Novotny, P., Fruscione, M., Sloan, J. A., & Schrag, D. (2016). Symptom Monitoring With Patient-Reported Outcomes During Routine Cancer Treatment: A Randomized Controlled Trial. Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology, 34(6), 557–565. https://doi.org/10.1200/JCO.2015.63.0830.

[23] Papageorgiou, L., Le Provost, J. B., Di Palma, M., Langlois, M., Salma, I., Lopes, M., Minvielle, E., Abbas, M., & Scotté, F. (2024). Supportive Care Needs of Newly Diagnosed Cancer Patients in a Comprehensive Cancer Center: Identifying Care Profiles and Future Perspectives. Cancers, 16(5), 1017. https://doi.org/10.3390/cancers16051017.

A.4. Patient-Reported Fatigue Following Chemotherapy among Adults with Breast Cancer

Category	Description
CBE # / eCQM CBE #:	CBE 3720 / N/A
Quality #:	TBD
Description:	The PRO-PM will assess fatigue following chemotherapy administered with curative intent to adult female patients with breast cancer.
Measure Steward:	Purchaser Business Group on Health
Numerator:	The mean of the patient-level PROMIS Fatigue scores at the follow-up survey.
Denominator:	Adult patients with stages I-III female breast cancer receiving an initial chemotherapy regimen.
Exclusions:	● Patients on a therapeutic clinical trial ● Patients with recurrence/disease progression ● Patients who leave the practice during the follow-up period ● Patients who died during the follow-up period
Measure Type:	Patient-Reported Outcome-based Performance Measure (PRO-PM)
High Priority Measure:	Yes
Collection Type:	MIPS CQM Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure

Category	Description
Rationale:	We are proposing this measure because it addresses a CMS high priority as a PRO-PM and fills a gap in providing the patient reported symptom of fatigue experienced following chemotherapy for breast cancer, lending to performance improvement. This measure is an important addition to MIPS for those patients diagnosed with and receiving treatment for breast cancer. Based on a recent study, stakeholder generated recommendations for performance measures on how adults with cancer feel and function included depression/anxiety, pain, and fatigue as top priorities.[24] This oncology PRO-PM's conceptual development is grounded in the evidence-based premise that medical oncologists who provide the highest quality care (including medical and non-medical support services) to patients receiving curative-intent cytotoxic therapy can reduce longer-term symptom burden, thus improving a patient's transition into the cancer survivorship period.[25] [26] [27] Additionally, research suggests collecting and using patient-reported symptoms during cancer care can improve patient outcomes, such as increased survival, reduced symptom burden and improved patient experience.[28] Using a standardized symptom assessment process would facilitate appropriate follow-up to ensure patient needs are addressed, while supporting and improving patient-provider communication. Evidence from one study indicated 30 to 50 percent of breast cancer patients reported not discussing, nor receiving advice or desired help for three common symptoms including pain, fatigue, and emotional distress.[29] Fatigue was the most common symptom reported in the study (74 percent) with many patients reporting they discussed the symptom (78 percent).[30] However, patients who experienced fatigue were least likely to report receiving the desired help for it (40 percent).[31] Appropriate use of patient-reported outcome measures (PROMs), which measure cancer symptoms and patients' perceptions of their care, can improve the collection of clinically actionable data, supporting clinical improvement in the treatment of common symptoms and the overall care of patients with cancer, ultimately improving their quality of life.[32] This measure could be added to the Advancing Cancer Care MVP in the future and would fill a current quality measure inventory gap within the oncologic clinical topic. In addition, it would provide a specialty specific measure for the MIPS Oncology/Hematology specialty set under Table B.27a of this Appendix. This measure would address the patient voice/experience of care for those with breast cancer with fatigue experienced following chemotherapy. There is potential consideration for adding broader cancer diagnoses, such as colon and lung cancer, to this measure in the future. The PRMR Clinician Recommendation Committee did not reach consensus for this measure. This measure was endorsed by the CBE as CBE 3720. While concerns were discussed regarding electronic health record implementation, patient survey fatigue and low response impact, this measure is an important clinical topic for oncology clinicians in conjunction with the pain PRO-PM. More specifically, the measure provides a means to capture the patient voice while driving quality of care and improving patient outcomes. We are proposing this measure for implementation at the individual clinician level in addition to the group level. Testing was completed at the clinician level with a small sample size due to accessibility to data. The measure was found during the MERIT submission process to be feasible at the clinician level and data element testing was completed showing exact agreement values between 71.63 to 100 percent, with the lowest sensitivity variable being 'recurrence,' which would correlate to a small subset of the patient population. The requirements for quality measure scoring include a case minimum threshold; therefore, we are proposing to allow this measure for group and clinician level implementation as it is an important concept and meets all testing and development criteria for MIPS quality measures. Note: Refer to the PRMR Clinician Recommendation Committee Spreadsheet of Final Recommendations to CMS and HHS at *https://p4qm.org/sites/default/files/2024-02/PRMR-Final-MUC-Recommendation-Spreadsheet%20%283%29.xlsx*.

[24] See footnote Smith et al., 2019 in Table A.3 of this Appendix.
[25] See footnote Smith et al., 2019 in Table A.3 of this Appendix.
[26] See footnote NCCN, 2024 in Table A.3 of this Appendix.
[27] See footnote Bubis et al., 2018 in Table A.3 of this Appendix.
[28] See footnote Basch et al., 2016 in Table A.3 of this Appendix.
[29] See footnote Smith et al., 2019 in Table A.3 of this Appendix.
[30] See footnote Smith et al., 2019 in Table A.3 of this Appendix.
[31] See footnote Smith et al., 2019 in Table A.3 of this Appendix.
[32] See footnote Smith et al., 2019 in Table A.3 of this Appendix.

A.5. Adult COVID-19 Vaccination Status

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients aged 18 years and older seen for a visit during the performance period that are up-to-date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Patients that are up to date on their COVID-19 vaccinations as defined by CDC recommendations on current vaccination as of the date of the encounter.
Denominator:	All patients aged 18 years and older seen for a visit during the performance period.
Exclusions:	Patient received hospice services any time during the performance period.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQM Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure

Rationale:	We are proposing this process measure because it represents an important clinical topic following the recently ended Public Health Emergency (PHE) for COVID-19. This process measure represents a CMS high priority clinical topic and fills a gap in MIPS by addressing COVID-19 vaccination status for all patients and ensuring clinician vaccination efforts at the point of care (for example, care for wellness and prevention against COVID-19). Widespread vaccination to prevent a severe COVID-19 infection is critically important to stemming the morbidity and mortality caused by this virus. The CDC reports millions of cases and deaths caused by COVID-19.[33] In 2020 and 2021, COVID-19 was the third leading cause of death in the U.S., exceeded only by cancer and heart disease.[34] The percent of the population reporting receipt of the updated 2023-24 COVID-19 vaccine is 13.1 percent (95 percent confidence interval: 12.5-13.7) for children and 22.5 percent (21.7-22.7) for adults 18 years and older, including 41.5 percent (40.2-42.9) among adults age 65 years and older.[35] [36] This recent data suggests a considerable gap in care for patients in the measure population and allows clinicians the opportunity to positively affect vaccination rates. Additionally, during measure testing, the measure developer found even the 75th percentile of performance yielded only 58 percent of a clinician's patient load being vaccinated with one booster. The measure was initially submitted to the CY 2022 Call for Quality Measures and included on the Measures under Consideration (MUC) list for review. During the 2022 cycle, the Measure Applications Partnership (MAP) recommended not to support the measure and requested the measure be revised before resubmitting for consideration to, among other things, include the most recent CDC recommendations for the numerator and use the current CDC definition of "up-to-date" for assessment of the quality action for each denominator eligible patient. These requests were addressed, and the measure was resubmitted to the CY 2023 Call for Quality Measures. We acknowledge the recommendations for boosters have continued to evolve; however, the quality action in this measure is aligned with current and potential future recommendations. Since December 2020, there have been 19 ACIP recommendations relating to COVID-19 vaccination. On September 12, 2023, ACIP recommended all persons aged 6 months and older receive an updated COVID-19 vaccine.[37] Updated COVID-19 vaccines are considered the 2023-2024 formula developed by the pharmaceutical and biotechnology companies Moderna, Pfizer-BioNTech, and Novavax. Because this measure uses the CDC's definition of "up-to-date," please refer to the CDC's website[38] to confirm the current definition of "up-to-date." Based on clinical recommendations and systemic reviews, there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[39] [40] [41] While this measure does not meet the definition of a fully developed measure as outlined in the Measures Management System (MMS),[42] MIPS currently includes several quality measures that assess for vaccine administration, which have been implemented for multiple years.[43] We request interested parties consider whether the measure is "beyond the measure concept phase of development and [has] started testing, at a minimum, with strong encouragement and preference for measures that have completed or are near completion of reliability and validity testing" when submitting a quality measure for possible inclusion (83 FR 53636; 84 FR 62954). While we take under consideration whether a measure is fully tested, it is not the only relevant standard for MIPS. Nevertheless, we believe this consideration reinforces the importance of all clinicians actively addressing vaccination against the COVID-19 virus. According to the World Health Organization (WHO), getting vaccinated is one of the most important steps an individual can take to not only to protect oneself, but to help end the pandemic and stop the emergence of new variants.[44] The PRMR Clinician Recommendation Committee did not reach consensus on this measure for rulemaking, expressing concerns about data collection for vaccines administered through off-site locations (for example, pharmacies), as well as vaccine hesitancy that may vary across geography, political affiliation, ethnicity, and income. The committee considered the measure's importance to patients, with emphasis on those at higher risk for complications from COVID-19. ACIP recommendations support the measure, all of which are evidence-based.[45] This measure is not currently CBE endorsed. Although CBE endorsement is preferred, it is still recommended this measure be added to MIPS because it is an evidence-based measure, satisfying the requirement set forth at section 1848(q)(2)(D)(v) of the Act, stating that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. The CDC COVID-19 Immunization Schedule, based on ACIP recommendations, can be referenced at the following webpage: *https://www.cdc.gov/vaccines/schedules/index.html*. Clinical recommendations are in universal agreement that COVID-19 vaccines are safe, effective, and may prevent costly and harmful hospitalizations. The MIPS quality measure set includes several vaccine administration quality measures that have been implemented for several years; however, such measures do not include the COVID-19 vaccination.[46] This measure could also be considered for potential inclusion in the Primary Care MVP as it would fill a current quality measure inventory gap within the vaccination clinical topic for primary care settings. This measure, along with other activities, are a part of a larger Federal effort to promote and track vaccine uptake.[47] Since vaccine uptake is partially driven by patients requesting the vaccine followed by clinicians administering it to eligible patients, the patient/clinician relationship is a vital aspect for ensuring patients are vaccinated. This clinician-level measure would provide useful information regarding the success of vaccination efforts at the point of care, and, again, represents a priority topic to engage clinicians in quality improvements that drive positive health outcomes for their patients. We acknowledge this measure may not be selected by all clinicians, but this factor aligns with MIPS allowing for clinician choice in choosing quality measures that best represent their scope of care. Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination. As with all quality measures within MIPS, we continue to monitor all updates to the clinical recommendations and guidelines and address changes as needed utilizing the current annual revision cycle.

Category	Description
	Note: Refer to the PRMR Clinician Recommendation Committee Spreadsheet of Final Recommendations to CMS and HHS at *https://p4qm.org/sites/default/files/2024-02/PRMR-Final-MUC-Recommendation-Spreadsheet%20%283%29.xlsx*.

[33] CDC. (2024). COVID Data Tracker. Atlanta, GA: U.S. Department of Health and Human Services. *https://covid.cdc.gov/covid-data-tracker.*

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[35] CDC. (2024). Vaccination Trends – Children. https://www.cdc.gov/respiratory-viruses/data-research/dashboard/vaccination-trends-children.html.

[36] CDC. (2024). Vaccination Trends – Adults. https://www.cdc.gov/respiratory-viruses/data-research/dashboard/vaccination-trends-adults.html.

[37] Centers for Disease Control and Prevention (CDC). (2023). Use of Updated COVID-19 Vaccines 2023–2024 Formula for Persons Aged ≥6 Months: Recommendations of the Advisory Committee on Immunization Practices — United States. https://www.cdc.gov/mmwr/volumes/72/wr/mm7242e1.htm.

[38] CDC. (2024). Stay Up to Date with COVID-19 Vaccines. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.

[39] Fitzpatrick, M. C., Moghadas, S. M., Pandey, A., & Galvani, A. P. (2022). Two Years of US COVID-19 Vaccines Have Prevented Millions of Hospitalizations and Deaths. To the Point (blog), Commonwealth Fund. December 13. https://doi.org/10.26099/whsf-fp90.

[40] Polack, F. P., Thomas, S. J., Kitchin, N., Absalon, J., Gurtman, A., Lockhart, S., Perez, J. L., Pérez Marc, G., Moreira, E. D., Zerbini, C., Bailey, R., Swanson, K. A., Roychoudhury, S., Koury, K., Li, P., Kalina, W. V., Cooper, D., Frenck, R. W., Jr, Hammitt, L. L., Türeci, Ö., … C4591001 Clinical Trial Group. (2020). Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. The New England Journal of Medicine, 383(27), 2603–2615. https://doi.org/10.1056/NEJMoa2034577.

[41] Graña, C., Ghosn, L., Evrenoglou, T., Jarde, A., Minozzi, S., ... & Boutron, I. (2022). Efficacy and Safety of COVID-19 Vaccines. Cochrane Database of Systematic Reviews, 2023(3). https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD015477/full.

[42] CMS. (2023). Measure Implementation – Measure Selection. https://mmshub.cms.gov/measure-lifecycle/measure-implementation/selection.

[43] See 2024 MIPS Quality Measures List: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2632/2024%20MIPS%20Quality%20Measures%20List.xlsx.

[44] World Health Organization. (2021, July). Vaccine Efficacy, Effectiveness and Protection. https://www.who.int/news-room/feature-stories/detail/vaccine-efficacy-effectiveness-and-protection.

[45] CDC. (2023, December 12). Vaccine Recommendations and Guidelines of the ACIP: COVID-19 ACIP Vaccine Recommendations. https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html.

[46] See 2024 MIPS Quality Measures List: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2632/2024%20MIPS%20Quality%20Measures%20List.xlsx.

[47] Department of Health & Human Services. Vaccines Federal Implementation Plan for the United States: 2021-2025. https://www.hhs.gov/sites/default/files/vaccines-federal-implementation-plan-2021-2025.pdf.

A.6. Melanoma: Tracking and Evaluation of Recurrence

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients who had an excisional surgery for melanoma or melanoma in situ with initial American Joint Committee on Cancer (AJCC) staging of 0, I, or II, in the past 5 years in which the operating clinician examines and/or diagnoses the patient for recurrence of melanoma.
Measure Steward:	American Academy of Dermatology
Numerator:	NUMERATOR CRITERIA 1: Documentation by the clinician who performed the surgery that an exam for recurrence of melanoma was performed on the patient within the performance period. NUMERATOR CRITERIA 2: All patients that were diagnosed with a recurrent melanoma in the current performance period.
Denominator:	DENOMINATOR CRITERIA 1 & 2: All patients that the clinician has performed a type of excisional surgery for melanoma or melanoma in situ in the past 5 years with an initial AJCC staging of 0, I, or II.
Exclusions:	Patients who died during the performance period
Measure Type:	Process
High Priority Measure:	Yes
Collection Type:	MIPS CQM Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure

Category	Description
Rationale:	We are proposing this measure because it evaluates the frequency of recurrence for melanoma along with the type of recurrence after an excisional procedure, in addition to driving communication regarding the recurrence status of melanoma patients. The measure also addresses a CMS high priority process measure for care coordination on the clinical topic as miscommunication between the excising clinician and the clinician continuing care has been identified as a gap. This measure allows for and promotes the development of a system in which melanomas can be accurately tracked to increase the effectiveness of understanding melanoma recurrence and follow-up care. Melanoma recurrence requires precise evaluation. As indicated by one study, patients who have undergone treatment of primary melanoma, early detection of a local recurrence has important implications. An isolated local recurrence in a patient with favorable features can be treated with repeat wide local excision, with good oncologic outcomes. For these patients, long-term prognosis is not adversely affected by the local recurrence if it is detected and treated early, and 5-year survival continues to be a function of primary tumor thickness.[48] [49] [50] [51] Regular clinical examination offers the highest diagnostic yield in detecting melanoma recurrences.[52] Common follow-up recommendations for all patients indicate the follow-up schedule is influenced by risk of recurrence, prior primary melanoma, and family history of melanoma. It also includes other factors such as atypical moles/dysplastic nevi.[53] For patients who present with stage I-II melanoma and are rendered free of disease after initial treatment, recurrence rates are distributed as follows: approximately 15 to 20 percent are local or in transit.[54] Data suggests the time between the risk of recurrence to reach its low plateau depends on the stage of disease at first presentation.[55] In a retrospective study of patients who initially presented with stage I melanoma (N = 1568), 80 percent of the 293 recurrences developed within the first 3 years, but some recurrences (<8 percent) were detected 5 to 10 years after the initial treatment.[56] A prospective study found that for patients with stage I or II at initial presentation, the risk of recurrence reached a low level by 4.4 years after initial diagnosis.[57] Therefore, we are proposing this measure to incentivize clinicians who treat patients with melanoma to perform these potentially lifesaving exams. The PRMR Clinician Recommendation Committee did not reach consensus in recommending the measure for inclusion in MIPS. The committee agreed with the importance of the measure's intent. There was significant concern raised about the burden of tracking and reporting, reliability of the measure and interpretation of testing results, and the impact of lower reliability on clinician compensation. However, the measure was fully tested at the clinician level and has been determined to be implementable in MIPS. The measure has been available for MIPS reporting as a QCDR measure since 2022, which attests to its feasibility as no implementation issues have been identified. This measure is not currently CBE endorsed. Although CBE endorsement is preferred, it is still recommended this measure be added to MIPS because it is an evidence-based measure, satisfying the requirement set forth at section 1848(q)(2)(D)(v) of the Act, stating that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. This measure aligns with NCCN guidelines. This measure fills a gap in MIPS within the dermatologic clinical topic, as there are no other dermatology measures related to the outcome of melanoma recurrence. There is potential to replace current structure measure Q137: Melanoma: Continuity of Care with this more robust outcome measure as indicated in Table C.2 of this Appendix. While the MIPS Dermatology specialty set includes 13 measures, only 6 are specialty specific. This measure is relevant to specialty clinicians and could provide a new measure option for a specialty area that currently encompasses many topped-out measures, while also potentially aiding in the development of a meaningful MVP. Note: Refer to the PRMR Clinician Recommendation Committee Spreadsheet of Final Recommendations to CMS and HHS at *https://p4qm.org/sites/default/files/2024-02/PRMR-Final-MUC-Recommendation-Spreadsheet%20%283%29.xlsx*.

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[51] Rhodes A. R. (2006). Cutaneous Melanoma and Intervention Strategies to Reduce Tumor-related Mortality: What we know, what we don't know, and what we think we know that isn't so. *Dermatologic Therapy*, *19*(1), 50–69. https://doi.org/10.1111/j.1529-8019.2005.00056.x.

[52] See footnote Rueth et al., 2015.

[53] Trotter, S. C., Sroa, N., Winkelmann, R. R., Olencki, T., & Bechtel, M. (2013). A Global Review of Melanoma Follow-up Guidelines. *The Journal of Clinical and Aesthetic Dermatology*, *6*(9), 18–26.
[54] See footnote Trotter et al., 2013.
[55] See footnote Trotter et al., 2013.
[56] See footnote Trotter et al., 2013.
[57] NCCN. NCCN Guidelines – Melanoma: Cutaneous. https://www.nccn.org/guidelines/guidelines-detail?category=1&id=1492.

A.7. First Year Standardized Waitlist Ratio (FYSWR)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	The number of newly initiated patients on dialysis in a practitioner group who are under the age of 75 and were either listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant within the first year of initiating dialysis. The practitioner group is inclusive of physicians and advanced practice providers. The measure is the ratio-observed number of waitlist events in a practitioner group to its expected number of waitlist events. The measure uses the expected waitlist events calculated from a Cox model, which is adjusted for age, patient comorbidities, and other risk factors at the time of dialysis.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Numerator 1. Patients who initiated dialysis and had documentation of status at the end of the first year after initiating dialysis. Numerator 2. The ratio of the observed number of waitlist events in a practitioner group to the model-based expected number of waitlist events.
Denominator:	Denominator 1. Patients aged 75 years of age or less who have initiated dialysis during January 1st – December 31st of the previous performance period. Denominator 2. The denominator for the First Year Standardized Waitlist Ratio (FYSWR) is the total number of patients under the age of 75 in the practitioner group according to each patient's treatment history for patients within the first year following initiation of dialysis.
Exclusions:	Patients admitted to a skilled nursing facility (SNF). Patients in hospice on their initiation of dialysis date or during the month of evaluation. Patients that were on the kidney or kidney-pancreas waitlist prior to initiation of dialysis. Patients who had a transplant prior to initiation of dialysis.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQM Specifications
Measure-Specific Case Minimum/Performance Period:	If a dialysis practitioner group has fewer than 11 patients or 2 expected events, then the dialysis practitioner group is excluded from reporting outcomes.

Category	Description
Rationale:	This measure was originally proposed in the CY 2024 PFS proposed rule (88 FR 52771 through 52772) but was not finalized in the CY 2024 PFS final rule (88 FR 79565 through 88 FR 79566) due to implementation issues within MIPS regarding timing and application of the risk adjustment methodology. We are again proposing this measure because it addresses a CMS high priority clinical topic: patients with end-stage renal disease (ESRD). We indicated we would allow further refinement and streamlining of the measure analytic for future MIPS implementation. The measure and measure analytic have been revised to include two submission criteria, allowing for determination of data completeness and the full utilization of the risk-adjusted model in the second submission criterion to create a continuous variable analytic, assessing the ratio of observed to expected waitlist events. ESRD affects nearly 786,000 Americans, and dialysis for ESRD patients represents a significant portion of annual Medicare expenditures.[58] While dialysis is a treatment for ESRD, it is associated with increased mortality and lower quality of life for ESRD patients when compared to kidney transplant.[59] This measure assesses whether patients who are in their first year of dialysis, and are found to be an expected waitlist event based upon the Cox model, were placed on either the kidney or kidney-pancreas transplant waitlist or received a living donor kidney transplant. Data submitted by the measure developer indicates a performance gap for a process that can be directly linked to improved patient outcomes. This measure is separate from the other transplant waitlist measure, proposed under Table A.8 of this Appendix, as it is limited to assessing the first year after initiation of dialysis and the timely addition of those patients to the transplant waitlist—a crucial step in driving positive outcomes in the patient population. National and large regional studies provide strong empirical support for the association between processes within the clinical scope and control of dialysis practitioners followed by subsequent patient transplant wait listing. For example, the clinical assessments, provisions and/or referrals made by a dialysis practitioner are contributing factors for consideration in patient transplant wait listing. In one large regional study conducted on facilities in the state of Georgia, a standardized dialysis facility referral ratio was developed, adjusted for age, demographics, and comorbidities.[60] There was substantial variability across dialysis facilities in referral rates, and a Spearman correlation performed between ranking on the referral ratio and dialysis facility waitlist rates was highly significant ($r=0.35$, $p<0.001$).[61] A national study using registry data (United States Renal Data System) from 2005-2007 examined the association between whether patients were informed about kidney transplantation based on reporting on the Medical Evidence Form 2728 *(https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS2728.pdf)* and subsequent access to kidney transplantation (wait listing or receipt of a live donor transplant).[62] Approximately 30 percent of patients were uninformed about kidney transplantation, which was associated with half the rate of access to transplantation compared to patients who were informed.[63] In a related survey study of 388 hemodialysis patients, whether provision of information about transplantation by nephrologists or dialysis staff occurred was directly confirmed with patients.[64] The provision of such information was associated with a near threefold increase in likelihood of wait listing.[65] The intent of this measure is to track the initial placement on the kidney or kidney-pancreas transplantation waitlist or receipt of a living donor transplant within the first year after dialysis initiation, with the intended objective of improving the overall health of patients on dialysis. Being waitlisted or receiving a living donor kidney transplant represents a desirable change in health status for patients on dialysis, indicating achievement of a health condition conducive to kidney transplantation. Waitlisting is a direct step in the process of transplantation which drives quality by progressing patients towards the goal of transplantation and better health outcomes. Being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities, which may include providing education to patients about the option(s) of transplantation, referral of patients to a transplant center for evaluation, completion of the evaluation process, and optimizing the health of the patient while on dialysis. These efforts depend heavily and, in many cases, primarily, on dialysis practitioner groups. Aspects that are not directly in the clinician/groups control can be influenced through coordination of care, strong communication with transplant centers, and advocacy for patients. All clinicians should be involved and actively work towards providing patients with high quality care including ensuring placement on the transplant list as quickly as possible. The PRMR (formerly the MAP), did not support this measure for rulemaking with the potential for mitigation to update the measure and address the concern from the Renal Standing Committee regarding the evidence base and specifications, and thus recommended this measure be resubmitted for endorsement by a CBE. Although CBE endorsement is preferred, it is still recommended this measure be added to MIPS because it is an evidence-based measure, satisfying the requirement set forth at section 1848(q)(2)(D)(v) of the Act, stating that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. As discussed above, studies suggest a significant positive correlation between the clinician activities and the addition of patients to a transplant waitlist, which are necessary for patients to receive the improved outcomes associated with kidney transplant. Note: Refer to the 2022 MUC List-Final Recommendations to CMS and HHS at *https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fmmshub.cms.gov%2Fsites%2Fdefault%2Ffiles%2F2022-MUC-List.xlsx&wdOrigin=BROWSELINK.*

[58] National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). (2023). Kidney Disease Statistics for the United States. https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease.

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[61] See footnote Paul et al., 2018.

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[65] See footnote Salter et al., 2014.

A.8. Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	The measure tracks dialysis patients who are under the age of 75 in a practitioner group and on the kidney or kidney-pancreas transplant waitlist (all patients or patients in active status). This measure is a risk-adjusted percentage of waitlist events among dialysis patients.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Numerator 1: Percentage of Prevalent Patients Waitlisted (PPPW): Patients in the practitioner group's denominator with observed months on the waitlist for each month. Numerator 2: Percentage of Prevalent Patients Waitlisted in Active (aPPPW): Patients in the practitioner group's denominator with observed months on the waitlist in active status for each month.
Denominator:	Denominator 1 and 2: All risk-adjusted patient-months for patients who are under the age of 75 in the reporting month and who are assigned to a dialysis practitioner or practitioner group practice according to each patient's treatment history on the last day of each reporting month during the performance year.
Exclusions:	Patients who were admitted to a skilled nursing facility (SNF) during the month of evaluation were excluded from that month. Patients who were admitted to a skilled nursing facility (SNF) within one year of dialysis initiation according to the CMS-2728 form. Patients determined to be in hospice were excluded from month of evaluation and the remainder of reporting period. Patients with dementia at any time prior to or during the month.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQM Specifications
Measure-Specific Case Minimum/Performance Period:	If a dialysis practitioner group has fewer than 11 patients during the performance year, the dialysis practitioner group is excluded from reporting outcomes.

Category	Description
Rationale:	This measure was originally proposed in the CY 2024 PFS proposed rule (88 FR 52773 through 52774) but was not finalized in the CY 2024 PFS final rule (88 FR 79567 through 79568) due to implementation issues within MIPS regarding timing and application of the risk adjustment methodology. We are again proposing this measure because it addresses a CMS high priority clinical topic: patients with ESRD. We indicated we would allow further refinement and streamlining of the measure analytic for future MIPS implementation. The measure, including component calculations, was revised to allow for a proportional analytic to be used for the purposes of determining measure performance, while still incorporating the risk-adjusted model to ensure the appropriate denominator eligible patient population for numerator assessment. ESRD affects nearly 786,000 Americans, and dialysis for ESRD patients represents a significant portion of annual Medicare expenditures.[66] While dialysis is a treatment for ESRD, it is associated with increased mortality and lower quality of life for ESRD patients when compared to kidney transplant.[67] This measure would capture the adjusted count of patient months on the kidney and kidney-pancreas transplant waitlists for all dialysis patients in a dialysis practitioner or group practice by assessing patient status on the last day of each month during the reporting year, and those on the transplant waitlist in active status as of the last day of the month during the reporting year. This process measure is directly linked to driving positive outcomes and measure data indicates a performance gap. Most ESRD patients have to wait for access to a deceased donor transplant, with the national median being roughly 4 years.[68] Maintenance of 'active status' on the transplant list requires ongoing collaboration between dialysis practitioners, transplant centers, and transplant networks, thereby ensuring sustained suitability for a transplant while optimizing the health of patients.[69] This maintenance process is associated with higher transplantation rates and lowered mortality rates while on the waitlist.[70] In addition, the maintenance of 'active status' is an important health equity issue. Research has found disparities in access to kidney transplant by race.[71] Race-neutral efforts by clinicians to encourage maintenance of patients on the waitlist may reduce such disparities while improving their performance on this measure.[72] This measure and the previously proposed measure under Table A.7, the First Year Standardized Waitlist Ratio measure, work in tandem to assess initial and on-going care. This measure would assess monthly wait listing in active status of patients. It also would evaluate and encourage maintenance of patients on the waitlist. This is an important area to which dialysis practitioners can contribute through ensuring patients remain healthy and complete any ongoing testing activities required to remain active on the waitlist. In contrast to this measure, the First Year Standardized Waitlist Ratio measure would focus solely on new wait listings and living donor kidney transplants to incentivize early action, rather than ongoing maintenance on the waitlist, which this measure assesses. The PRMR conditionally supported this measure for rulemaking pending an update of the measure's specifications to include only the PPPW (CBE 3695) rate that was recommended for endorsement by the CBE's Renal Standing Committee. Although CBE endorsement is preferred, it is still recommended this measure be added to MIPS because it is an evidence-based measure, satisfying the requirement set forth at section 1848(q)(2)(D)(v) of the Act, stating that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. The CBE recommended endorsement for the PPPW subset of this measure. It is important to include the aPPPW rate in this measure as well to capture patients in active waitlist status, and the full scope of the transplant list with movement of patients between active and inactive status. The studies cited above provide the evidentiary basis for the adoption of this measure. After review, it was determined that the testing provided by the measure steward demonstrated statistically sufficient results for the reliability and validity of each of the numerator actions, meeting requirements described within the CMS MMS Hub (*https://mmshub.cms.gov/*) regarding quality measure testing. Note: Refer to the 2022 MUC List-Final Recommendations to CMS and HHS at *https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fmmshub.cms.gov%2Fsites%2Fdefault%2Ffiles%2F2022-MUC-List.xlsx&wdOrigin=BROWSELINK*.

[66] See footnote NIDDK, 2023.

[67] See footnote Wouk, 2021.

[68] Johansen, K. L., Chertow, G. M., Foley, R. N., Gilbertson, D. T., Herzog, C. A., Ishani, A., ... & Wetmore, J. B. (2021). US Renal Data System 2020 Annual Data Report: Epidemiology of Kidney Disease in the United States. American Journal of Kidney Diseases, 77(4), A7-A8. https://www.ajkd.org/article/S0272-6386(21)00024-X/fulltext.

[69] Grams, M. E., Massie, A. B., Schold, J. D., Chen, B. P., & Segev, D. L. (2013). Trends in the Inactive Kidney Transplant Waitlist and Implications for Candidate Survival. American Journal of Transplantation, 13(4), 1012-1018. https://onlinelibrary.wiley.com/doi/pdf/10.1111/ajt.12143.

[70] See footnote Grams et al., 2013.

[71] Kulkarni, S., Ladin, K., Haakinson, D., Greene, E., Li, L., & Deng, Y. (2019). Association of Racial Disparities with Access to Kidney Transplant after the Implementation of the New Kidney Allocation System. JAMA surgery, 154(7), 618-625. https://jamanetwork.com/journals/jamasurgery/fullarticle/2729436.

[72] See footnote Kulkarni et al., 2019.

Table Group B: New Specialty Measure Sets Proposed for Addition and Modifications to Previously Finalized Specialty Measure Sets Proposed for the CY 2025 Performance Period/2027 MIPS Payment Year and Future Years

We are proposing to add one new specialty measure set: Optometry. In the CY 2023 PFS final rule, we finalized a combined Ophthalmology/Optometry specialty set (87 FR 70275 and 87 FR 70434 through 70439). Based on interested parties' request, we are proposing to revert this combined specialty set to "Ophthalmology" under Table B.28 of this Appendix with all measures retained as finalized under the CY 2024 PFS final rule (88 FR 79777 through 79784). We are simultaneously proposing to create a separate Optometry specialty set with a more limited number of quality measures based on differences in scope of practice to ophthalmology. The Optometry specialty set is proposed for comment under Table B.29 of this Appendix.

We are proposing to modify the below previously finalized specialty measure sets based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and feedback provided by specialty societies. There may be instances where the quality measures within a specialty set remain static, but the individual measures have proposed substantive changes in Table Group D of this Appendix. In the first column, existing measures with substantive changes described in Table Group D of this Appendix are noted with an asterisk (*), core measures that align with Core Quality Measure Collaborative (CQMC) core measure set(s) are noted with the symbol (§), and high priority measures are noted with an exclamation point (!). The Indicator column includes a "high priority type" in parentheses after each high priority indicator (!) to represent the regulatory definition of high priority measures. In addition, eCQMs that are endorsed by a CBE are shown in Table Group B of this Appendix as follows: CBE # / eCQM CBE #.

Under § 414.1305, a high priority measure means an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, opioid, or health equity-related quality measure. Further details of these types of measures may be found in the CMS Measures Management System Hub (*https://mmshub.cms.gov/*).

Previously finalized measures that have no substantive changes are not open for comment under this proposed rule. We seek comment on proposed additions and proposed removals under applicable specialty sets in Table Group B of this Appendix.

The following specialty sets have no measures added, no measures removed, and no substantive changes proposed for the CY 2025 performance period/2027 MIPS payment year: Anesthesiology and Dentistry.

The following specialty sets have no measures added and no measures removed, but have substantive changes proposed as addressed under Table Group D: Audiology, Electrophysiology Cardiac Specialist, Certified Nurse Midwife, Chiropractic Medicine, Diagnostic Radiology, General Surgery, Hospitalists, Mental/Behavioral Health and Psychiatry, Neurology, Nutrition/Dietician, Ophthalmology, Orthopedic Surgery, Pathology, Pediatrics, Physical Medicine, Physical Therapy/Occupational Therapy, Plastic Surgery, Podiatry, and Thoracic Surgery.

Note: In the CY 2024 PFS final rule, new measure Q494: Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level) was finalized with a 1-year delay to the 2025 performance period (88 FR 79556 through 79560). As a result, measure Q436: Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques was finalized for removal with a 1-year delay to the 2025 performance period (88 FR 79896). These decisions are reflected within table B.10 Diagnostic Radiology specialty set of this Appendix.

B.1. Allergy/Immunology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Allergy/Immunology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Allergy/Immunology specialty set.

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the 6 months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS15 6v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQM Specifications	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQM Specifications	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	338	CMS31 4v2	eCQM Specifications, MIPS CQM Specifications	Outcome	**HIV Viral Suppression:** Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period, with an eligible encounter in the first 240 days of the performance period, whose last HIV viral load test result was less than 200 copies/mL during the performance period.	Health Resources and Services Administration
* § ! (Efficiency)	N/A / N/A	340	N/A	MIPS CQM Specifications	Process	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6-month period of the 24-month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration
* ! (Care Coordination)	N/A / N/A	374	CMS50 v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	398	N/A	MIPS CQM Specifications	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.1. Allergy/Immunology

MEASURES PROPOSED FOR ADDITION TO THE ALLERGY/IMMUNOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up-to-date on their COVID-19 vaccinations as defined by CDC recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We are proposing to include this measure in the Allergy/ Immunology specialty set as it would be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[73] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set would help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[74] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set. See Table A.5 of this Appendix for rationale, including clinical evidence

[73] Ikeokwu, A. E., Lawrence, R., Osieme, E. D., Gidado, K. M., Guy, C., & Dolapo, O. (2023). Unveiling the Impact of COVID-19 Vaccines: A Meta-Analysis of Survival Rates Among Patients in the United States Based on Vaccination Status. *Cureus*, *15*(8), e43282. https://doi.org/10.7759/cureus.43282.

[74] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

B.1. Allergy/Immunology

MEASURES PROPOSED FOR **ADDITION** TO THE ALLERGY/IMMUNOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								supporting the inclusion of this measure in MIPS.

B.2. Anesthesiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Anesthesiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, as applicable. This specialty set has no proposed changes.

B.2. Anesthesiology

PREVIOUSLY FINALIZED MEASURES IN THE ANESTHESIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	404	N/A	MIPS CQM Specifications	Intermediate Outcome	**Anesthesiology Smoking Abstinence:** The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.	American Society of Anesthesiologists
! (Outcome)	N/A / N/A	424	N/A	MIPS CQM Specifications	Outcome	**Perioperative Temperature Management:** Percentage of patients, regardless of age, who undergo surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer for whom at least one body temperature greater than or equal to 35.5 degrees Celsius (or 95.9 degrees Fahrenheit) was achieved within the 30 minutes immediately before or 15 minutes immediately after anesthesia end time.	American Society of Anesthesiologists
! (Patient Safety)	N/A / N/A	430	N/A	MIPS CQM Specifications	Process	**Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy:** Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
! (Patient Safety)	N/A / N/A	463	N/A	MIPS CQM Specifications	Process	**Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics):** Percentage of patients aged 3 through 17 years, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists

B.2. Anesthesiology

PREVIOUSLY FINALIZED MEASURES IN THE ANESTHESIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A / N/A	477	N/A	MIPS CQM Specifications	Process	**Multimodal Pain Management:** Percentage of patients, aged 18 years and older, undergoing selected surgical procedures that were managed with multimodal pain medicine.	American Society of Anesthesiologists

B.3. Audiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Audiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Audiology specialty set that have proposed substantive changes in Table Group D of this Appendix as indicated by an * in the Indicator column.

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	134	CMS2v14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within 2 days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the 6 months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Care Coordination)	NA / NA	261	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness:** Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness.	Audiology Quality Consortium
*	N/A / N/A	317	CMS22v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS139v13	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§	2152/ N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN

B.4a. Cardiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Cardiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Cardiology specialty set.

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	0081 / 0081e	005	CMS13 5v13	eCQM Specifications, MIPS CQM Specifications	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
§	0067 / N/A	006	N/A	MIPS CQM Specifications	Process	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070 / 0070e	007	CMS14 5v13	eCQM Specifications, MIPS CQM Specifications	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association
§	0083 / 0083e	008	CMS14 4v13	eCQM Specifications, MIPS CQM Specifications	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§	0066 / N/A	118	N/A	MIPS CQM Specifications	Process	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%)**: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	187	N/A	MIPS CQM Specifications	Process	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy**: Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.	American Heart Association
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the 6 months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	236	CMS16 5v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Inter-mediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first 6 months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS15 6v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQM Specifications	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
*	N/A / N/A	317	CMS22 v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Efficiency)	N/A / N/A	322	N/A	MIPS CQM Specifications	Efficiency	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low-risk surgery patients 18 years or older for preoperative evaluation during the 12-month submission period.	American College of Cardiology Foundation

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	326	N/A	MIPS CQM Specifications	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
* ! (Outcome)	N/A / N/A	344	N/A	MIPS CQM Specifications	Outcome	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	438	CMS347v8	eCQM Specifications, MIPS CQM Specifications	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the performance period: •All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR •Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR; •Patients aged 40 to 75 years with a diagnosis of diabetes; OR; •Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	N/A / N/A	441	N/A	MIPS CQM Specifications	Intermediate Outcome	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.4a. Cardiology

MEASURES PROPOSED FOR **ADDITION** TO THE CARDIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)	We are proposing to include this measure in the Cardiology specialty set as it would be clinically relevant to this clinician type. This PRO-PM would help to fill a gap for patients receiving palliative care by capturing the patient's voice and experience of care by assessing communication and shared decision making with the clinician. This is an important patient-centered measure that helps patients feel heard and understood which can effectively improve the quality of care received and outcomes for patients in palliative care. Allowing patients to feel heard and understood adds an important dimension to the care planning for this unique patient population commonly cared for by clinicians in this specialty. As more patients are living longer with multiple comorbidities, especially true for the advanced heart disease patient population, early emergence of palliative care into the overall care of cardiac patients can notably improve their quality of life, patient satisfaction, and reduction in symptoms.[75] This measure is predicated on existing guidelines and conceptual models[76] and can facilitate and improve effective patient-clinician communication that engenders trust, acknowledgement, and a whole-person orientation to the care that is provided. Through the benefits of enhanced patient-provider communication, this measure would improve the quality of care received and outcomes for patients receiving palliative care. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule.

[75] Kilic, Y., Smer, A., & Goldstein, N. (2020). The Importance of Palliative Care in Cardiology: Differences Between Countries. JACC. Case Reports, 2(2), 326–329. https://doi.org/10.1016/j.jaccas.2019.11.069.

[76] National Consensus Project for Quality Palliative Care. (2018). Clinical Practice Guidelines for Quality Palliative Care, 4th edition. https://www.nationalcoalitionhpc.org/ncp.

B.4a. Cardiology

MEASURES PROPOSED FOR **ADDITION** TO THE CARDIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up-to-date on their COVID-19 vaccinations as defined by CDC recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We are proposing to include this measure in the Cardiology specialty set as it would be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[77] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set would help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[78] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

[77] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[78] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

B.4b. Electrophysiology Cardiac Specialist

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Electrophysiology Cardiac Specialist specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Electrophysiology Cardiac Specialist specialty set that have proposed substantive changes in Table Group D of this Appendix as indicated by an * in the Indicator column.

B.4b. Electrophysiology Cardiac Specialist

PREVIOUSLY FINALIZED MEASURES IN THE ELECTROPHYSIOLOGY CARDIAC SPECIALIST SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	2474 / N/A	392	N/A	MIPS CQM Specifications	Outcome	**Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation:** Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation. This measure is submitted as four rates stratified by age and gender: • Submission Age Criteria 1: Females 18-64 years of age • Submission Age Criteria 2: Males 18-64 years of age • Submission Age Criteria 3: Females 65 years of age and older • Submission Age Criteria 4: Males 65 years of age and older	American College of Cardiology Foundation
* ! (Outcome)	N/A / N/A	393	N/A	MIPS CQM Specifications	Outcome	**Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision:** Infection rate following CIED device implantation, replacement, or revision.	American College of Cardiology Foundation

B.5. Certified Nurse Midwife

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Certified Nurse-Midwife specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Certified Nurse Midwife specialty set that have proposed substantive changes in Table Group D of this Appendix as indicated by an * in the Indicator column.

B.5. Certified Nurse-Midwife

PREVIOUSLY FINALIZED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan**: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	335	N/A	MIPS CQM Specifications	Outcome	**Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period, delivered a live singleton at < 39 weeks of gestation, and had elective deliveries (without medical indication) by cesarean birth or induction of labor.	Centers for Medicare & Medicaid Services

B.5. Certified Nurse-Midwife

PREVIOUSLY FINALIZED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	336	N/A	MIPS CQM Specifications	Process	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
§	N/A / N/A	475	CMS349v7	eCQM Specifications	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
	N/A / N/A	496	N/A	MIPS CQM Specifications	Process	**Cardiovascular Disease (CVD) Risk Assessment Measure – Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument:** Percentage of pregnant or postpartum patients who received a cardiovascular disease (CVD) risk assessment with a standardized instrument.	University of California, Irvine

B.5. Certified Nurse-Midwife

PREVIOUSLY FINALIZED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
! (Safety)	N/A / N/A	504	N/A	MIPS CQM Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association
* ! (Outcome)	N/A / N/A	505	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit' within 120 days after an index assessment.	American Psychiatric Association

B.6. Chiropractic Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Chiropractic Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Chiropractic Medicine specialty set that have proposed substantive changes in Table Group D of this Appendix as indicated by an * in the Indicator column.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within 2 days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	217	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	218	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	219	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	220	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	222	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist, or hand impairments. The change in FS is assessed using the FOTO Elbow/Wrist/Hand FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
§ ! (Outcome)	N/A / N/A	478	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.7. Clinical Social Work

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Clinical Social Work specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Clinical Social Work specialty set.

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan**: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	134	CMS2v 14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS14 9v13	eCQM Specifications	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
*	N/A / N/A	282	N/A	MIPS CQM Specifications	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology/ American Psychiatric Association
* ! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQM Specifications	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQM Specifications	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology / American Psychiatric Association

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A / N/A	305	CMS13 7v13	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or medication treatment events for SUD, or one long-acting medication event for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
§ ! (Outcome)	0710 / 0710e	370	CMS15 9v13	eCQM Specifications, MIPS CQM Specifications	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Patient Safety)	N/A / N/A	382	CMS17 7v13	eCQM Specifications	Process	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 16 years at the start of the measurement period with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk.	Mathematica
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQM Specifications	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN
! (Outcome)	N/A / N/A	502	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association
! (Safety)	N/A / N/A	504	N/A	MIPS CQM Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	505	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit' within 120 days after an index assessment.	American Psychiatric Association

B.7. Clinical Social Work

MEASURES PROPOSED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM ®) Scores at 12 Months**: The Patient Activation Measure® (PAM ®) is a 10- or 13-item questionnaire that assesses an individual's knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We are proposing to include this measure in the Clinical Social Work specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It is utilized in research within the U.S. and internationally and has also been shown to be valid and reliable in different clinical settings and under different payment models.[79] The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule.

[79] Phreesia. (2024). Patient Activation Measure (PAM). https://www.phreesia.com/patient-activation-measure/?utm_source=google&utm_%20medium=paid_%20search&utm_%20destinationmedium=mql_form&utm_campaign=payer_care_management_paid_search&utm_vendor=phreesia&utm_audience1=payer&utm_content=648172611574&utm_destinationco.

B.8. Dentistry

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Dentistry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. This specialty set has no proposed changes.

B.8. Dentistry

PREVIOUSLY FINALIZED MEASURES IN THE DENTISTRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	378	CMS 75v13	eCQM Specifications	Outcome	**Children Who Have Dental Decay or Cavities:** Percentage of children, 1 - 20 years of age at the start of the measurement period, who have had tooth decay or cavities during the measurement period as determined by a dentist.	Centers for Medicare & Medicaid Services
	N/A / N/A	379	CMS 74v14	eCQM Specifications	Process	**Primary Caries Prevention Intervention as Offered by Dentists:** Percentage of children, 1 – 20 years of age, who received two fluoride varnish applications during the measurement period as determined by a dentist.	Centers for Medicare & Medicaid Services

B.9. Dermatology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Dermatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Dermatology specialty set.

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
*	N/A/ N/A	176	N/A	MIPS CQM Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the 6 months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50 v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	410	N/A	MIPS CQM Specifications	Outcome	**Psoriasis: Clinical Response to Systemic Medications:** Percentage of psoriasis vulgaris patients receiving systemic medication who meet minimal physician-or patient- reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician-and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment.	American Academy of Dermatology
! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQM Specifications	Process	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology
* ! (Outcome)	N/A / N/A	485	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Psoriasis – Improvement in Patient-Reported Itch Severity:** The percentage of patients, aged 8 years and older, with a diagnosis of psoriasis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to four, and who achieve a score reduction of three or more points at a follow up visit.	American Academy of Dermatology
* ! (Outcome)	N/A / N/A	486	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Dermatitis – Improvement in Patient-Reported Itch Severity:** The percentage of patients, aged 8 years and older, with a diagnosis of dermatitis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 3 or more points at a follow up visit.	American Academy of Dermatology
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.9. Dermatology

MEASURES PROPOSED FOR ADDITION TO THE DERMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Care Coordination)	N/A / N/A	TBD	N/A	MIPS CQM Specifications	Process	**Melanoma: Tracking and Evaluation of Recurrence:** Percentage of patients who had an excisional surgery for melanoma or melanoma in situ with initial American Joint Committee on Cancer (AJCC) staging of 0, I, or II in the past 5 years in which the operating provider examines and/or diagnoses the patient for recurrence of melanoma.	American Academy of Dermatology	We are proposing to include this measure in the Dermatology specialty set as it would be clinically relevant to this clinician type. Clinicians within this specialty care for patients diagnosed with melanoma and are most likely to be the clinician to evaluate the frequency of melanoma recurrence following excisional procedures for this patient population.[80] This measure addresses the CMS high priority outcome for care coordination, as a lack of communication has been recognized between the excising clinician and clinician continuing care. This measure would allow for the development of a system in which melanomas can be accurately tracked to increase the understanding of the effectiveness of care. The incorporation of this measure in this specialty set would help promote communications between the dermatologist treating the melanoma and the clinicians continuing care. Melanoma recurrence is an outcome that needs precise evaluation.[81] The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. See Table A.6 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

[80] Rebecca, V. W., Sondak, V. K., & Smalley, K. S. (2012). A Brief History of Melanoma: From Mummies to Mutations. *Melanoma Research*, *22*(2), 114–122. https://doi.org/10.1097/CMR.0b013e328351fa4d.

[81] Freeman, M., & Laks, S. (2019). Surveillance Imaging for Metastasis in High-Risk Melanoma: Importance in Individualized Patient Care and Survivorship. *Melanoma Management*, *6*(1), MMT12. https://doi.org/10.2217/mmt-2019-0003.

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE DERMATOLOGY SPECIALTY SET Note: In this proposed rule, we are proposing the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	137	N/A	MIPS CQM Specifications	Structure	**Melanoma: Continuity of Care – Recall System:** Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12-month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment.	American Academy of Dermatology	This measure is being proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.

B.10. Diagnostic Radiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Diagnostic Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. As indicated in the Table Group B introduction, measure Q494 has been added to the previously finalized measure set below and measure Q436 has been removed under this proposed rule as previously finalized through the CY 2024 PFS final rule (88 FR 79556 through 79560 and 88 FR 79896). We request comment on the measures available in the proposed Diagnostic Radiology specialty set that have proposed substantive changes in Table Group D of this Appendix as indicated by an * in the Indicator column.

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices.	American College of Radiology
* ! (Appropriate Use)	N/A / N/A	360	N/A	MIPS CQM Specifications	Process	**Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies:** Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study.	American College of Radiology
! (Appropriate Use)	N/A / N/A	364	N/A	MIPS CQM Specifications	Process	**Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines:** Percentage of final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up (e.g., type of imaging or biopsy) or for no follow-up, and source of recommendations (e.g., guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians).	American College of Radiology

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	405	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Appropriate Follow-up Imaging for Incidental Abdominal Lesions:** Percentage of final reports for imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with a specific recommendation for no follow-up imaging recommended based on radiological findings: • Cystic renal lesion that is simple appearing* (Bosniak I or II) • Adrenal lesion less than or equal to 1.0 cm • Adrenal lesion greater than 1.0 cm but less than or equal to 4.0 cm classified as likely benign or diagnostic benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols	American College of Radiology
! (Appropriate Use)	N/A / N/A	406	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Appropriate Follow-Up Imaging for Incidental Thyroid Nodules in Patients:** Percentage of final reports for computed tomography (CT), CT angiography (CTA) or magnetic resonance imaging (MRI) or magnetic resonance angiogram (MRA) studies of the chest or neck for patients aged 18 years and older with no known thyroid disease with a thyroid nodule < 1.0 cm noted incidentally with follow-up imaging recommended.	American College of Radiology

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	3633e, 3662e / N/A	494	CMS1056v2	eCQM Specifications	Intermediate Outcome	**Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level):** This measure provides a standardized method for monitoring the performance of diagnostic CT to discourage unnecessarily high radiation doses, a risk factor for cancer, while preserving image quality. It is expressed as a percentage of patients with CT exams that are out-of-range based on having either excessive radiation dose or inadequate image quality relative to evidence-based thresholds based on the clinical indication for the exam. All diagnostic CT exams of specified anatomic sites performed in inpatient, outpatient and ambulatory care settings are eligible. This measure is not telehealth eligible. This eCQM requires the use of additional software to access primary data elements stored within radiology electronic health records and translate them into data elements that can be ingested by this eCQM. Additional details are included in the Guidance field.	Alara Imaging, Inc. in collaboration with the University of California, San Francisco (UCSF)

B.11. Emergency Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Emergency Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Emergency Medicine specialty set.

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069/ N/A	065	CMS154v13	eCQM Specifications, MIPS CQM Specifications	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	066	CMS146v13	eCQM Specifications, MIPS CQM Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the 7-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQM Specifications	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
§	N/A / N/A	187	N/A	MIPS CQM Specifications	Process	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.	American Heart Association
*	N/A / N/A	317	CMS22v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQM Specifications	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQM Specifications	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Efficiency)	N/A / N/A	415	N/A	MIPS CQM Specifications	Efficiency	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older:** Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.	American College of Emergency Physicians
! (Efficiency)	N/A / N/A	416	N/A	MIPS CQM Specifications	Efficiency	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years:** Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.	American College of Emergency Physicians
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.11. Emergency Medicine

MEASURES PROPOSED FOR ADDITION TO THE EMERGENCY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services	We are proposing to include this measure in the Emergency Medicine specialty set as it would be clinically relevant to this clinician type. "Emergency departments (EDs) are a potentially important setting for elder mistreatment identification because they provide care for a large number of older adults who may be elder mistreatment victims especially given that the ED is sometimes the only clinical setting that the patient may visit."[82] The process of standardized screening using one or a combination of validated assessment(s) and/or instrument(s) should be done to ensure that signs of abuse or neglect are not overlooked.

[82] Rosen, T., Platts-Mills, T. F., & Fulmer, T. (2020). Screening for Elder Mistreatment in Emergency Departments: Current Progress and Recommendations for Next Steps. *Journal of Elder Abuse & Neglect, 32*(3), 295–315. https://doi.org/10.1080/08946566.2020.1768997.

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE EMERGENCY MEDICINE SPECIALTY SET Note: In this proposed rule, we are proposing the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	134	CMS2v14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to 2 days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services	We are proposing to remove this measure from the Emergency Medicine specialty set beginning with the CY 2025 performance period/2027 MIPS payment year. Complete emergency medicine applicable coding is not available within this quality measure. Therefore, this measure has minimal eligibility for this clinician type.
N/A / N/A	254	N/A	MIPS CQM Specifications	Process	**Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain:** Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location.	American College of Emergency Physicians	This measure is being proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.

B.12. Endocrinology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Endocrinology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Endocrinology specialty set.

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS12 2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS13 1v13	eCQM Specifications, MIPS CQM Specifications	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
§	0066 / N/A	118	N/A	MIPS CQM Specifications	Process	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	126	N/A	MIPS CQM Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	134	CMS2v 14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to 2 days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the 6 months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS16 5v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediat e Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first 6 months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	374	CMS50 v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 6 months after the fracture.	National Committee for Quality Assurance
§	N/A / N/A	438	CMS34 7v8	eCQM Specifications, MIPS CQM Specifications	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients – all considered at high risk of cardiovascular events – who were prescribed or were on statin therapy during the performance period: •All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR •Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR •Patients aged 40 to 75 years with a diagnosis of diabetes; OR •Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services
*	N/A / N/A	462	CMS64 5v8	eCQM Specifications	Process	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	N/A / N/A	488	CMS95 1v3	eCQM Specifications, MIPS CQM Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.12. Endocrinology

MEASURES PROPOSED FOR ADDITION TO THE ENDOCRINOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up-to-date on their COVID-19 vaccinations as defined by CDC recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We are proposing to include this measure in the Endocrinology specialty set as it would be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[83] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set would help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[84] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

[83] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[84] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

B.13. Family Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Family Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Family Medicine specialty set.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS1 22v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
§	0081 / 0081e	005	CMS1 35v13	eCQM Specifications, MIPS CQM Specifications	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
§	0067 / N/A	006	N/A	MIPS CQM Specifications	Process	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070 / 0070e	007	CMS1 45v13	eCQM Specifications, MIPS CQM Specifications	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	0083 / 0083e	008	CMS144v13	eCQM Specifications, MIPS CQM Specifications	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
*	N/A / N/A	009	CMS128v13	eCQM Specifications	Process	**Antidepressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. A. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0069 / N/A	065	CMS154v13	eCQM Specifications, MIPS CQM Specifications	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	066	CMS146v13	eCQM Specifications, MIPS CQM Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the 7-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQM Specifications	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	0055 / N/A	117	CMS131v13	eCQM Specifications, MIPS CQM Specifications	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
	N/A / N/A	126	N/A	MIPS CQM Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* § ! (Patient Safety)	N/A / N/A	130	CMS68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	134	CMS2v14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to 2 days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	176	N/A	MIPS CQM Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within 2 days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* § ! (Outcome)	N/A / N/A	236	CMS1 65v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first 6 months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS1 56v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQM Specifications	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
! (Opioid)	N/A / N/A	305	CMS1 37v13	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or medication treatment events for SUD, or one long-acting medication event for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
§	N/A / N/A	309	CMS1 24v13	eCQM Specifications	Process	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21-64 who had cervical cytology performed within the last 3 years • Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0101 / N/A	318	CMS1 39v13	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§ ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement /Experience	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The CBE endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE)	Centers for Medicare & Medicaid Services
§	N/A / N/A	326	N/A	MIPS CQM Specifications	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQM Specifications	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQM Specifications	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
§ ! (Outcome)	N/A / N/A	338	CMS3 14v2	eCQM Specifications, MIPS CQM Specifications	Outcome	**HIV Viral Suppression:** Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period, with an eligible encounter in the first 240 days of the performance period, whose last HIV viral load test result was less than 200 copies/mL during the performance period.	Health Resources and Services Administration
§ ! (Outcome)	0710 / 0710e	370	CMS1 59v13	eCQM Specifications, MIPS CQM Specifications	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Care Coordination)	N/A / N/A	374	CMS5 0v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§ ! (Patient Experience)	N/A / N/A	377	CMS9 0v14	eCQM Specifications	Process	**Functional Status Assessments for Heart Failure:** Percentage of patients 18 years of age and older with heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQM Specifications	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
	N/A / N/A	387	N/A	MIPS CQM Specifications	Process	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
§	N/A / N/A	394	N/A	MIPS CQM Specifications	Process	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the Human Papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	398	N/A	MIPS CQM Specifications	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
§	N/A / N/A	400	N/A	MIPS CQM Specifications	Process	**One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation:** Percentage of patients age >= 18 years have never been tested for Hepatitis C Virus (HCV) infection who receive an HCV infection test AND who have treatment initiated within three months or who are referred to a clinician who treats HCV infection within one month if tested positive for HCV.	American Gastroenterological Association

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	401	N/A	MIPS CQM Specifications	Process	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic Hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 6 months after the fracture.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	438	CMS347v8	eCQM Specifications, MIPS CQM Specifications	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients – all considered at high risk of cardiovascular events – who were prescribed or were on statin therapy during the performance period: •All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR •Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR •Patients aged 40 to 75 years with a diagnosis of diabetes; OR •Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	N/A / N/A	441	N/A	MIPS CQM Specifications	Intermediate Outcome	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg – AND • Most recent tobacco status is Tobacco Free – AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated – AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQM Specifications	Process	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	Centers for Medicare & Medicaid Services
* ! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQM Specifications	Process	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Opioid)	N/A / N/A	468	N/A	MIPS CQM Specifications	Process	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
§	N/A / N/A	475	CMS3 49v7	eCQM Specifications	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
! (Outcome)	N/A / N/A	476	CMS7 71v6	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	3568 / N/A	483	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM):** The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM Patient Reported Outcome Measure (PROM) a comprehensive and parsimonious set of 11 patient-reported items – to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the clinician or practice.	The American Board of Family Medicine
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	N/A / N/A	488	CMS951v3	eCQM Specifications, MIPS CQM Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	497	N/A	MIPS CQM Specifications	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN
! (Outcome)	N/A / N/A	502	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
! (Safety)	N/A / N/A	504	N/A	MIPS CQM Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association
* ! (Outcome)	N/A / N/A	505	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit' within 120 days after an index assessment.	American Psychiatric Association

B.13. Family Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up-to-date on their COVID-19 vaccinations as defined by CDC recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We are proposing to include this measure in the Family Medicine specialty set as it would be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[85] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set would help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[86] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

[85] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[86] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE FAMILY MEDICINE SPECIALTY SET Note: In this proposed rule, we are proposing the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / 3475e	472	CMS249v7	eCQM Specifications	Process	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.

B.14. Gastroenterology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Gastroenterology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Gastroenterology specialty set.

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	185	N/A	MIPS CQM Specifications	Process	**Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy.	American Gastroenterological Association
§	N/A / N/A	226	CMS138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the 6 months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	NA / N/A	275	N/A	MIPS CQM Specifications	Process	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.	American Gastroenterological Association
*	N/A / N/A	317	CMS22v 13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	0658 / N/A	320	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 45 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.	American Gastroenterological Association
* ! (Care Coordination)	N/A / N/A	374	CMS50v 13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	N/A / N/A	401	N/A	MIPS CQM Specifications	Process	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis**: Percentage of patients aged 18 years and older with a diagnosis of chronic Hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Equity	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE GASTROENTEROLOGY SPECIALTY SET Note: In this proposed rule, we are proposing the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	439	N/A	MIPS CQM Specifications	Efficiency	**Age Appropriate Screening Colonoscopy:** The percentage of screening colonoscopies performed in patients greater than or equal to 86 years of age from January 1 to December 31.	American Gastroenterological Association	This measure is being proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.

B.15. General Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the General Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed General Surgery specialty set that have proposed substantive changes in Table Group D of this Appendix as indicated by an * in the Indicator column.

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the 6 months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	264	N/A	MIPS CQM Specifications	Process	**Sentinel Lymph Node Biopsy for Invasive Breast Cancer**: The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients before or after neoadjuvant systemic therapy, who undergo a sentinel lymph node (SLN) procedure.	American Society of Breast Surgeons

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22 v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	354	N/A	MIPS CQM Specifications	Outcome	**Anastomotic Leak Intervention**: Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery.	American College of Surgeons
* § ! (Outcome)	N/A / N/A	355	N/A	MIPS CQM Specifications	Outcome	**Unplanned Reoperation within the 30-Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30-day postoperative period.	American College of Surgeons
! (Outcome)	N/A / N/A	356	N/A	MIPS CQM Specifications	Outcome	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQM Specifications	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN

B.16. Geriatrics

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Geriatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Geriatrics specialty set.

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v 14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	134	CMS2v14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to 2days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0022 / N/A	238	CMS156v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS149v13	eCQM Specifications	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
*	N/A / N/A	282	N/A	MIPS CQM Specifications	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology/ American Psychiatric Association

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQM Specifications	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQM Specifications	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology / American Psychiatric Association
! (Patient Safety)	0101 / N/A	318	CMS139 v13	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§ ! (Outcome)	0710 / 0710e	370	CMS159 v13	eCQM Specifications, MIPS CQM Specifications	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Outcome)	N/A / N/A	476	CMS771 v6	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Equity	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	N/A / N/A	488	CMS951 v3	eCQM Specifications, MIPS CQM Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
	1662/ N/A	489	N/A	MIPS CQM Specifications	Process	**Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy**: Percentage of patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (Stages 1-5, not receiving Renal Replacement Therapy (RRT)) and proteinuria who were prescribed ACE inhibitor or ARB therapy within a 12-month period.	Renal Physicians Association
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
*	NA / N/A	497	N/A	MIPS CQM Specifications	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), ACIP, American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.16. Geriatrics

MEASURES PROPOSED FOR ADDITION TO THE GERIATRICS SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)	We are proposing to include this measure in the Geriatrics specialty set as it would be clinically relevant to this clinician type. This PRO-PM would help to fill a gap for patients receiving palliative care by capturing the patient's voice and experience of care by assessing communication and shared decision making with the clinician. This is an important patient-centered measure that helps patients feel heard and understood which can effectively improve the quality of care received and outcomes for patients in palliative care. Allowing patients to feel heard and understood adds an important dimension to the care planning for this unique patient population commonly cared for by clinicians in this specialty. As more patients are living longer with multiple comorbidities, especially true for the advanced heart disease patient population, early emergence of palliative care into the overall care of cardiac patients can notably improve their quality of life, patient satisfaction, and reduction in symptoms.[87] This measure is predicated on existing guidelines and conceptual models[88] and can facilitate and improve effective patient-clinician communication that engenders trust, acknowledgement, and a whole-person orientation to the care that is provided. Through the benefits of enhanced patient-provider communication, this measure would improve the quality of care received and outcomes for patients receiving palliative care. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule.

[87] See footnote Kilic et al., 2020 in Table B.4a of this Appendix.

[88] See footnote National Consensus Project for Quality Palliative Care, 2018 in Table B.4a of this Appendix.

B.16. Geriatrics

MEASURES PROPOSED FOR **ADDITION** TO THE GERIATRICS SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We are proposing to include this measure in the Geriatrics specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It is utilized in research within the U.S. and internationally and has also been shown to be valid and reliable in different clinical settings and under different payment models.[89] The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule.

[89] See footnote Phreesia, 2024 in Table B.7 of this Appendix.

B.16. Geriatrics

MEASURES PROPOSED FOR ADDITION TO THE GERIATRICS SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up-to-date on their COVID-19 vaccinations as defined by CDC recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We are proposing to include this measure in the Geriatrics specialty set as it would be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[90] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set would help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[91] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

[90] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[91] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

B.17. Hospitalists

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Hospitalists specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on measures available in the proposed Hospitalists specialty set that have proposed substantive changes in Table Group D of this Appendix as indicated by an * in the Indicator column.

B.17. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	0081 / 0081e	005	CMS13 5v13	eCQM Specifications, MIPS CQM Specifications	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
§	0083 / 0083e	008	CMS14 4v13	eCQM Specifications, MIPS CQM Specifications	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance

B.17. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.18. Infectious Disease

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Infectious Disease specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Infectious Disease specialty set.

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069 / N/A	065	CMS154v13	eCQM Specifications, MIPS CQM Specifications	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	066	CMS146v13	eCQM Specifications, MIPS CQM Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the 7-day period from three days prior to the episode date through 3 days after the episode date.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
*	N/A / N/A	176	N/A	MIPS CQM Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
§	N/A / N/A	205	CMS1188v2	eCQM Specifications, MIPS CQM Specifications	Process	**Sexually Transmitted Infection (STI) Testing for People with HIV:** Percentage of patients 13 years of age and older with a diagnosis of HIV who had tests for syphilis, gonorrhea, and chlamydia performed within the performance period.	Health Resources and Services Administration
§	N/A / N/A	226	CMS138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications,	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were	National Committee for Quality Assurance

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
				MIPS CQM Specifications		screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the 6 months prior to the measurement period if identified as a tobacco user.	
§	N/A / N/A	240	CMS117v13	eCQM Specifications	Process	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DtaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (HiB); three hepatitis B (HepB); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (HepA); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	National Committee for Quality Assurance
§ ! (Outcome)	NA / N/A	338	CMS314v2	eCQM Specifications, MIPS CQM Specifications	Outcome	**HIV Viral Suppression:** Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period, with an eligible encounter in the first 240 days of the performance period, whose last HIV viral load test result was less than 200 copies/mL during the performance period.	Health Resources and Services Administration
* § ! (Efficiency)	N/A / N/A	340	N/A	MIPS CQM Specifications	Process	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6-month period of the 24-month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration
	N/A / N/A	387	N/A	MIPS CQM Specifications	Process	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
§	N/A / N/A	394	N/A	MIPS CQM Specifications	Process	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the Human Papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	475	CMS349v7	eCQM Specifications	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.18. Infectious Disease

MEASURES PROPOSED FOR **ADDITION** TO THE INFECTIOUS DISEASE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We are proposing to include this measure in the Infectious Disease specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It is utilized in research within the U.S. and internationally and has also been shown to be valid and reliable in different clinical settings and under different payment models.[92] The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule.

[92] See footnote Phreesia, 2024 in Table B.7 of this Appendix.

B.18. Infectious Disease

MEASURES PROPOSED FOR **ADDITION** TO THE INFECTIOUS DISEASE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up-to-date on their COVID-19 vaccinations as defined by CDC recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We are proposing to include this measure in the Infectious Disease specialty set as it would be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[93] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set would help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[94] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

[93] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[94] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

B.19. Internal Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Internal Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Internal Medicine specialty set.

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v 13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
§	0081 / 0081e	005	CMS135v 13	eCQM Specifications, MIPS CQM Specifications	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
§	0067 / N/A	006	N/A	MIPS CQM Specifications	Process	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070 / 0070e	007	CMS145v 13	eCQM Specifications, MIPS CQM Specifications	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	0083 / 0083e	008	CMS144 v13	eCQM Specifications, MIPS CQM Specifications	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
*	N/A / N/A	009	CMS128 v13	eCQM Specifications	Process	**Antidepressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQM Specifications	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	0055 / N/A	117	CMS131 v13	eCQM Specifications, MIPS CQM Specifications	Process	**Diabetes: Eye Exam**: Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
	N/A / N/A	126	N/A	MIPS CQM Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* § ! (Patient Safety)	N/A / N/A	130	CMS68v 14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	134	CMS2v1 4	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	176	N/A	MIPS CQM Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Outcome)	N/A / N/A	236	CMS165 v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156 v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQM Specifications	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
*	N/A / N/A	277	N/A	MIPS CQM Specifications	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQM Specifications	Process	**Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea (OSA) that were prescribed an evidence-based therapy that had documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available).	American Academy of Sleep Medicine

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A / N/A	305	CMS137 v13	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or medication treatment events for SUD, or one long-acting medication event for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
§	N/A / N/A	309	CMS124 v13	eCQM Specifications	Process	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21-64 who had cervical cytology performed within the last 3 years • Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
! (Patient Safety)	0101 / N/A	318	CMS139 v13	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The CBE endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE)	Centers for Medicare & Medicaid Services
§	N/A / N/A	326	N/A	MIPS CQM Specifications	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQM Specifications	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQM Specifications	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
§ ! (Outcome)	N/A / N/A	338	CMS314 v2	eCQM Specifications, MIPS CQM Specifications	Outcome	**HIV Viral Suppression:** Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period, with an eligible encounter in the first 240 days of the performance period, whose last HIV viral load test result was less than 200 copies/mL during the performance period.	Health Resources and Services Administration
§ ! (Outcome)	0710 / 0710e	370	CMS159 v13	eCQM Specifications, MIPS CQM Specifications	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Care Coordination)	N/A / N/A	374	CMS50v 13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§ ! (Patient Experience)	N/A / N/A	377	CMS90v 14	eCQM Specifications	Process	**Functional Status Assessments for Heart Failure:** Percentage of patients 18 years of age and older with heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQM Specifications	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
	N/A / N/A	387	N/A	MIPS CQM Specifications	Process	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
! (Outcome)	N/A / N/A	398	N/A	MIPS CQM Specifications	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
§	N/A / N/A	400	N/A	MIPS CQM Specifications	Process	**One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation:** Percentage of patients age >= 18 years have never been tested for Hepatitis C Virus (HCV) infection who receive an HCV infection test AND who have treatment initiated within three months or who are referred to a clinician who treats HCV infection within one month if tested positive for HCV.	American Gastroenterological Association

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	401	N/A	MIPS CQM Specifications	Process	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic Hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	438	CMS347 v8	eCQM Specifications, MIPS CQM Specifications	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the performance period: • All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR • Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR •Patients aged 40 to 75 years with a diagnosis of diabetes; OR • Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	N/A / N/A	441	N/A	MIPS CQM Specifications	Intermediate Outcome	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQM Specifications	Process	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	Centers for Medicare & Medicaid Services
! (Opioid)	N/A / N/A	468	N/A	MIPS CQM Specifications	Process	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
§	N/A / N/A	475	CMS349 v7	eCQM Specifications	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
! (Outcome)	N/A / N/A	476	CMS771 v6	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	3568 / N/A	483	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM):** The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM Patient Reported Outcome Measure (PROM) a comprehensive and parsimonious set of 11 patient-reported items - to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the clinician or practice.	The American Board of Family Medicine
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	N/A / N/A	488	CMS951 v3	eCQM Specifications, MIPS CQM Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)
*	N/A / N/A	497	N/A	MIPS CQM Specifications	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), ACIP, American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	502	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
! (Safety)	N/A / N/A	504	N/A	MIPS CQM Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association

B.19. Internal Medicine

MEASURES PROPOSED FOR ADDITION TO THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by CDC recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We are proposing to include this measure in the Internal Medicine specialty set as it would be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[95] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set would help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the (ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[96] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

[95] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[96] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE INTERNAL MEDICINE SPECIALTY SET Note: In this proposed rule, we are proposing the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / 3475e	472	CMS249v7	eCQM Specifications	Process	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.

B.20. Interventional Radiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Interventional Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Interventional Radiology specialty set.

B.20. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES IN THE INTERVENTIONAL RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices.	American College of Radiology
*! (Care Coordination)	N/A / N/A	374	CMS 50v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
*! (Outcome)	N/A / N/A	413	N/A	MIPS CQM Specifications	Intermediate Outcome	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of 90 minutes or less.	Society of Interventional Radiology
*! (Outcome)	N/A / N/A	420	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
	N/A / N/A	421	N/A	MIPS CQM Specifications	Process	**Appropriate Assessment of Retrievable Inferior Vena Cava (IVC) Filters for Removal:** Percentage of patients in whom a retrievable IVC filter is placed who, within 3 months post-placement, have a documented assessment for the appropriateness of continued filtration, device removal or the inability to contact the patient with at least two attempts.	Society of Interventional Radiology
! (Patient Safety)	N/A / N/A	465	N/A	MIPS CQM Specifications	Process	**Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries:** The percentage of patients with documentation of angiographic endpoints of embolization AND the documentation of embolization strategies in the presence of unilateral or bilateral absent uterine arteries.	Society of Interventional Radiology

B.20. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES IN THE INTERVENTIONAL RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.20. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE INTERVENTONAL RADIOLOGY SPECIALTY SET Note: In this proposed rule, we are proposing the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	409	N/A	MIPS CQM Specifications	Outcome	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a Modified Rankin Score (mRS) score of 0 to 2 at 90 days following endovascular stroke intervention.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.

B.21. Mental/Behavioral Health and Psychiatry

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Mental/Behavioral Health and Psychiatry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on measures available in the proposed Mental/Behavioral Health and Psychiatry specialty set that have proposed substantive changes in Table Group D of this Appendix as indicated by an * in the Indicator column.

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	009	CMS128v13	eCQM Specifications	Process	**Antidepressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	134	CMS2v14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS149v13	eCQM Specifications	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
*	N/A / N/A	282	N/A	MIPS CQM Specifications	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology/ American Psychiatric Association
* ! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQM Specifications	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQM Specifications	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology / American Psychiatric Association

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A / N/A	305	CMS13 7v13	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or medication treatment events for SUD, or one long-acting medication event for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare and Medicaid Services
§	N/A / N/A	366	CMS13 6v14	eCQM Specifications	Process	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly prescribed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. (a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. (b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0710 / 0710e	370	CMS159v13	eCQM Specifications, MIPS CQM Specifications	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Patient Safety)	N/A / N/A	382	CMS177v13	eCQM Specifications	Process	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 16 years at the start of the measurement period with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk.	Mathematica
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQM Specifications	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	468	N/A	MIPS CQM Specifications	Process	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN
! (Outcome)	N/A / N/A	502	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association
! (Safety)	N/A / N/A	504	N/A	MIPS CQM Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association
* ! (Outcome)	N/A / N/A	505	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit' within 120 days after an index assessment.	American Psychiatric Association

B.22. Nephrology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Nephrology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Nephrology specialty set.

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS13 9v13	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§	N/A / N/A	400	N/A	MIPS CQM Specifications	Process	**One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation:** Percentage of patients age >= 18 years have never been tested for Hepatitis C Virus (HCV) infection who receive an HCV infection test AND who have treatment initiated within three months or who are referred to a clinician who treats HCV infection within one month if tested positive for HCV.	American Gastroenterological Association
! (Outcome)	N/A/ N/A	482	N/A	MIPS CQM Specifications	Intermediate Outcome	**Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate**: Percentage of adult hemodialysis (HD) patient-months using a catheter continuously for three months or longer for vascular access attributable to an individual practitioner or group practice.	Centers for Medicare & Medicaid Services
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	488	CMS95 1v3	eCQM Specifications, MIPS CQM Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
	1662/ N/A	489	N/A	MIPS CQM Specifications	Process	**Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (Stages 1-5, not receiving Renal Replacement Therapy (RRT)) and proteinuria who were prescribed ACE inhibitor or ARB therapy within a 12-month period.	Renal Physicians Association
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.22. Nephrology

MEASURES PROPOSED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)	We are proposing to include this measure in the Nephrology specialty set as it would be clinically relevant to this clinician type. This PRO-PM would help to fill a gap for patients receiving palliative care by capturing the patient's voice and experience of care by assessing communication and shared decision making with the clinician. This is an important patient-centered measure that helps patients feel heard and understood which can effectively improve the quality of care received and outcomes for patients in palliative care. Allowing patients to feel heard and understood adds an important dimension to the care planning for this unique patient population commonly cared for by clinicians in this specialty. As more patients are living longer with multiple comorbidities, especially true for the advanced heart disease patient population, early emergence of palliative care into the overall care of cardiac patients can notably improve their quality of life, patient satisfaction, and reduction in symptoms.[97] This measure is predicated on existing guidelines and conceptual models[98] and can facilitate and improve effective patient-clinician communication that engenders trust, acknowledgement, and a whole-person orientation to the care that is provided. Through the benefits of enhanced patient-provider communication, this measure would improve the quality of care received and outcomes for patients receiving palliative care. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule.
	N/A / N/A	TBD	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit	Centers for Medicare & Medicaid Services	We are proposing to include this measure in the Nephrology specialty set as it would be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-

[97] See footnote Kilic et al., 2020 in Table B.4a of this Appendix.

[98] See footnote National Consensus Project for Quality Palliative Care, 2018 in Table B.4a of this Appendix.

B.22. Nephrology

MEASURES PROPOSED FOR ADDITION TO THE NEPHROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
						during the performance period that are up to date on their COVID-19 vaccinations as defined by CDC recommendations on current vaccination.		19, is critically important to stemming the morbidity and mortality caused by this disease.[99] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set would help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[100] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

[99] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[100] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

B.22. Nephrology

MEASURES PROPOSED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQM Specifications	Process	**First Year Standardized Waitlist Ratio (FYSWR):** The number of incident (newly initiated on dialysis) patients in a practitioner (inclusive of physicians and advanced practice providers) group who are under the age of 75, and were listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant within the first year of initiating dialysis. The measure is calculated to compare the observed number of waitlist events in a practitioner group to its expected number of waitlist events. The measure uses the expected waitlist events calculated from a Cox model, adjusted for age, patient comorbidities, and other risk factors at incidence of dialysis.	Centers for Medicare & Medicaid Services	We are proposing to include this measure in the Nephrology specialty set as it would be clinically relevant to this clinician type. The measure's intended objective consists of improving the overall health of patients on dialysis, with nephrologists at the forefront of caring for this patient population. Clinicians within this specialty are responsible for the education of patients about the option of transplantation, referral of patients to a transplant center for evaluation, completion of the evaluation process, and optimizing the health of the patient while on dialysis. All clinicians should be involved and actively work towards providing patients with high quality care including ensuring placement on the transplant list as quickly as possible. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.22. Nephrology

MEASURES PROPOSED FOR ADDITION TO THE NEPHROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQM Specifications	Process	**Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW):** The percentage of patients in each dialysis practitioner group practice who were on the kidney or kidney-pancreas transplant waitlist (all patients or patients in active status). Results are averaged across patients prevalent on the last day of each month during the reporting year. The measure is a directly standardized percentage, which is adjusted for covariates (e.g., age and risk factors).	Centers for Medicare & Medicaid Services	We are proposing to include this measure in the Nephrology specialty set as would be clinically relevant to this clinician type. The maintenance of end stage renal disease patients on active status on the waitlist is additionally important given demonstrated disparities and positive association with subsequent transplantation. These practices are important for nephrologists who are at the forefront of caring for this patient population. This is an important area to which dialysis practitioners can contribute through ensuring patients remain healthy and complete any ongoing testing activities required to remain active on the waitlist. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. See Table A.8 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.23. Neurology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Neurology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Neurology specialty set that have proposed substantive changes in Table Group D of this Appendix as indicated by an * in the Indicator column.

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	134	CMS2v 14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title and Description	Measure Steward
§	N/A / N/A	226	CMS138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	268	N/A	MIPS CQM Specifications	Process	**Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy:** Percentage of all patients of childbearing potential (12 years and older) diagnosed with epilepsy who were counseled at least once a year about how epilepsy and its treatment may affect contraception and pregnancy.	American Academy of Neurology
*	N/A / N/A	277	N/A	MIPS CQM Specifications	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQM Specifications	Process	**Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea (OSA) that were prescribed an evidence-based therapy that had documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available).	American Academy of Sleep Medicine
*	N/A / 2872e	281	CMS149v13	eCQM Specifications	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	282	N/A	MIPS CQM Specifications	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology/ American Psychiatric Association
* ! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQM Specifications	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQM Specifications	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology / American Psychiatric Association
*	N/A / N/A	290	N/A	MIPS CQM Specifications	Process	**Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for depression, anxiety, apathy, AND psychosis once during the measurement period.	American Academy of Neurology
*	N/A / N/A	291	N/A	MIPS CQM Specifications	Process	**Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for cognitive impairment or dysfunction once during the measurement period.	American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	293	N/A	MIPS CQM Specifications	Process	**Rehabilitative Therapy Referral for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were referred to physical, occupational, speech, or recreational therapy once during the measurement period.	American Academy of Neurology

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22 v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare and Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50 v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A / N/A	386	N/A	MIPS CQM Specifications	Process	**Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, lawful physician-hastened death, or hospice) or whose existing end of life plan was reviewed or updated at least once annually or more frequency as clinically indicated (i.e., rapid progression).	American Academy of Neurology
! (Efficiency)	N/A / N/A	419	N/A	MIPS CQM Specifications	Process	**Overuse of Imaging for the Evaluation of Primary Headache:** Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present.	American Academy of Neurology
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.24. Neurosurgical

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Neurosurgical specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Neurosurgical specialty set.

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	187	N/A	MIPS CQM Specifications	Process	**Stroke and Stroke Rehabilitation**: Thrombolytic Therapy: Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.	American Heart Association
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Outcome)	N/A / N/A	344	N/A	MIPS CQM Specifications	Outcome	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
* ! (Outcome)	N/A / N/A	413	N/A	MIPS CQM Specifications	Intermediate Outcome	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of 90 minutes or less.	Society of Interventional Radiology

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	459	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Back Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
§ ! (Outcome)	N/A / N/A	461	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Leg Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
§ ! (Outcome)	N/A / N/A	471	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status After Lumbar Surgery:** For patients age 18 and older who had lumbar discectomy/laminectomy or fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy or fusion procedure.	Minnesota Community Measurement

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE NEUROSURGICAL SPECIALTY SET Note: In this proposed rule, we are proposing the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
NA / NA	260	N/A	MIPS CQM Specifications	Outcome	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons	This measure is being proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.
N/A / N/A	409	N/A	MIPS CQM Specifications	Outcome	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a Modified Rankin Score (mRS) score of 0 to 2 at 90 days following endovascular stroke intervention.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.

B.25. Nutrition/Dietician

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Nutrition/Dietician specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Nutrition/Dietician specialty set that have proposed substantive changes in Table Group D of this Appendix as indicated by an * in the Indicator column.

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS12 2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	NA / N/A	134	CMS2v 14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
§	N/A / N/A	239	CMS15 5v13	eCQM Specifications	Process	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. ● Percentage of patients with height, weight, and body mass index (BMI) percentile documentation ● Percentage of patients with counseling for nutrition ● Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.26. Obstetrics/Gynecology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Obstetrics/Gynecology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Obstetrics/Gynecology specialty set.

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	236	CMS165v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
§	N/A / N/A	309	CMS124v13	eCQM Specifications	Process	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21-64 who had cervical cytology performed within the last 3 years • Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
§	N/A / N/A	310	CMS153v13	eCQM Specifications	Process	**Chlamydia Screening in Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	335	N/A	MIPS CQM Specifications	Outcome	**Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period, delivered a live singleton at < 39 weeks of gestation, and had elective deliveries (without medical indication) by cesarean birth or induction of labor.	Centers for Medicare & Medicaid Services

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	336	N/A	MIPS CQM Specifications	Process	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
! (Patient Safety)	2063 / N/A	422	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury:** Percentage of patients who undergo cystoscopy to evaluate for lower urinary tract injury at the time of hysterectomy for pelvic organ prolapse.	American Urogynecologic Society

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Outcome)	N/A / N/A	432	N/A	MIPS CQM Specifications	Outcome	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
§ ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQM Specifications	Process	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	448	N/A	MIPS CQM Specifications	Process	**Appropriate Workup Prior to Endometrial Ablation:** Percentage of patients, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results are documented before undergoing an endometrial ablation.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349v 7	eCQM Specifications	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
	N/A / N/A	496	N/A	MIPS CQM Specifications	Process	**Cardiovascular Disease (CVD) Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument:** Percentage of pregnant or postpartum patients who received a cardiovascular disease (CVD) risk assessment with a standardized instrument.	University of California, Irvine
*	N/A / N/A	497	N/A	MIPS CQM Specifications	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF),ACIP, American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
! (Safety)	N/A / N/A	504	N/A	MIPS CQM Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association
* ! (Outcome)	N/A / N/A	505	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit' within 120 days after an index assessment.	American Psychiatric Association

B.26. Obstetrics/Gynecology

MEASURES PROPOSED FOR ADDITION TO THE OBSTRETRICS/GYNECOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by CDC recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We are proposing to include this measure in the Obstetrics/ Gynecology specialty set as it would be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[101] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set would help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[102] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

[101] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[102] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE OBSTRETRICS/GYNECOLOGY SPECIALTY SET Note: In this proposed rule, we are proposing the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	433	N/A	MIPS CQM Specifications	Outcome	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogyneco-logic Society	This measure is being proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.
N/A / 3475e	472	CMS249v7	eCQM Specifications	Process	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.

B.27a. Oncology/Hematology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Oncology/Hematology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Oncology/Hematology specialty set.

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	102	CMS129v14	eCQM Specifications, MIPS CQM Specifications	Process	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	134	CMS2v14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Experience)	0384 / 0384e	143	CMS157v13	eCQM Specifications, MIPS CQM Specifications	Process	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Society of Clinical Oncology
§	N/A / N/A	226	CMS138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
§	N/A / N/A	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
*	N/A / N/A	317	CMS22v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/Experience	**CAHPS for MIPs Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The CBE endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE).	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	1858 / N/A	450	N/A	MIPS CQM Specifications	Process	**Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer:** Percentage of female patients aged 18 to 70 with stage I (T1c) – III HER2 positive breast cancer for whom appropriate treatment is initiated.	American Society of Clinical Oncology
* §	1859 / N/A	451	N/A	MIPS CQM Specifications	Process	**RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed.	American Society of Clinical Oncology
§ ! (Appropriate Use)	0210 / N/A	453	N/A	MIPS CQM Specifications	Process	**Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving systemic cancer-directed therapy in the last 14 days of life.	American Society of Clinical Oncology
§ ! (Appropriate Use)	0216 / N/A	457	N/A	MIPS CQM Specifications	Process	**Percentage of Patients who Died from Cancer Admitted to Hospice for Less than 3 Days (lower score – better):** Percentage of patients who died from cancer and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology
*	N/A / N/A	462	CMS645v8	eCQM Specifications	Process	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	490	N/A	MIPS CQM Specifications	Process	**Appropriate Intervention of Immune-Related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors:** Percentage of patients, aged 18 years and older, with a diagnosis of cancer, on immune checkpoint inhibitor therapy, and grade 2 or above diarrhea and/or grade 2 or above colitis, who have immune checkpoint inhibitor therapy held and corticosteroids or immunosuppressants prescribed or administered.	Society for Immunotherapy of Cancer (SITC)
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.27a. Oncology/Hematology

MEASURES PROPOSED FOR ADDITION TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Appropriate Use)	N/A / N/A	TBD	N/A	MIPS CQM Specifications	Process	**Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy:** Percentage of patients, aged 18 years and older, with a diagnosis of metastatic non-small cell lung cancer or squamous cell carcinoma of head and neck on first-line immune checkpoint inhibitor (ICI) therapy, who had a positive PD-L1 biomarker expression test result prior to giving ICI therapy.	Society for Immunotherapy of Cancer (SITC)	We are proposing to include this measure in the Oncology/ Hematology specialty set as it would be clinically relevant to this clinician type. Immunotherapy is a rapidly developing and changing subspecialty in the realm of oncology, and this measure would fill a gap within the oncologic clinical topic. The incorporation of this measure in this specialty set would help promote appropriate intervention and timeliness of PD-L1 biomarker expression testing prior to initiation of first-line treatment for the metastatic non-small cell lung cancer or squamous cell carcinoma of head and neck. This timeliness of treatment initiation can lead to improvements in patient mortality and morbidity.[103] It's important to address the proper diagnosis of metastatic non-small cell lung cancer or squamous cell carcinoma that may impact treatment decisions so that appropriate treatment delivery is not delayed, nor ineffective therapies prescribed which could both result in poor clinical outcomes and unnecessary healthcare costs.[104] See Table A.1 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

[103] See footnote Pai et al., 2020 in Table A.1 of this Appendix

[104] See footnotes Lim et al., 2015 and Pai et al., 2020 in Table A.1 of this Appendix.

B.27a. Oncology/Hematology

MEASURES PROPOSED FOR **ADDITION** TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQM Specifications	Process	**Appropriate Germline Testing for Ovarian Cancer Patients:** Percentage of patients, aged 18 and older, diagnosed with epithelial ovarian, fallopian tube, or primary peritoneal cancer who undergo germline testing within 6 months of diagnosis.	American Society of Clinical Oncology	We are proposing to include this measure in the Oncology/ Hematology specialty set as it would be clinically relevant to this clinician type and would fill a gap within the oncologic clinical topic. This measure addresses patients diagnosed with epithelial ovarian, fallopian tube, or primary peritoneal cancer who undergo germline testing within 6 months of their diagnosis and is predicated on existing clinical guidelines and recommendations. It also addresses a CMS priority that could allow for more personalized diagnostic, predictive, prognostic, and therapeutic strategies for the patient. Current recommendations for all women diagnosed with ovarian cancer is to receive genetic testing, however, only approximately 30 percent of women undergo any genetic testing.[105] The high incidence of these mutations and the advent of therapy targeted toward BRCA mutations warrant testing in all individuals diagnosed with ovarian cancer for the purpose of determining treatment recommendations, risk of other cancers, and need for cascade testing of family members. See Table A.2 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

[105] See footnote Konstantinopoulos et al., 2020 in Table A.2 of this Appendix.

B.27a. Oncology/Hematology

MEASURES PROPOSED FOR ADDITION TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	CBE 3718 / N/A	TBD	N/A	MIPS CQM Specifications	Patient-Reported Outcome-based Performance Measure (PRO-PM)	**Patient-Reported Pain Interference Following Chemotherapy among Adults with Breast Cancer:** The PRO-PM will assess pain interference following chemotherapy administered with curative intent to adult patients with breast cancer.	Purchaser Business Group on Health	We are proposing to include this measure in the Oncology/ Hematology specialty set as it would be clinically relevant to this clinician type and would fill a gap within the oncologic clinical topic. This measure addresses a CMS high priority as a patient-reported outcome-based performance quality measure accounting for patient experience of care for this patient population. It is predicated on existing clinical guidelines and recommendations.[106] For the breast cancer patient population, it's important to routinely assess pain to properly identify barriers to acceptable pain management and to intervene appropriately, which can improve the patient's health outcome and quality of life.[107] See Table A.3 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
! (Outcome)	CBE 3720 / N/A	TBD	N/A	MIPS CQM Specifications	Patient-Reported Outcome-based Performance Measure (PRO-PM)	**Patient-Reported Fatigue Following Chemotherapy among Adults with Breast Cancer:** The PRO-PM will assess fatigue following chemotherapy administered with curative intent to adult patients with breast cancer.	Purchaser Business Group on Health	We are proposing to include this measure in the Oncology/ Hematology specialty set as it would be clinically relevant to this clinician type, addresses a CMS high priority as a PRO-PM, and would fill a gap within the oncologic clinical topic. It takes into consideration the patient voice/experience of care for those patients with breast cancer with fatigue experienced following chemotherapy. PRO assessment in routine care remains underutilized, and very few PRO-PMs have been validated for the cancer population. By taking into consideration patient voice, necessary interventions can be completed to help improve their quality of life during cancer treatment. See Table A.4 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

[106] Tegegn, H. K., & Gebreyohannes, E. A. (2017). Adequacy of Cancer Pain Management and Pain Interference With Daily Functioning Among Patients Visiting the Oncology Ward of an Ethiopian University. *Journal of Global Oncology*, *3(2)*. https://ascopubs.org/doi/10.1200/JGO.2017.009738.

[107] See footnote Tegegn & Gebreyohannes, 2017.

B.27a. Oncology/Hematology

MEASURES PROPOSED FOR **ADDITION** TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by CDC recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We are proposing to include this measure in the Oncology/ Hematology specialty set as it would be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[108] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set would help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[109] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

[108] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[109] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE ONCOLOGY/HEMATOLOGY SPECIALTY SET Note: In this proposed rule, we are proposing the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
0383 / N/A	144	N/A	MIPS CQM Specifications	Process	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology	This measure is being proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.
1860 / N/A	452	N/A	MIPS CQM Specifications	Process	**Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and RAS (KRAS or NRAS) gene mutation spared treatment with anti-EGFR monoclonal antibodies.	American Society of Clinical Oncology	This measure is being proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.

B.27b. Radiation Oncology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Radiation Oncology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Radiation Oncology specialty set.

B.27b. Radiation Oncology

PREVIOUSLY FINALIZED MEASURES IN THE RADIATION ONCOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	N/A / N/A	102	CMS 129v14	eCQM Specifications, MIPS CQM Specifications	Process	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	0384 / 0384e	143	CMS 157v13	eCQM Specifications, MIPS CQM Specifications	Process	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Society of Clinical Oncology
§	N/A / N/A	226	CMS 138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.27b. Radiation Oncology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE RADIATION ONCOLOGY SPECIALTY SET Note: In this proposed rule, we are proposing the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
0383 / N/A	144	N/A	MIPS CQM Specifications	Process	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology	This measure is being proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.

B.28. Ophthalmology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Ophthalmology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Ophthalmology specialty set that have proposed substantive changes in Table Group D of this Appendix as indicated by an * in the Indicator column. As indicated in the Table Group B Introduction, we are proposing to rename this specialty set from "Ophthalmology/ Optometry" to "Ophthalmology" under this proposed rule. We are also proposing a new Optometry specialty set under Table B.29 of this Appendix.

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / 0086e	012	CMS14 3v13	eCQM Specifications	Process	**Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more visits within 12 months.	American Academy of Ophthalmology
* ! (Care Coordination)	N/A / N/A	019	CMS14 2v13	eCQM Specifications, MIPS CQM Specifications	Process	**Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once during the performance period.	American Academy of Ophthalmology

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	0055 / N/A	117	CMS13 1v13	eCQM Specifications, MIPS CQM Specifications	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Outcome)	0563 / N/A	141	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Outcome	**Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 20% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 20% from the pre-intervention level, a plan of care was documented within the 12 month performance period.	American Academy of Ophthalmology

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	0565 / 0565e	191	CMS13 3v13	eCQM Specifications, MIPS CQM Specifications	Outcome	**Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery:** Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.	American Academy of Ophthalmology
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS15 6v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	303	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey.	American Academy of Ophthalmology
! (Patient Experience)	N/A / N/A	304	N/A	MIPS CQM Specifications	Patient Engagement/ Experience	**Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey.	American Academy of Ophthalmology
* ! (Care Coordination)	N/A / N/A	374	CMS50 v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	384	N/A	MIPS CQM Specifications	Outcome	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.	American Academy of Ophthalmology

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PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	385	N/A	MIPS CQM Specifications	Outcome	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.	American Academy of Ophthalmology
! (Outcome)	N/A / N/A	389	N/A	MIPS CQM Specifications	Outcome	**Cataract Surgery: Difference Between Planned and Final Refraction:** Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 1.0 diopters of their planned (target) refraction.	American Academy of Ophthalmology
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

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PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	499	N/A	MIPS CQM Specifications	Process	**Appropriate Screening and Plan of Care for Elevated Intraocular Pressure Following Intravitreal or Periocular Steroid Therapy:** Percentage of patients who had an intravitreal or periocular corticosteroid injection (e.g., triamcinolone, preservative-free triamcinolone, dexamethasone, dexamethasone intravitreal implant, or fluocinolone intravitreal implant) who, within seven (7) weeks following the date of injection, are screened for elevated intraocular pressure (IOP) with tonometry with documented IOP =<25 mm Hg for injected eye OR if the IOP was >25 mm Hg, a plan of care was documented.	American Society of Retina Specialists
*	N/A / N/A	500	N/A	MIPS CQM Specifications	Process	**Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up:** Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 8 weeks.	American Society of Retina Specialists
*	N/A / N/A	501	N/A	MIPS CQM Specifications	Process	**Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up:** Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) and acute vitreous hemorrhage in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 2 weeks.	American Society of Retina Specialists

B.29. Optometry

As indicated in the introductory language of Table Group B of this Appendix to this proposed rule, we are proposing to add a new Optometry specialty set. In addition to the considerations discussed in the introductory language of Table Group B, the Optometry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are proposing to add to this specialty set. We request comment on the measures available in the proposed Optometry specialty set.

B.29. Optometry

MEASURES PROPOSED FOR ADDITION TO THE OPTOMETRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	N/A / N/A	019	CMS 142v13	eCQM Specifications, MIPS CQM Specifications	Process	**Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once during the performance period.	American Academy of Ophthalmology	We are proposing to include this measure in the Optometry specialty set as it would be clinically relevant to this clinician type. An Optometrist is needed to inform a primary care clinician about a particular patient's retinopathy severity, possible diabetic macular edema, or other ocular co-morbidities. Retinopathy serves as a strong predictor of other serious medical conditions such as heart attack, stroke, kidney failure, amputation, and others.[110] Without regular reporting from the optometrist on this issue, the primary care clinician lacks valuable information key to the overall management of the patient. This measure is essential to patient safety and completes the feedback essential for treating a deadly, common disease.[111] Better communication between eye specialists and primary care clinicians can play a critical role in patient care, as it's an important mechanism for clinicians to communicate with one another about a patients' disease symptoms, adherence to care plan, and treatment plans.[112] The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule.

[110] Nag, S., Bilous, R., Kelly, W., Jones, S., Roper, N., & Connolly, V. (2007). All-cause and Cardiovascular Mortality in Diabetic Subjects Increases Significantly with Reduced Estimated Glomerular Filtration Rate (eGFR): 10 Years' Data from the South Tees Diabetes Mortality Study. *Diabetic Medicine: A Journal of the British Diabetic Association*, *24*(1), 10–17. https://doi.org/10.1111/j.1464-5491.2007.02023.x.

[111] Reutens A. T. (2013). Epidemiology of Diabetic Kidney Disease. *The Medical Clinics of North America*, *97*(1), 1–18. https://doi.org/10.1016/j.mcna.2012.10.001.

[112] Storey, P., and Haller, J. (2016). The Significance of Physician Communication in the Care of Patients With Diabetes. Retina Today. https://retinatoday.com/articles/2016-sept/the-significance-of-physician-communication-in-the-care-of-patients-with-diabetes.

B.29. Optometry

MEASURES PROPOSED FOR ADDITION TO THE OPTOMETRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	0055 / N/A	117	CMS 131v13	eCQM Specifications, MIPS CQM Specifications	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance	We are proposing to include this measure in the Optometry specialty set as it would be clinically relevant to this clinician type. This measure could help accurately assess a clinician's ability to diagnose and treat patients safely and efficiently. We believe the numerator options, give more granular data can be captured to discern between patients with and without evidence of retinopathy. This information could give insight into those patients with controlled blood sugar and those with uncontrolled blood sugar The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule.
* § ! (Patient Safety)	N/A / N/A	130	CMS 68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services	We are proposing to include this measure in the Optometry specialty set as it is clinically relevant to this clinician type. Documentation of current medications in the medical record facilitates the process of medication review and reconciliation by the clinician, which is necessary for reducing ADEs and promoting medication safety. The need for clinician-to-clinician coordination regarding medication records, and the existing gap in implementation, is highlighted in the American Medical Association's Physician's Role in Medication Reconciliation, which states that "critical patient information, including medical and medication histories, current medications the patient is receiving and taking, and sources of medications, is essential to

B.29. Optometry

MEASURES PROPOSED FOR ADDITION TO THE OPTOMETRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								the delivery of safe medical care."[113] The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule.
§	N/A / N/A	226	CMS 138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance	We are proposing to include this measure in the Optometry specialty set as it is clinically relevant to this clinician type. Tobacco use is the leading preventable cause of disease, disability, and death in the U.S. cigarette smoking results in more than 480,000 premature deaths each year and accounts for approximately 1 in every 5 deaths.[114] Due to the harmful effect tobacco use can have on patients' health, we believe that clinicians should engage with their patients to screen for tobacco use and, if positive, provide tobacco cessation counseling annually. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule.
* ! (Patient Safety)	0022 / N/A	238	CMS 156v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance	We are proposing to include this measure in the Optometry specialty set as it is clinically relevant to this clinician type. Treating patients with high-risk medications such as anti-depressants or pain medications, may be associated with increased risk of harm from drug side-effects and toxicity.[115] Medication errors can occur anywhere throughout the many steps in the medication management process, with one of the most common

[113] American Medical Association. (2007). The Physician's Role in Medication Reconciliation: Issues, Strategies, and Safety Principles. Retrieved from https://brucelambert.soc.northwestern.edu//book_reviews/med-rec-monograph.pdf.

[114] CDC. (2023). Smoking and Tobacco Use – Adult Data. https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm.

[115] Zhan, C., Sangl, J., Bierman, A. S., Miller, M. R., Friedman, B., Wickizer, S. W., & Meyer, G. S. (2001). Potentially Inappropriate Medication Use in the Community-Dwelling Elderly: Findings from the 1996 Medical Expenditure Panel Survey. *JAMA*, *286*(22), 2823–2829. https://doi.org/10.1001/jama.286.22.2823.

B.29. Optometry

MEASURES PROPOSED FOR ADDITION TO THE OPTOMETRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								error sources being poor interprofessional communication resulting in poor collaborative medication management.[116] The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule.
* ! (Care Coordination)	N/A / N/A	374	CMS 50v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services	We are proposing to include this measure in the Optometry specialty set as it is clinically relevant to this clinician type. Including this measure would ensure patients referred to Optometrist for a consultation complete the encounter with a consult report being returned to the referring physician. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule.

[116] Pereira, F., Bieri, M., Del Rio Carral, M., Martins, M. M., & Verloo, H. (2022). Collaborative Medication Management for Older Adults After Hospital Discharge: A Qualitative Descriptive Study. *BMC Nursing*, *21*(1), 284. https://doi.org/10.1186/s12912-022-01061-3.

B.30. Orthopedic Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Orthopedic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Orthopedic Surgery specialty set that have proposed substantive changes in Table Group D of this Appendix as indicated by an * in the Indicator column.

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	134	CMS2v14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
*	N/A / N/A	178	N/A	MIPS CQM Specifications	Process	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once during the performance period.	American College of Rheumatology
*	N/A / N/A	180	N/A	MIPS CQM Specifications	Process	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan during the performance period.	American College of Rheumatology

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PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	217	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Knee Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	218	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Hip Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	219	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	220	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Shoulder Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	222	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist, or hand impairments. The change in FS is assessed using the FOTO Elbow/Wrist/Hand FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS13 9v13	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	350	N/A	MIPS CQM Specifications	Process	**Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy:** Percentage of patients regardless of age undergoing a total knee or total hip replacement with documented shared decision- making with discussion of conservative (non-surgical) therapy (e.g., non-steroidal anti-inflammatory drug (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure.	American Association of Hip and Knee Surgeons
! (Patient Safety)	N/A / N/A	351	N/A	MIPS CQM Specifications	Process	**Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients regardless of age undergoing a total knee or total hip replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g., History of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke).	American Association of Hip and Knee Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Experience)	N/A / N/A	376	CMS56 v13	eCQM Specifications	Process	**Functional Status Assessment for Total Hip Replacement:** Percentage of patients 19 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 300 – 425 days after the surgery.	Centers for Medicare & Medicaid Services
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
§ ! (Outcome)	N/A / N/A	459	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Back Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	461	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Leg Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	470	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status After Primary Total Knee Replacement:** For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) or a 71 or greater on the KOOS, JR tool at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
§ ! (Outcome)	N/A / N/A	471	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status After Lumbar Surgery:** For patients age 18 and older who had lumbar discectomy/laminectomy or fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy or fusion procedure.	Minnesota Community Measurement

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	478	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	3493 / N/A	480	N/A	Administrative Claims	Outcome	**Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS):** This measure is a re-specified version of the measure, "Hospital-level Risk-standardized Complication rate (RSCR) following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)" (National Quality Forum 1550), which was developed for patients 65 years and older using Medicare claims. This re-specified measure attributes outcomes to Merit-based Incentive Payment System participating clinicians and/or clinician groups ("provider") and assesses each provider's complication rate, defined as any one of the specified complications occurring from the date of index admission to up to 90 days post date of the index procedure.	Centers for Medicare & Medicaid Services

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.31. Otolaryngology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Otolaryngology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Otolaryngology specialty set.

B.31. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	066	CMS146v13	eCQM Specifications, MIPS CQM Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
§	N/A / N/A	226	CMS138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.31. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0022 / N/A	238	CMS156v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	277	N/A	MIPS CQM Specifications	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQM Specifications	Process	**Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea (OSA) that were prescribed an evidence-based therapy that had documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available).	American Academy of Sleep Medicine
*	N/A / N/A	317	CMS22 v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS139v13	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQM Specifications	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation

B.31. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQM Specifications	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
* § ! (Outcome)	N/A / N/A	355	N/A	MIPS CQM Specifications	Outcome	**Unplanned Reoperation within the 30-Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30-day postoperative period.	American College of Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQM Specifications	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	398	N/A	MIPS CQM Specifications	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement

B.31. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQM Specifications	Process	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.31. Otolaryngology

MEASURES PROPOSED FOR **ADDITION** TO THE OTOLARYNGOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by CDC recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We are proposing to include this measure in the Otolaryngology specialty set as it would be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[117] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set would help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[118] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.32. Pathology

[117] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[118] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Pathology specialty set that have proposed substantive changes in Table Group D of this Appendix as indicated by an * in the Indicator column.

B.32. Pathology

PREVIOUSLY FINALIZED MEASURES IN THE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	249	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Barrett's Esophagus:** Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia.	College of American Pathologists
§	N/A / N/A	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
! (Care Coordination)	N/A / N/A	395	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Lung Cancer Reporting (Biopsy/Cytology Specimens):** Pathology reports based on lung biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type following the International Association for the Study of Lung Cancer (IASLC) guidance or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report.	College of American Pathologists
! (Care Coordination)	N/A / N/A	396	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Lung Cancer Reporting (Resection Specimens):** Pathology reports based on lung resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer (NSCLC), histologic type.	College of American Pathologists
! (Care Coordination)	N/A / N/A	397	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Melanoma Reporting:** Pathology reports for primary malignant cutaneous melanoma that include the pT category, thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors.	College of American Pathologists
! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQM Specifications	Process	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology
! (Care Coordination)	3661 / N/A	491	N/A	MIPS CQM Specifications	Process	**Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status:**	College of American Pathologists

B.32. Pathology

PREVIOUSLY FINALIZED MEASURES IN THE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
						Percentage of surgical pathology reports for primary colorectal, endometrial, gastroesophageal or small bowel carcinoma, biopsy or resection, that contain impression or conclusion of or recommendation for testing of mismatch repair (MMR) by immunohistochemistry (biomarkers MLH1, MSH2, MSH6, and PMS2), or microsatellite instability (MSI) by DNA-based testing status, or both.	

B.33. Pediatrics

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Pediatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Pediatrics specialty set that have proposed substantive changes in Table Group D of this Appendix as indicated by an * in the Indicator column.

B.33. Pediatrics

PREVIOUSLY FINALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069 / N/A	065	CMS154v13	eCQM Specifications, MIPS CQM Specifications	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	066	CMS146v13	eCQM Specifications, MIPS CQM Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQM Specifications	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
§	N/A / N/A	134	CMS2v14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services

B.33. Pediatrics

PREVIOUSLY FINALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	205	CMS1188v2	eCQM Specifications, MIPS CQM Specifications	Process	**Sexually Transmitted Infection (STI) Testing for People with HIV:** Percentage of patients 13 years of age and older with a diagnosis of HIV who had tests for syphilis, gonorrhea, and chlamydia performed within the performance period.	Health Resources and Services Administration
§	N/A / N/A	226	CMS138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
§	N/A / N/A	239	CMS155v13	eCQM Specifications	Process	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. • Percentage of patients with counseling for nutrition. • Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance
§	N/A / N/A	240	CMS117v13	eCQM Specifications	Process	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DtaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (Hib); three hepatitis B (HepB); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (HepA); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	National Committee for Quality Assurance

B.33. Pediatrics

PREVIOUSLY FINALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A / N/A	305	CMS137v13	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or medication treatment events for SUD, or one long-acting medication event for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
§	N/A / N/A	310	CMS153v13	eCQM Specifications	Process	**Chlamydia Screening in Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance
§	N/A / N/A	366	CMS136v14	eCQM Specifications	Process	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly prescribed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. (a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. (b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
§ ! (Outcome)	0710 / 0710e	370	CMS159v13	eCQM Specifications, MIPS CQM Specifications	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement

B.33. Pediatrics

PREVIOUSLY FINALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	382	CMS177v13	eCQM Specifications	Process	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 16 years at the start of the measurement period with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk.	Mathematica
§	N/A / N/A	394	N/A	MIPS CQM Specifications	Process	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the Human Papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	398	N/A	MIPS CQM Specifications	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
* ! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQM Specifications	Process	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.34. Physical Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Physical Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Physical Medicine specialty set that have proposed substantive changes in Table Group D of this Appendix as indicated by an * in the Indicator column.

B.34. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS 68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.34. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS 138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS 22v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS 50v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	468	N/A	MIPS CQM Specifications	Process	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.34. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.35. Physical Therapy/Occupational Therapy

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Physical Therapy/Occupational Therapy specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Physical Therapy/Occupational Therapy specialty set that have proposed substantive changes in Table Group D of this Appendix as indicated by an * in the Indicator column.

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	048	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
	N/A / N/A	126	N/A	MIPS CQM Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	N/A / N/A	127	N/A	MIPS CQM Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	134	CMS2v 14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	217	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	218	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	219	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	220	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	222	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist, or hand impairments. The change in FS is assessed using the FOTO Elbow/Wrist/Hand FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS149v13	eCQM Specifications	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
* ! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQM Specifications	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQM Specifications	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology / American Psychiatric Association
*	N/A / N/A	291	N/A	MIPS CQM Specifications	Process	**Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for cognitive impairment or dysfunction once during the measurement period.	American Academy of Neurology

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0101 / N/A	318	CMS139v13	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§ ! (Outcome)	N/A / N/A	478	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN
! (Outcome)	N/A / N/A	502	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.36. Plastic Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Plastic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Plastic Surgery specialty set that have proposed substantive changes in Table Group D of this Appendix as indicated by an * in the Indicator column.

B.36. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* § ! (Outcome)	N/A / N/A	355	N/A	MIPS CQM Specifications	Outcome	**Unplanned Reoperation within the 30-Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30-day postoperative period.	American College of Surgeons

B.36. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	356	N/A	MIPS CQM Specifications	Outcome	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQM Specifications	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.37. Podiatry

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Podiatry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Podiatry specialty set that have proposed substantive changes in Table Group D of this Appendix as indicated by an * in the Indicator column.

B.37. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	126	N/A	MIPS CQM Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	N/A / N/A	127	N/A	MIPS CQM Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* ! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	219	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.37. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS 138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS 22v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS 139v13	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.37. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.38. Preventive Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Preventive Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Preventive Medicine specialty set.

B.38. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS 122v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance

B.38. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	048	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQM Specifications	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
	N/A / N/A	126	N/A	MIPS CQM Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* § ! (Patient Safety)	N/A / N/A	130	CMS 68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	134	CMS 2v14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.38. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQM Specifications	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
* ! (Care Coordination)	N/A / N/A	374	CMS 50v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.38. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	438	CMS 347v8	eCQM Specifications, MIPS CQM Specifications	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the performance period: •All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR •Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR •Patients aged 40 to 75 years with a diagnosis of diabetes; OR •Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS 349v7	eCQM Specifications	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	N/A / N/A	488	CMS 951v3	eCQM Specifications, MIPS CQM Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.38. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	497	N/A	MIPS CQM Specifications	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), ACIP, American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.38. Preventive Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE PREVENTIVE MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by CDC recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We are proposing to include this measure in the Preventive Medicine specialty set as it would be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[119] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set would help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[120] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

[119] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[120] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

B.39. Pulmonology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Pulmonology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Pulmonology specialty set.

B.39. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	0102 / N/A	052	N/A	MIPS CQM Specifications	Process	**Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation and Long-Acting Inhaled Bronchodilator Therapy**: Percentage of patients aged 18 years and older with a diagnosis of COPD with a documented FEV1/FVC < 70% measured by spirometry, who are symptomatic and were prescribed a long-acting inhaled bronchodilator.	American Thoracic Society
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.39. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	236	CMS165v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	277	N/A	MIPS CQM Specifications	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQM Specifications	Process	**Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea (OSA) that were prescribed an evidence-based therapy that had documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available).	American Academy of Sleep Medicine
* ! (Care Coordination)	N/A / N/A	374	CMS50v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	398	N/A	MIPS CQM Specifications	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement

B.39. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.39. Pulmonology

MEASURES PROPOSED FOR **ADDITION** TO THE PULMONOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by CDC recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We are proposing to include this measure in the Pulmonology Medicine specialty set as it would be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[121] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set would help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[122] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.40. Rheumatology

[121] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[122] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Rheumatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Rheumatology specialty set.

B.40. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.40. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title and Description	Measure Steward
*	N/A / N/A	176	N/A	MIPS CQM Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
*	2523 / N/A	177	N/A	MIPS CQM Specifications	Process	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity using an ACR-preferred RA disease activity assessment tool at ≥50% of encounters for RA for each patient during the performance period.	American College of Rheumatology
*	N/A / N/A	178	N/A	MIPS CQM Specifications	Process	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once during the performance period.	American College of Rheumatology
*	N/A / N/A	180	N/A	MIPS CQM Specifications	Process	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan during the performance period.	American College of Rheumatology

B.40. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.40. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee Quality Assurance
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.40. Rheumatology

MEASURES PROPOSED FOR **ADDITION** TO THE RHEUMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by CDC recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We are proposing to include this measure in the Rheumatology Medicine specialty set as it would be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[123] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set would help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[124] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

[123] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[124] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

B.41. Skilled Nursing Facility

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Skilled Nursing Facility specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Skilled Nursing Facility specialty set.

B.41. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	0067 / N/A	006	N/A	MIPS CQM Specifications	Process	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070 / 0070e	007	CMS1 45v13	eCQM Specifications, MIPS CQM Specifications	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association
§	0083 / 0083e	008	CMS1 44v13	eCQM Specifications, MIPS CQM Specifications	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§	0066 / N/A	118	N/A	MIPS CQM Specifications	Process	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association

B.41. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0022 / N/A	238	CMS156v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
§	N/A / N/A	326	N/A	MIPS CQM Specifications	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.41. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.41. Skilled Nursing Facility

MEASURES PROPOSED FOR **ADDITION** TO THE SKILLED NURSING FACILITY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by CDC recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We are proposing to include this measure in the Skilled Nursing Facility specialty set as it would be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[125] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set would help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[126] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

[125] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.
[126] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

B.42. Speech Language Pathology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Speech Language Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Speech Language Pathology specialty set.

B.42. Speech Language Pathology

PREVIOUSLY FINALIZED MEASURES IN THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	134	CMS2v 14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan**: Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.42. Speech Language Pathology

PREVIOUSLY FINALIZED MEASURES IN THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	291	N/A	MIPS CQM Specifications	Process	**Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for cognitive impairment or dysfunction once during the measurement period.	American Academy of Neurology
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.42. Speech Language Pathology

MEASURES PROPOSED FOR **ADDITION** TO THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / 2872e	281	CMS149v13	eCQM Specifications	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology	We are proposing to include this measure in the Speech Language Pathology specialty set as it would be clinically relevant to this clinician type. Speech language pathologists (SLPs) utilize standardized instruments with demonstrated reliability for dementia screening. These instruments typically assess orientation to time, place, and person.[127] Other tests (for example, story recall/story retelling) assess episodic memory and can be useful for screening early dementia.[128] If screening reveals cognitive impairment, the individual is referred to an SLP for a comprehensive evaluation of communicative function. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule.
*	N/A / N/A	282	N/A	MIPS CQM Specifications	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology/ American Psychiatric Association	We are proposing to include this measure in the Speech Language Pathology specialty set as it would be clinically relevant to this clinician type. SLPs play a critical role in diagnosis and management of dysphagia in patients with dementia through comprehensive assessment, diet consistency modifications, educating their caregiver on the use of compensatory strategies, prescribing exercise programs, and referring them to other professionals as needed. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule.

[127] Rabin, L. A., Paré, N., Saykin, A. J., Brown, M. J., Wishart, H. A., Flashman, L. A., & Santulli, R. B. (2009). Differential Memory Test Sensitivity for Diagnosing Amnestic Mild Cognitive Impairment and Predicting Conversion to Alzheimer's Disease. *Aging, Neuropsychology, and Cognition, 16*(3), 357–376. https://doi.org/10.1080/13825580902825220.

[128] See footnote Rabin et al., 2009.

B.42. Speech Language Pathology

MEASURES PROPOSED FOR ADDITION TO THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQM Specifications	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association / American Academy of Neurology	We are proposing to include this measure in the Speech Language Pathology specialty set as it would be clinically relevant to this clinician type. Dementia patients are at high risk for safety concerns due to underlying cognitive communication impairment which may impact judgment, reasoning, and memory as well as physical weakness resulting from other medical conditions.[129] SLPs work directly with individuals with dementia and their caregivers to screen, assess, and establish care plans to address these issues through cognitive-communication exercises, use of compensatory strategies, environmental modifications, referrals to other professionals, and providing caregiver training. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule.
* ! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQM Specifications	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology / American Psychiatric Association	We are proposing to include this measure in the Speech Language Pathology specialty set as it would be clinically relevant to this clinician type. SLPs provide information about the nature of dementia and its course of progression. SLPs make recommendations for environmental modifications, such as using alarms and pill boxes for medication reminders, visual aids, and provide education on communication strategies and modifications to caregiver behaviors to ensure the safety of the patient and compliance with the plan of care. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule.

[129] Thyrian, J. R., Hertel, J., Wucherer, D., Eichler, T., Michalowsky, B., Dreier-Wolfgramm, A., Zwingmann, I., Kilimann, I., Teipel, S., & Hoffmann, W. (2017). Effectiveness and Safety of Dementia Care Management in Primary Care: A Randomized Clinical Trial. *JAMA Psychiatry*, *74*(10), 996–1004. https://doi.org/10.1001/jamapsychiatry.2017.2124.

B.42. Speech Language Pathology

MEASURES PROPOSED FOR **ADDITION** TO THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Patient Experience)	N/A / N/A	386	N/A	MIPS CQM Specifications	Process	**Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, lawful physician-hastened death, or hospice) or whose existing end of life plan was reviewed or updated at least once annually or more frequency as clinically indicated (i.e., rapid progression).	American Academy of Neurology	We are proposing to include this measure in the Speech Language Pathology specialty set as it would be clinically relevant to this clinician type. Over the course of the disease, individuals with ALS exhibit difficulty producing intelligible speech to communicate basic needs and wants.[130] SLPs are trained to address communication deficits via exercise programs, use of communication strategies, and introducing augmentative and alternative communication (AAC) methods. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule.

[130] National Institute of Neurological Disorders and Stroke. (2024). Amyotrophic Lateral Sclerosis. https://www.ninds.nih.gov/health-information/disorders/amyotrophic-lateral-sclerosis-als.

B.43. Thoracic Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Thoracic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Thoracic Surgery specialty set that have proposed substantive changes in Table Group D of this Appendix as indicated by an * in the Indicator column.

B.43. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS 68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Outcome)	0129 / N/A	164	N/A	MIPS CQM Specifications	Outcome	**Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours.	Society of Thoracic Surgeons
! (Outcome)	0114 / N/A	167	N/A	MIPS CQM Specifications	Outcome	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.	Society of Thoracic Surgeons
* ! (Outcome)	0115 / N/A	168	N/A	MIPS CQM Specifications	Outcome	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason.	Society of Thoracic Surgeons

B.43. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS 138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	356	N/A	MIPS CQM Specifications	Outcome	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS 50v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	0119 / N/A	445	N/A	MIPS CQM Specifications	Outcome	**Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG):** Percent of patients aged 18 years and older undergoing isolated CABG who die, including both all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and those deaths occurring after discharge from the hospital, but within 30 days of the procedure.	Society of Thoracic Surgeons
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.43. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.44. Urgent Care

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Urgent Care specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Urgent Care specialty set.

B.44. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069 / N/A	065	CMS154v13	eCQM Specifications, MIPS CQM Specifications	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	066	CMS146v13	eCQM Specifications, MIPS CQM Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQM Specifications	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.44. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22 v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQM Specifications	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQM Specifications	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQM Specifications	Process	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.44. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.44. Urgent Care

MEASURES PROPOSED FOR **ADDITION** TO THE URGENT CARE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / N/A	488	CMS95 1v3	eCQM Specifications, MIPS CQM Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation	We are proposing to include this measure in the Urgent Care specialty set as it would be clinically relevant to this clinician type. This measure encourages an estimated glomerular filtration rate (eGFR) and urinary albumin-to-creatinine ratio (uACR) evaluation annually for patients diagnosed with diabetes. The measure aims for early detection which can reduce associated health risk of the co-morbidities of diabetes and CKD. Having an established source of care is important in this high-risk population, however, in the general US population, approximately 15 percent of adults do not have a primary care physician.[131] According to the American Diabetes Association annual assessment of glomerular filtration rate (GFR) in adolescents, in addition to adults, with diabetes is necessary to appropriately screen for early diabetic nephropathy, and the assessment of GFR is essential to accurately diagnose diabetic kidney disease early in the disease process.[132] Including this measure in this specialty set could assist in capturing at-risk patients who may lack a primary care physician.

[131] Toth-Manikowski, S. M., Hsu, J. Y., Fischer, M. J., Cohen, J. B., Lora, C. M., Tan, T. C., He, J., Greer, R. C., Weir, M. R., Zhang, X., Schrauben, S. J., Saunders, M. R., Ricardo, A. C., Lash, J. P., & Chronic Renal Insufficiency Cohort (CRIC) Study Investigators (2022). Emergency Department/Urgent Care as Usual Source of Care and Clinical Outcomes in CKD: Findings From the Chronic Renal Insufficiency Cohort Study. *Kidney Medicine*, *4*(4), 100424. https://doi.org/10.1016/j.xkme.2022.100424.

[132] Bjornstad, P., Cherney, D. Z., & Maahs, D. M. (2015). Update on Estimation of Kidney Function in Diabetic Kidney Disease. *Current Diabetes Reports*, *15*(9), 57. https://doi.org/10.1007/s11892-015-0633-2.

B.45. Urology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Urology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Urology specialty set.

B.45. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	102	CMS129v14	eCQM Specifications, MIPS CQM Specifications	Process	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services

B.45. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	134	CMS2v14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022/ N/A	238	CMS156v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.45. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005/ N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	**CAHPS for MIPS Clinician/Group Survey**: The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The CBE endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE)	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.45. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Outcome)	N/A / N/A	432	N/A	MIPS CQM Specifications	Outcome	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the bladder recognized either during or within 30 days after surgery.	American Urogyneco-logic Society
§ ! (Appropriate Use)	0210/ N/A	453	N/A	MIPS CQM Specifications	Process	**Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving systemic cancer-directed therapy in the last 14 days of life.	American Society of Clinical Oncology
§ ! (Appropriate Use)	0216/ N/A	457	N/A	MIPS CQM Specifications	Process	**Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better):** Percentage of patients who died from cancer, and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology
*	N/A / N/A	462	CMS645v8	eCQM Specifications	Process	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.45. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	476	CMS771v6	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute
! (Appropriate Use)	N/A/ N/A	481	CMS646v5	eCQM Specifications	Process	**Intravesical Bacillus-Calmette Guerin for Non-Muscle Invasive Bladder Cancer**: Percentage of patients initially diagnosed with non-muscle invasive bladder cancer and who received intravesical Bacillus-Calmette-Guerin (BCG) within 6 months of bladder cancer staging.	Oregon Urology
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	N/A / N/A	488	CMS951v3	eCQM Specifications, MIPS CQM Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.45. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.45. Urology

MEASURES PROPOSED FOR **ADDITION** TO THE UROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by CDC recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We are proposing to include this measure in the Urology specialty set as it would be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[133] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set would help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[134] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure would reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

[133] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[134] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

B.45. Urology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE UROLOGY SPECIALTY SET Note: In this proposed rule, we are proposing the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	104	N/A	MIPS CQM Specifications	Process	**Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer**: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed androgen deprivation therapy in combination with external beam radiotherapy to the prostate.	American Urological Association Education and Research	This measure is being proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.
N/A / N/A	433	N/A	MIPS CQM Specifications	Outcome	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society	This measure is being proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.

B.46. Vascular Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Vascular Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. We request comment on the measures available in the proposed Vascular Surgery specialty set.

B.46. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS 68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS 138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS 165v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance

B.46. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	259	N/A	MIPS CQM Specifications	Outcome	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post Operative Day #2):** Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2).	Society for Vascular Surgeons
*	N/A / N/A	317	CMS 22v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	344	N/A	MIPS CQM Specifications	Outcome	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQM Specifications	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS 50v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.46. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	420	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
§ ! (Outcome)	N/A / N/A	441	N/A	MIPS CQM Specifications	Intermediate Outcome	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.46. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE VASCULAR SURGERY SPECIALTY SET Note: In this proposed rule, we are proposing the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
NA / NA	260	N/A	MIPS CQM Specifications	Outcome	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons	This measure is being proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.

Table Group C: Previously Finalized Quality Measures Proposed for Removal for the CY 2025 Performance Period/2027 MIPS Payment Year and Future Years

In this proposed rule, we are proposing to remove 11 previously finalized MIPS quality measures for the CY 2025 performance period/2027 MIPS payment year and future years which are discussed in detail in the removal tables below. We note measure Q436: Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques was already finalized for removal with a 1-year delay to the CY 2025 performance period as noted in the Table Group B introduction (88 FR 79896); therefore, measure Q436 does not have a removal table in this proposed rule and there are 10 removal tables under Table Group C.

The CY 2019 PFS final rule (83 FR 59763 through 59765) and CY 2020 PFS final rule (84 FR 62957 through 62959) discusses our incremental approach to removing process measures.

Under our measure removal criteria, consideration is given to the following, but is not limited to:

- Whether the removal of the process measure impacts the number of measures available for a specific specialty.
- Whether the measure addresses a priority area highlighted in the Measure Development Plan at *https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/Measure-development.*
- Whether the measure promotes positive outcomes in patients.
- Considerations and evaluation of the measure's performance data.
- Whether the measure is designated as high priority or not.
- If they do not meet case minimum and reporting volumes required for benchmarking after being in the program for two consecutive CY performance periods.
- After factoring in other considerations (such as, but not limited to: the robustness of the measure; whether it addresses a measurement gap; if the measure is a patient-reported outcomes; consideration of the measure in developing MVPs).
- If we determine the measure is not available for MIPS reporting by or on behalf of all MIPS eligible clinicians.

Further considerations are given in the evaluation of the measure's performance data to determine whether there is or no longer is variation in performance. As discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763), an additional criterion we use for the removal of measures includes extremely topped-out measures, which refers to measures topped out with an average (mean) performance rate between 98-100 percent.

For a measure proposed for removal due to criteria relating to the benchmark and performance data, further information regarding 2024 MIPS benchmarking data can be located at *https://qpp.cms.gov/benchmarks.*

C.1. Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	104
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM Specifications
Measure Description:	Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed androgen deprivation therapy in combination with external beam radiotherapy to the prostate.
Measure Steward:	American Urological Association Education and Research
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because the limited patient population as well as adoption of this quality measure does not allow for the creation of a benchmark. For more information on benchmarks, see the MIPS 2024 Quality Benchmarks User Guide *https://www.cms.gov/files/document/2024-quality-benchmarks-user-guide-scoring-examples-pdf.pdf.* The current 2024 MIPS benchmarking data is located at *https://qpp.cms.gov/benchmarks.*
In the Circumstance the Measure Was Retained:	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2025 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.2. Melanoma: Continuity of Care – Recall System

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	137
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM Specifications
Measure Description:	Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12 month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Structure
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because this measure is duplicative of the Melanoma: Tracking and Evaluation of Recurrence measure being proposed in Table A.6 of this Appendix. Measure Q137 establishes a recall system linked to the process of notifying patients, with a current diagnosis or history of melanoma, when their next physical exam is due, as well as to follow up with patients who did not make an appointment within the specified timeframe or who missed a scheduled appointment. It does not assess whether the patient completed an annual skin exam nor if the process to follow up for those patients who missed an appointment is effective. The new measure proposed in Table A.6 of this Appendix is a process measure that not only assesses a significantly similar patient population, but also assesses patients who had excisional surgery for melanoma or melanoma in situ in the past 5 years for completion of an exam and/or diagnosed for recurrence of melanoma. We believe the new measure provides a more meaningful impact to quality improvement for this patient population.
In the Circumstance the Measure Was Retained:	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2025 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.3. Oncology: Medical and Radiation – Plan of Care for Pain

Category	Description
CBE# / eCQM CBE #:	0383 / N/A
Quality #:	144
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM Specifications
Measure Description:	Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because this measure is duplicative of measure Q143: Oncology: Medical and Radiation – Pain Intensity Quantified. Measure Q143 specifically questions cancer patients, currently receiving chemotherapy or radiation therapy, to quantify their pain intensity at each visit using a standardized tool. This measure is more robust than measure Q144 as it encourages the clinician to initiate a discussion regarding pain intensity with the patient at every denominator eligible visit. Measure Q144 is narrower in scope focusing on cancer patients identified with pain. To identify this patient population, a clinician would still need to screen their patients. Measure Q143 promotes screening of a broader patient population for pain, which still allows clinicians to administer care if pain is present. Additionally, measure Q143 is available for reporting within the eCQM Specifications collection type, allowing clinicians more measure options if reporting via eCQMs.
In the Circumstance the Measure Was Retained:	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2025 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.4. Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	254
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM Specifications
Measure Description:	Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location.
Measure Steward:	American College of Emergency Physicians
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because this measure has reached the end of the topped-out lifecycle (82 FR 53640) and has a limited opportunity to improve clinical outcomes. Topped-out process measures are those with a median performance rate of 95 percent or higher (81 FR 77286).[135] This measure's continued topped-out status is based on the current 2024 MIPS benchmarking data located at *https://qpp.cms.gov/benchmarks*, in addition to previous years MIPS benchmarking data. For more information on benchmarks, see the MIPS 2024 Quality Benchmarks User Guide at *https://www.cms.gov/files/document/2024-quality-benchmarks-user-guide-scoring-examples-pdf.pdf.*
In the Circumstance the Measure Was Retained:	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2025 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.5. Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):

Category	Description
CBE# / eCQM CBE #:	N/A / N/A

[135] See the 2024 MIPS Call for Measures Fact Set: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2711/2024-MIPS-Call-for-Measures-and-Activities.zip.

Category	Description
Quality #:	260
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM Specifications
Measure Description:	Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.
Measure Steward:	Society for Vascular Surgeons
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because this measure would be duplicative of measure Q344: Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) if the proposed changes to the measure are finalized. We are proposing in Table D.34 of this Appendix substantive changes to measure Q344, which describe the inclusion of the measure concept represented in Q260. Measure Q260 is focused on performing CEA on asymptomatic patients who are at low risk for morbidity and therefore are expected to have very low complication rates as indicated by patients being discharged to home by post-operative day #2. As a result, we are proposing to maintain measure Q344 and remove measure Q260 from MIPS.
In the Circumstance the Measure Was Retained:	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2025 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.6. Clinical Outcome Post Endovascular Stroke Treatment

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	409
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM Specifications
Measure Description:	Percentage of patients with a Modified Rankin Score (mRS) score of 0 to 2 at 90 days following endovascular stroke intervention.
Measure Steward:	Society of Interventional Radiology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) at the measure steward's request as it is no longer being maintained for inclusion.
In the Circumstance the Measure Was Retained:	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2025 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.7. Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	433
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM Specifications
Measure Description:	Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.
Measure Steward:	American Urogynecologic Society
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because this measure would be duplicative of measure Q432: Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair, if the proposed changes to the measure are finalized. We are proposing in Table D.46 of this Appendix substantive changes to measure Q432, which describe the inclusion of the measure concept represented in measure Q433. In addition, we are proposing to update the measure title and description for measure Q432 to include patients who sustain a bowel injury at the time of any pelvic organ prolapse repair.
In the Circumstance the Measure Was Retained:	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2025 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.8. Age Appropriate Screening Colonoscopy

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	439
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM Specifications
Measure Description:	The percentage of screening colonoscopies performed in patients greater than or equal to 86 years of age from January 1 to December 31.
Measure Steward:	American Gastroenterological Association
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because the quality action being measured has become standard of care, based upon MIPS performance data, and thus has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this inverse measure is 0.15 percent for the MIPS CQM Specifications collection type. For an inverse measure, a lower calculated performance rate indicates better clinical care or control. As such, the MIPS CQM Specifications collection type is considered extremely topped out. The average performance rate is based on the current 2024 MIPS benchmarking data located at *https://qpp.cms.gov/benchmarks.* For more information on benchmarks, see the MIPS 2024 Quality Benchmarks User Guide at *https://www.cms.gov/files/document/2024-quality-benchmarks-user-guide-scoring-examples-pdf.pdf.*
In the Circumstance the Measure Was Retained:	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2025 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.9. Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies

Category	Description
CBE# / eCQM CBE #:	1860 / N/A
Quality #:	452
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM Specifications
Measure Description:	Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and RAS (KRAS or NRAS) gene mutation spared treatment with anti-EGFR monoclonal antibodies.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because this measure is duplicative of measure Q451: RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy. Measures Q451 and Q452 ask the same clinical question but approach questioning from different clinical perspectives. Measure Q451 assesses patients who have already received anti-EGFR monoclonal therapy to determine if they received RAS gene mutation testing prior to initiation of therapy, while measure Q452 is a standard-of-care measure, as well as the counter clinical perspective to measure Q451. Measure Q452 only evaluates for patients who received anti-EGFR monoclonal treatment. Therefore, measure Q452 is a component of the quality action within measure Q451. The molecular biomarkers for the evaluation of colorectal cancer guidelines[136] strongly recommend "Patients with colorectal carcinoma being considered for anti-EGFR therapy must receive RAS mutational testing," which is the standard of care being evaluated by this measure. Measure Q451 provides an opportunity for a retrospective review and has the potential to improve clinical outcomes. For example, if the performance rates show there is a gap in medical care or high incidence of initiating therapy without first testing for the RAS gene mutation, clinical processes can be revised to improve practice. "Clinical care review is the process of retrospectively examining potential errors or gaps in medical care, with a goal of future practice improvement." [137]
In the Circumstance the Measure Was Retained:	If the measure is not finalized for removal in the CY 2025 PFS final rule, we are proposing to apply the following substantive changes to the measure specifications: (1) add denominator instructions to clarify the denominator eligible timeframe for diagnosis and (2) only patients who have been newly diagnosed with Stage IV colorectal cancer, or patients who have distant metastases at the time of colon cancer diagnosis, are to be included in the denominator of the measure to ensure the appropriate patient population is assessed for the numerator action. If the measure is not finalized for removal in the CY 2025 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention would be addressed under Table Group C. The substantive changes outlined above would be applied to the measure specifications.

[136] Sepulveda, A. R., Hamilton, S. R., Allegra, C. J., Grody, W., Cushman-Vokoun, A. M., Funkhouser, W. K., Kopetz, S. E., Lieu, C., Lindor, N. M., Minsky, B. D., Monzon, F. A., Sargent, D. J., Singh, V. M., Willis, J., Clark, J., Colasacco, C., Rumble, R. B., Temple-Smolkin, R., Ventura, C. B., & Nowak, J. A. (2017). Molecular Biomarkers for the Evaluation of Colorectal Cancer: Guideline From the American Society for Clinical Pathology, College of American Pathologists, Association for Molecular Pathology, and the American Society of Clinical Oncology. *Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology, 35(13)*, 1453–1486. https://doi.org/10.1200/JCO.2016.71.9807.

[137] Walker, L. E., Nestler, D. M., Laack, T. A., Clements, C. M., Erwin, P. J., Scanlan-Hanson, L., & Bellolio, M. F. (2018). Clinical Care Review Systems in Healthcare: A Systematic Review. *International Journal of Emergency Medicine*, *11*(1), 6. https://doi.org/10.1186/s12245-018-0166-y.

C.10. Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture

Category	Description
CBE# / eCQM CBE #:	N/A / 3475e
Quality #:	472
CMS eCQM ID:	CMS249v7
Collection Type:	eCQM Specifications
Measure Description:	Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS (finalized in 83 FR 60104 through 60105) because the quality action being measured has become standard of care, based upon MIPS performance data, and thus has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this inverse measure is 1.1 percent for the eCQM Specifications collection type. For an inverse measure, a lower calculated performance rate indicates better clinical care or control. As such, the eCQM Specifications collection type is considered extremely topped out. The average performance rate is based on the current 2024 MIPS benchmarking data located at *https://qpp.cms.gov/benchmarks.* For more information on benchmarks, see the MIPS 2024 Quality Benchmarks User Guide at *https://www.cms.gov/files/document/2024-quality-benchmarks-user-guide-scoring-examples-pdf.pdf.*
In the Circumstance the Measure Was Retained:	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2025 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

Table Group D: Proposed Substantive Changes to Previously Finalized MIPS Quality Measures for the CY 2025 Performance Period/2027 MIPS Payment Year and Future Years

The D Tables within this proposed rule provide the substantive changes proposed for the MIPS quality measures in CY 2025. We note that some MIPS quality measures available in traditional MIPS and MVPs are adopted by the Medicare Shared Savings Program for utilization in the Alternative Payment Model (APM) Performance Pathway (APP) and/or APP Plus, as proposed in section IV.A.4.c.(3) of this proposed rule. For such measures, the collection type applicable for purposes of the APP and/or APP Plus (Medicare CQM for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQM)) is also specified as a collection type available for such measures described in Table Group D.

The changes that are made to the denominator codes sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2025 may not be identified within this proposed rule due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2025 CPT and ICD-10 updates and assessment of these codes' inclusion by the Measure Steward, these changes may be postponed until CY 2025. The 2025 Quality Measure Release Notes provide a comprehensive, detailed reference of exact code changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types in the Quality Payment Program website at *https://qpp.cms.gov*. In addition, eCQMs that are endorsed by a CBE are shown in Table D of this Appendix as follows: CBE # / eCQM CBE #.

In addition to the proposed substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but they are important to communicate to interested parties. These changes align with the scope of the current coding; however, though not substantive in nature, these changes would expand or contract the measure's current eligible population. Therefore, please refer to the current year measure specification and the 2025 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes to ensure correct implementation. Language has also been added, to all applicable 2025 quality measure specifications, in the form of an 'Instructions Note' to clarify that telehealth encounters are allowed for determination of denominator eligibility. Only where telehealth encounters previously were not allowed as denominator eligible would the D table corresponding to a measure reflect an update to the denominator allowing for telehealth encounters in the 'Substantive Change' cell.

The eCQM Technical Release Notes should also be carefully reviewed for revisions within the logic portion of the measure. In addition to the proposed substantive changes, there may be revisions within the logic that are not considered substantive in nature, however, it is important to review to ensure proper implementation of the measure. As not all systems and clinical workflows are the same, it is important to review these changes in the context of a specific system and/or clinical workflow.

D.1. Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)

Category	Description
CBE # / eCQM CBE #:	0059 / N/A
Quality #:	001
CMS eCQM ID:	CMS122v13
Current Collection Type:	Medicare Part B Claims Measure Specifications/ eCQM Specifications/ MIPS CQM Specifications/ Medicare CQM Specifications (collection type available only in the APP and/or APP Plus)
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.
Substantive Change:	**The measure title is revised from "Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)" to:** Diabetes: Glycemic Status Assessment Greater Than 9%. **The measure description is revised to read: For all collection types:** Percentage of patients 18-75 years of age with diabetes who had a glycemic status assessment (hemoglobin A1c [HbA1c] or glucose management indicator [GMI]) > 9.0% during the measurement period. **Updated denominator exclusion: For all collection types: Removed:** specific encounter requirements from the frailty/advanced illness exclusion. **The measure numerator is revised to read: For all collection types:** Patients whose most recent glycemic status assessment (HbA1c or GMI) (performed during the measurement period) is > 9.0% or is missing, or was not performed during the measurement period. **Updated guidance: For the eCQM Specifications collection type: Revised:** If the glycemic status assessment (HbA1c or GMI) is in the medical record, the test can be used to determine numerator compliance. **Added:** Glycemic status assessment (HbA1c or GMI) must be reported as a percentage (%). If multiple glycemic status assessments were recorded for a single date, use the lowest result. **Updated numerator instructions: For the MIPS CQM Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** GMI as an assessment option. **Updated numerator options: For the MIPS CQM Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** GMI as an assessment option. **Updated numerator note: For the MIPS CQM Specifications and the Medicare Part B Claims Measure Specifications collection types: Added**: If multiple glycemic status assessments were recorded for a single date, use the lowest result.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale	We are proposing to revise this measure to include glucose management indicators (GMI) to broaden the acceptable methods for monitoring the glycemic status of patients with diabetes. This measure revision supports those clinicians that are using this monitoring method to ensure management of persons with diabetes using continuous glucose monitoring.[138] We are also proposing to update the denominator exclusion by removing the requirement for patients to have had at least one inpatient or two outpatient encounters to recognize a diagnosis of advanced illness. The removal of this requirement within the denominator exclusion reduces the burden of identifying applicable encounters, while still identifying patients with an indication of frailty. This is particularly applicable for those patients seen outside of their reporting clinician's medical record. This revision would update the denominator exclusion to remove any patient 66 years of age and older who has a diagnosis of advanced illness during the measurement period or the year prior from the denominator of measure Q001. Decreasing complexity and burden of this element ensures consistent implementation allowing for more comparable data.

[138] ElSayed, N. A., Aleppo, G., Aroda, V. R., Bannuru, R. R., Brown, F. M., Bruemmer, D., Collins, B. S., Hilliard, M. E., Isaacs, D., Johnson, E. L., Kahan, S., Khunti, K., Leon, J., Lyons, S. K., Perry, M. L., Prahalad, P., Pratley, R. E., Seley, J. J., Stanton, R. C., Gabbay, R. A., … on behalf of the American Diabetes Association (2023). 7. Diabetes Technology: Standards of Care in Diabetes-2023. *Diabetes Care*, *46*(Suppl 1), S111–S127. https://doi.org/10.2337/dc23-S007.

D.2. Anti-Depressant Medication Management

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	009
CMS eCQM ID:	CMS128v13
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).
Substantive Change:	**The measure initial patient population is revised to read:** Patients 18 years of age and older as of the IPSD who were dispensed antidepressant medications during the Intake Period, and were diagnosed with major depression 60 days prior to, or 60 days after the dispensing event and had a visit 60 days prior to, or 60 days after the dispensing event. **Updated logic and logic definition: Revised:** logic to base it on age and IPSD.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale	We are proposing to revise the initial patient population look-back window to evaluate the age of the patient when medication is dispensed during the intake period. The updated timeframe distinguishes between a new prescription and a continuing prescription to ensure the measure logic is more accurate in determining the antidepressant treatment has met the numerator's quality action. We are also proposing to update the logic to look at the age and IPSD so that the look-back window allows all patients to be assessed for the exclusion criteria related to previous anti-depression medication.

D.3. Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care

Category	Description
CBE # / eCQM CBE #:	N/A/ N/A
Quality #:	019
CMS eCQM ID:	CMS142v13
Current Collection Type:	eCQM Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once during the performance period.
Substantive Change:	**Modified collection type**: eCQM Specifications collection type. **Updated Guidance: Revised:** The communication of results, including the level of severity of diabetic retinopathy and presence or absence of macular edema to the primary care physician providing ongoing care of a patient's diabetes should be completed soon after the dilated exam is performed.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to remove the MIPS CQM Specifications collection type as it has reached the end of the topped-out lifecycle (82 FR 53640). The average performance rate and topped-out status is based on the current MIPS benchmarking data located at *https://qpp.cms.gov/benchmarks*. However, the benchmarking data continues to show a gap for the eCQM Specifications collection type and as such, we are proposing to retain that collection type. Additionally, we are proposing to revise the measure guidance to define required information to be included within the report for the purposes of numerator compliance. This ensures all appropriate information is being communicated for patient care coordination.

D.4. Advance Care Plan

Category	Description
CBE # / eCQM CBE #:	0326 / N/A
Quality #:	047
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Specifications, MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.
Substantive Change:	**Updated the denominator criteria: For the MIPS CQM Specifications and the Medicare Part B Specifications collection types: Added:** coding for neuropsychology.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to update denominator criteria to include coding for neuropsychology as this measure is applicable to their scope of care.

D.5. Diabetes: Eye Exam

Category	Description
CBE # / eCQM CBE #:	0055 / N/A
Quality #:	117
CMS eCQM ID:	CMS131v13
Current Collection Type:	eCQM Specifications/ MIPS CQM Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.
Substantive Change:	**Updated denominator exclusion: For all collection types: Removed:** specific encounter requirements from the frailty/advanced illness exclusion.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale	We are proposing to update the denominator exclusion by removing the requirement for patients to have had at least one inpatient or two outpatient encounters to recognize a diagnosis of advanced illness. The removal of this requirement within the denominator exclusion reduces the burden of identifying applicable encounters, while still identifying patients with an indication of frailty. This is particularly applicable for those patients seen outside of their reporting clinician's medical record. This revision would update the denominator exclusion to remove any patient 66 years of age and older who has a diagnosis of advanced illness during the measurement period or the year prior from the denominator of measure Q117. Decreasing complexity and burden of this element ensures consistent implementation allowing for more comparable data.

D.6. Documentation of Current Medications in the Medical Record

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	130
CMS eCQM ID:	CMS68v14
Current Collection Type:	eCQM Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.
Substantive Change:	**The measure description is revised to read: For all collection types:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. **Updated guidance: For the eCQM specifications collection type: Revised**: allows for documentation to be completed on the day of the encounter. **Updated initial patient population: For the eCQM specifications collection type: Removed**: age criteria. **Updated denominator: For the MIPS CQM Specifications collection type: Removed:** age criteria. **Updated denominator criteria: For the MIPS CQM Specifications collection type: Removed:** age criteria. **Added:** coding for pediatric audiology services. **Updated numerator note: For the MIPS CQM Specifications collection type: Revised:** allows for documentation to be completed on the day of the encounter.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to update multiple components of the measure to remove the age criteria so that all patients, regardless of age, are assessed for having a list of their current medications documented in their medical record. This revision broadens the denominator, supporting assessment of current medications for all patient age ranges. Assessing for missing information about the dosage, route, or frequency of a medication supports clinical communication and may assist in avoiding patient harm.[139] Additionally, we are proposing to update the measure to allow for the quality action to occur on the day of the encounter rather than limiting to during the encounter. This allows for flexibility to align with the clinician's workflows and systems. We are also proposing to update the denominator criteria to include coding for pediatric audiology services as this measure is applicable to their scope of care.

[139] Owen, M. C., Chang, N. M., Chong, D. H., & Vawdrey, D. K. (2011). Evaluation of Medication List Completeness, Safety, and Annotations. *AMIA Annual Symposium Proceedings. AMIA Symposium*, *2011*, 1055–1061. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3243276/.

D.7. Oncology: Medical and Radiation – Pain Intensity Quantified

Category	Description
CBE # / eCQM CBE #:	0384 / 0384e
Quality #:	143
CMS eCQM ID:	CMS157v13
Current Collection Type:	eCQM Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.
Substantive Change:	**Updated initial patient population: For the eCQM Specifications collection type: Revised:** Population 1: All patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy. Population 2: All patient visits, regardless of patient age, with a diagnosis of cancer currently receiving radiation therapy.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to revise this measure to split the initial patient population to delineate between patients who are receiving radiation therapy and are assessed for pain intensity and their pain level quantified. This additional patient population would allow clinicians reporting this measure the ability to distinguish their performance between patients receiving chemotherapy and those receiving radiation services. It would also align the measure across all collection types.

D.8. Falls: Plan of Care

Category	Description
CBE # / eCQM CBE #:	0101 / N/A
Quality #:	155
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.
Substantive Change:	**Modified collection type:** MIPS CQM Specifications collection type.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to revise this measure by removing the Medicare Part B Claims Measure Specifications collection type for this measure as it has reached the end of the topped-out lifecycle (82 FR 53640). The average performance rate is based on the current 2024 MIPS benchmarking data located at *https://qpp.cms.gov/benchmarks*.

D.9. Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration

Category	Description
CBE # / eCQM CBE #:	0115 / N/A
Quality #:	168
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) for mediastinal bleeding with or without tamponade, unplanned coronary artery intervention (native vessel, graft or both), valve dysfunction, aortic reintervention or other cardiac reason during the current hospitalization. **The measure numerator is revised to read:** Patients undergoing isolated CABG surgery who require a return to the OR for mediastinal bleeding with or without tamponade, unplanned coronary artery intervention (native vessel, graft or both), valve dysfunction, aortic reintervention or other cardiac reason during the current hospitalization. **Updated numerator options: Added:** unplanned coronary artery intervention (native vessel, graft, or both) and aortic reintervention
Measure Steward:	Society of Thoracic Surgeons
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale	We are proposing to revise this measure to broaden the scope of cardiac complications that may require a return to the operating room following isolated CABG surgery. These revisions support the measure to decrease surgical re-exploration following CABG surgery, which is a serious complication and impacts length of stay, efficient use of resources, and increases risk for additional injury and death.[140] Although rates of re-exploration after cardiac surgery have significantly declined recently, it has been linked to much higher complications, mortality, and hospitalizations.[141]

[140] Tran, Z., Williamson, C., Hadaya, J., Verma, A., Sanaiha, Y., Chervu, N., Gandjian, M., & Benharash, P. (2022). Trends and Outcomes of Surgical Reexploration After Cardiac Operations in the United States. *The Annals of Thoracic Surgery*, *113*(3), 783–792. https://doi.org/10.1016/j.athoracsur.2021.04.011.

[141] See footnote Tran et al., 2022.

D.10. Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	176
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.
Substantive Change:	**Updated denominator instructions: Added:** new biosimilar medications.
Measure Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale	We are proposing to update the list of medications by adding new biosimilar medications to the existing list in the denominator instructions. This expansion would provide an up-to-date list of appropriate biologics and/or immune response modifiers that clinicians may have prescribed for their patients, thereby ensuring that the right patients are identified in the denominator of this measure. These targeted immunotherapies are associated with a high risk of progression to active TB infection, therefore screening for latent TB prior to initiating first course therapy is highly recommended since it has been shown to effectively reduce the incidence of progression in patients with latent TB.[142]

[142] CDC. (2020). Latent Tuberculosis Infection – A Guide for Primary Health Care Providers. https://www.cdc.gov/tb/media/pdfs/Latent-TB-Infection-A-Guide-for-Primary-Health-Care-Providers.pdf.

D.11. Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity

Category	Description
CBE # / eCQM CBE #:	2523 / N/A
Quality #:	177
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity using an ACR-preferred RA disease activity assessment tool at ≥50% of encounters for RA for each patient during the measurement year.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 18 years and older with two or more diagnoses of rheumatoid arthritis (RA) at least 90 days apart who have an assessment of disease activity using an ACR-preferred RA disease activity assessment tool at ≥50% of encounters for RA for each patient during the performance period. **The measure denominator is revised to read:** Patients aged 18 years and older with two or more RA diagnoses documented at least 90 days apart with at least one encounter with an RA diagnosis occurring during the performance period and an additional encounter with an RA diagnosis occurring in the performance period or prior performance period. **Updated denominator definition: Added:** Encounter – An encounter during the performance period where one of the CPT or HCPCS codes listed in the patient encounter criteria is used without a telehealth modifier (i.e., only non-telehealth visits are to be considered for this measure). Additional encounter - An additional encounter during the performance period or prior performance period where one of the CPT or HCPCS codes listed in the patient encounter is used to confirm an RA diagnosis with ICD-10-CM diagnosis codes as listed in the Denominator criteria. **Updated denominator criteria: Added:** An additional encounter with an RA diagnosis during the performance period or prior performance period that is at least 90 days before or after an encounter with an RA diagnosis during the performance period. **Updated numerator definition: Revised:** A result within the valid range of the selected tool qualifies for meeting numerator performance as long as a result is captured at ≥50% of each patient's qualified encounters. If the result of a recorded disease activity assessment is outside the valid range of scores for the tool (e.g., a CDAI score of 101 when the maximum possible score is 76.0) or is only recorded as a disease activity level (e.g., low, moderate, or high) in place of a calculated numerical score, this score should not be included in the count to meet the ≥50% requirement in the numerator.
Measure Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale	We are proposing to revise the denominator to provide greater specificity on the timeframe and criteria for denominator coding and how it should be captured to ensure the appropriate patients are being identified for this measure. Diagnosing RA requires "a combination of physical exams, blood tests for inflammatory markers, and imaging tests (like X-rays and MRIs), in addition to patient-reported symptoms," which can take multiple visits to determine an accurate assessment of RA disease activity.[143] Therefore, this change would align more closely with the workflow of clinicians and allows the assessment of a patient for RA disease activity during more than one clinical visit. These changes support a comprehensive perspective of the patient's disease activity level and should promote optimal treatment outcomes. We are proposing to revise the definition for 'Assessment of Disease Activity' to confirm that only those assessments where the disease activity is correctly recorded are included in the numerator quality action for the purposes of meeting performance. Not only do the results need to be within the range of the selected validated qualifying tool, but also a calculated numeric score and not simply a disease activity level. This ensures that all assessment information is correctly captured to drive appropriate care.

[143] Brody, B. (2020). The American College of Rheumatology Updated Its Approved Disease Activity Measures for Rheumatoid Arthritis — Here's What That Means. https://creakyjoints.org/living-with-arthritis/symptoms/approved-disease-activity-measures-for-rheumatoid-arthritis/.

D.12. Rheumatoid Arthritis (RA): Functional Status Assessment

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	178
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 18 years and older with two or more diagnoses of rheumatoid arthritis (RA) at least 90 days apart for whom a functional status assessment was performed at least once during the performance period. **The measure denominator is revised to read:** Patients aged 18 years and older with two or more RA diagnoses documented at least 90 days apart with at least one encounter with an RA diagnosis occurring during the performance period and an additional encounter with an RA diagnosis occurring in the performance period or prior performance period. **Updated denominator definition: Added:** Encounter – An encounter during the performance period where one of the CPT or HCPCS codes listed in the patient encounter criteria is used. Additional encounter – An additional encounter during the performance period or prior performance period where one of the CPT or HCPCS codes listed in the patient encounter is used to confirm an RA diagnosis with ICD-10-CM diagnosis codes as listed in the Denominator criteria. **Updated denominator criteria: Added:** an additional encounter with an RA diagnosis during the performance period or prior performance period that is at least 90 days before or after an encounter with an RA diagnosis during the performance period.
Measure Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale	We are proposing to revise the denominator to provide greater specificity on the timeframe and criteria for denominator coding and how it should be captured to ensure the appropriate patients are being identified for this measure. Diagnosing RA requires "a combination of physical exams, blood tests for inflammatory markers, and imaging tests (like X-rays and MRIs), in addition to patient-reported symptoms," which can take multiple visits to determine an accurate assessment of RA disease activity.[144] Therefore, this change would align more closely with the workflow of clinicians and allows assessment of a patient for RA disease activity during more than one clinical visit. These changes support a comprehensive perspective of the patient's disease activity level and should promote optimal treatment outcomes.

[144] See footnote Brody, 2020 in Table D.11 of this Appendix.

D.13. Rheumatoid Arthritis (RA): Glucocorticoid Management

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	180
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 18 years and older with two or more diagnoses of rheumatoid arthritis (RA) at least 90 days apart who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone >5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan during the performance period. **The measure denominator is revised to read:** Patients aged 18 years and older with two or more RA diagnoses documented at least 90 days apart with at least one encounter with an RA diagnosis occurring during the performance period and an additional encounter with an RA diagnosis occurring in the performance period or prior performance period. **Updated denominator definition: Added:** Encounter – An encounter during the performance period where one of the CPT or HCPCS codes listed in the patient encounter criteria is used. Additional encounter -– An additional encounter during the performance period or prior performance period where one of the CPT or HCPCS codes listed in the patient encounter is used to confirm an RA diagnosis with ICD-10-CM diagnosis codes as listed in the Denominator criteria. **Updated denominator criteria: Added:** An additional encounter with an RA diagnosis during the performance period or prior performance period that is at least 90 days before or after an encounter with an RA diagnosis during the performance period.
Measure Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale	We are proposing to revise the denominator to provide greater specificity on the timeframe and criteria for denominator coding and how it should be captured to ensure the appropriate patients are being identified for this measure. Diagnosing RA requires "a combination of physical exams, blood tests for inflammatory markers, and imaging tests (like X-rays and MRIs), in addition to patient-reported symptoms," which can take multiple visits to determine an accurate assessment of RA disease activity.[145] Therefore, this change would align more closely with the workflow of clinicians and allows assessment of a patient for RA disease activity during more than one clinical visit. These changes support a comprehensive perspective of the patient's disease activity level and should promote optimal treatment outcomes.

[145] See footnote Brody, 2020 in Table D.11 of this Appendix.

D.14. Elder Maltreatment Screen and Follow-Up Plan

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	181
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.
Substantive Change:	**Updated denominator criteria: For all collection types: Added:** coding for emergency department.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to add encounter codes for emergency department (ED) visits to the denominator criteria as the emergency department is an appropriate setting for screening for elder maltreatment. "EDs are a potentially important setting for elder mistreatment identification because they provide care for a large number of older adults who may be elder mistreatment victims" especially given that the ED is sometimes the only clinical setting that the patient may visit.[146] Expanding the denominator to include ED visits ensures a more complete denominator patient population and provides support and delivery of interventions that could prevent actual abuse.

[146] See footnote Rosen et al., 2020 in Table B.11 of this Appendix.

D.15. Functional Outcome Assessment

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	182
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.
Substantive Change:	**Updated numerator definition: Revised:** Functional Outcome Assessment: Patient completed questionnaires designed to measure a patient's limitations in performing the usual human tasks of living and to directly quantify functional and behavioral symptoms. If a patient is unable to complete a questionnaire, a standardized clinical assessment tool may be used to measure a patient's limitations. **Added:** To Table 1. Definitions for Magnitude of Effects, Based on Mean Between-Group Differences – Modified*: clarification that list of standardized tools is not exhaustive.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to update the numerator definition to clarify that clinicians may use a standardized clinical assessment tool to measure a patient's limitation if they are unable to complete a questionnaire. This change would allow flexibility in performing the quality action and clarify that the list of standardized tools named in the measure are only examples, not an exhaustive list. The National Institute of Health indicates that it supports the use of standardized tools, stating they offer a clinician-designed approach to promoting care standardization that accommodates patients' individual differences, respects clinicians' clinical judgement, and keeps pace with the rapid growth of medical knowledge.[147]

[147] Farias, M., Jenkins, K., Lock, J., Rathod, R., Newburger, J., Bates, D. W., Safran, D. G., Friedman, K., & Greenberg, J. (2013). Standardized Clinical Assessment and Management Plans (SCAMPs) Provide a Better Alternative to Clinical Practice Guidelines. *Health Affairs (Project Hope)*, *32*(5), 911–920. https://doi.org/10.1377/hlthaff.2012.0667.

D.16. Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	185
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy.
Substantive Change:	**Updated denominator exception: Added:** To the 'Documentation of system reasons(s): patient cannot provide precise date or details from previous colonoscopy.
Measure Steward:	American Gastroenterological Association
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to update the denominator exception to exclude patients that are unable to provide the precise date or details from a previous colonoscopy. This addition would assist with data collection when a patient with a history of adenomatous polyps is unable to provide information regarding their last colonoscopy.

D.17. Controlling High Blood Pressure

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	236
CMS eCQM ID:	CMS165v13
Current Collection Type:	Medicare Part B Claims Measure Specifications / eCQM Specifications/ MIPS CQM Specifications/ Medicare CQM Specifications (collection type available only in the APP and/or APP Plus)
Current Measure Description:	Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.
Substantive Change:	**Updated denominator exclusion: For all collection types: Removed:** specific encounter requirements from the frailty/advanced illness exclusion.
Measure Steward:	National Committtee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale	We are proposing to update the denominator exclusion by removing the requirement for patients to have had at least one inpatient or two outpatient encounters to recognize a diagnosis of advanced illness. The removal of this requirement within the denominator exclusion reduces the burden of identifying applicable encounters, while still identifying patients with an indication of frailty. This is particularly applicable for those patients seen outside of their reporting clinician's medical record. This revision would update the denominator exclusion to remove any patient 66 years of age and older who has a diagnosis of advanced illness during the measurement period or the year prior from the denominator of measure Q236. Decreasing complexity and burden of this element ensures consistent implementation allowing for more comparable data.

D.18. Use of High-Risk Medications in Older Adults

Category	Description
CBE # / eCQM CBE #:	0022 / N/A
Quality #:	238
CMS eCQM ID:	CMS156v13
Current Collection Type:	eCQM Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.
Substantive Change:	**Updated numerator definition: For the MIPS CQM Specifications collection type:** Numerator (Submission Criteria 1): Table 1 - High-Risk Medications at any Dose or Duration **Removed:** From Anticholinergics, first-generation antihistamines: Carbinoxamine, Clemastine, Dexbrompheniramine, Dexchlorpheniramine, Pyrilamine From Antispasmodics: Belladonna alkaloids, Methscopolamine, Propantheline From Cardiovascular, alpha agonists, central: Methyldopa From Cardiovascular, other: Disopyramide From Central nervous system, antidepressants: Protriptyline Trimipramine From Central nervous system, barbiturates: Amobarbital, Butabarbital, Pentobarbital, Secobarbital From Central nervous system, vasodilators: Isoxsuprine From Endocrine system, sulfonylureas, long-duration: Chlorpropamide From Endocrine system, other: Megestrol From Pain medications, other: Meperidine **Added:** A row with one medication is considered a group (or drug class) of one; therefore, two orders of that same medication are numerator compliant. **Added:** To Central nervous system, barbiturates: Primidone Endocrine system, megestrol: Megestrol Pain medications, meperidine: Meperidine To Pain medications, other: Ketorolac, includes parenteral and oral Table 3 – High-Risk Medications With Average Daily Dose Criteria **Removed:** Alpha agonists, central: Reserpine >0.1 mg per day Numerator (Submission Criteria 2): Table 4 – High-Risk Medications **Removed:** From Benzodiazepines, long, short and intermediate acting: Flurazepam, Quazepam **Added:** To Benzodiazepines, long, short and intermediate acting: Clobazam
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to update the list of high-risk medications to align with 2023 AGS Beers Criteria[148] and ensure that older adults are not prescribed inappropriate medications. This change would also align with PY 2025 eCQM version (CMS156v13), which supports alignment between the collection types. We are also proposing to add clarification that the medications found within a single row of table one, within the specification, represent a unique group or drug class. Therefore, two orders from that group or drug class would be consider numerator compliant for this measure, which has an inverse analytic for the calculation of performance.

[148] The 2023 American Geriatrics Society Beers Criteria Update Expert Panel. (2023). American Geriatrics Society 2023 updated AGS Beers Criteria for potentially inappropriate medication use in older adults. Journal of the American Geriatrics Society, 71(7), 2052-2081. https://doi.org/10.1111/jgs.18372.

D.19. Barrett's Esophagus

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	249
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia.
Substantive Change:	**Updated denominator exception: For all collection types: Added**: Specimen site other than anatomic location of esophagus. **Updated denominator exclusion**: **For all collection types: Removed**: Specimen site other than anatomic location of esophagus.
Measure Steward:	College of American Pathologists
High Priority Measure:	No
Measure Type:	Process
Rationale	We are proposing to remove the denominator exclusion so that all patients with a diagnosis for Barrett's Esophagus are included in the denominator of the measure and are proposing to add a denominator exception for specimen sites other than the anatomic location of the esophagus. Revising the measure to include this element as a denominator exception would allow for an automated capture of the relevant cases with less manual intervention reducing overall burden of measure reporting.

D.20. Sleep Apnea: Severity Assessment at Initial Diagnosis

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	277
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.
Substantive Change:	**Updated denominator exception: Added:** patients previously diagnosed with OSA and severity assessed by another provider.
Measure Steward:	American Academy of Sleep Medicine
High Priority Measure:	No
Measure Type:	Process
Rationale	We are proposing to update the denominator exception by adding that patients previously diagnosed with obstructive sleep apnea (OSA), with severity assessed by another clinician and documented would not need to have the testing completed again. This denominator exceptions allows clinician judgement as to whether repeat testing is needed, as we don't want to promote overutilization. This revision increases clarity of this element and ensures consistent implementation allowing for more comparable data.

D.21. Dementia: Cognitive Assessment

Category	Description
CBE # / eCQM CBE #:	N/A / 2872e
Quality #:	281
CMS eCQM ID:	CMS149v13
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.
Substantive Change:	**Updated guidance: Added:** The measure requires a diagnosis of dementia is present before the routine assessment of cognition once in a 12-month period.
Measure Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale	We are proposing to update the measure guidance to clarify that the diagnosis of dementia must be present prior to the cognitive assessment. This would ensure that any cognitive assessments performed prior to the dementia diagnosis but occurred during the 12-month lookback period would not be attributed to this measure numerator.[149] This change would ensure consistency in the abstraction of the measure's numerator elements based upon a specific timeframe that support rigorous data for the calculation of MIPS performance rates.

[149] Office of the Assistance Secretary for Planning and Evaluation. (2016). Examining Models of Dementia Care: Final Report. https://aspe.hhs.gov/reports/examining-models-dementia-care-final-report-0.

D.22. Dementia: Functional Status Assessment

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	282
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.
Substantive Change:	**Updated denominator criteria: Added:** coding for speech language pathology and nuclear medicine.
Measure Steward:	American Academy of Neurology/American Psychiatric Association
High Priority Measure:	No
Measure Type:	Process
Rationale	We are proposing to add encounter codes for speech language pathologists and nuclear medicine to the denominator criteria as these are appropriate specialties to identify changes in functional status in patients diagnosed with dementia. Dementia, which can be caused by "different brain diseases," affects a person's activities of daily living including, but not limited to eating and swallowing, and speech.[150]

[150] American Speech-Language-Hearing Association (ASHA). Dementia. https://www.asha.org/public/speech/disorders/dementia/.

D.23. Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	286
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.
Substantive Change:	**Updated denominator criteria: Added:** coding for speech language pathology and nuclear medicine.
Measure Steward:	American Academy of Neurology/American Psychiatric Association
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to update the denominator criteria to include coding for speech language pathology and nuclear medicine as this measure is applicable to their scope of care. Dementia, which can be caused by "different brain diseases," affects a person's activities of daily living including, but not limited to eating and swallowing, and speech.[151]

[151] See footnote ASHA in Table D.22 of this Appendix.

D.24. Dementia: Education and Support of Caregivers for Patients with Dementia

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	288
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.
Substantive Change:	**Updated denominator criteria: Added:** coding for speech language pathology and nuclear medicine.
Measure Steward:	American Academy of Neurology/American Psychiatric Association
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to update the denominator criteria to include coding for speech language pathology and nuclear medicine as this measure is applicable to their scope of care. Dementia, which can be caused by "different brain diseases," affects a person's activities of daily living including, but not limited to eating and swallowing, and speech.[152]

[152] See footnote ASHA in Table D.22 of this Appendix.

D.25. Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	290
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for depression, anxiety, apathy, AND psychosis once during the measurement period.
Substantive Change:	**Updated denominator criteria: Added:** coding for neuropsychology and behavioral health.
Measure Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale	We are proposing to update the denominator criteria to include coding for neuropsychology and behavioral health as it's clinically appropriate for these clinician types to assess for depression, anxiety, apathy, and psychosis.

D.26. Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	291
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for cognitive impairment or dysfunction once during the measurement period.
Substantive Change:	**Updated denominator criteria: Added:** coding for neuropsychology, behavioral health, and physical and occupational therapy.
Measure Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale	We are proposing to update the denominator criteria to include coding for neuropsychology, behavioral health, and physical and occupational therapy as it's clinically appropriate for these clinician types to assess for cognitive impairment or dysfunction.

D.27. Rehabilitative Therapy Referral for Patients with Parkinson's Disease

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	293
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease who were referred to physical, occupational, speech, or recreational therapy once during the measurement period.
Substantive Change:	**Updated denominator criteria: Added:** coding for neuropsychology, behavioral health, and speech language pathology.
Measure Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to update the denominator criteria to include coding for neuropsychology, behavioral health, and speech language pathology as this measure is applicable to their scope of care.

D.28. Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	317
CMS eCQM ID:	CMS22v13
Current Collection Type:	Medicare Part B Claims Measure Specifications / eCQM Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.
Substantive Change:	**Updated denominator criteria: For the MIPS CQM Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** coding for nutrition/dietitian clinician type. **Updated numerator definition: For all collection types: Revised:** intervals for rescreening for first and second hypertensive BP readings.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale	We are proposing to add encounter codes for nutrition therapy to the denominator criteria for the MIPS CQM Specifications and the Medicare Part B Claims Measure Specifications collection types as this is an appropriate setting to identify people who may have elevated blood pressure (BP) readings. Nutritional approaches play a pivotal role in helping to reduce the risk of hypertension or control blood pressure in people with hypertension.[153] We are proposing to remove the minimum timeframe for follow-up screenings for patients with elevated BP readings for all collection types. This change allows clinician discretion to recommend a follow-up plan based on the patient's current health status. Additionally, this supports stability of this measure component, as the frequency is each visit, within the specification over time, while still maintaining consistency with the current guidelines.[154]

[153] Physicians Committee for Responsible Medicine. (2023). Nutrition Guide for Clinicians: Hypertension. https://nutritionguide.pcrm.org/nutritionguide/view/Nutrition_Guide_for_Clinicians/1342053/all/Hypertension.

[154] Whelton, P. K., Carey, R. M., Aronow, W. S., Casey, D. E., Jr, Collins, K. J., Dennison Himmelfarb, C., DePalma, S. M., Gidding, S., Jamerson, K. A., Jones, D. W., MacLaughlin, E. J., Muntner, P., Ovbiagele, B., Smith, S. C., Jr, Spencer, C. C., Stafford, R. S., Taler, S. J., Thomas, R. J., Williams, K. A., Sr, Williamson, J. D., ... Wright, J. T., Jr (2018). 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Journal of the American College of Cardiology*, *71*(19), e127–e248. https://doi.org/10.1016/j.jacc.2017.11.006.

D.29. Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients

Category	Description
CBE # / eCQM CBE #:	0658 / N/A
Quality #:	320
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 45 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.
Substantive Change:	**The measure description is revised to read: For all collection types:** Percentage of patients aged 45 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of 10 years for repeat colonoscopy documented in their colonoscopy report. **Updated numerator: For all collection types: Revised:** Patients who had recommended follow-up interval of 10 years for repeat colonoscopy documented in their colonoscopy report. **Updated numerator note: For all collection types: Added:** To meet the numerator, patients with a negative screening colonoscopy should have documentation that they received counseling or instruction to have a follow-up or repeat colonoscopy in 10 years. A 6 month period before or after 10 years is considered within the recommended follow-up interval. **Updated numerator options: For all collection types: Revised:** **Performance Met:** Recommended follow-up interval for repeat colonoscopy of 10 years documented in colonoscopy report and communicated with patient. **Denominator Exception:** Documentation of medical reason(s) for not recommending a 10 year follow-up interval (e.g., inadequate prep, familial or personal history of colonic polyps, patient had no adenoma and age is ≥ 66 years old, or life expectancy < 10 years, other medical reasons) **Performance Not Met:** A 10 year follow-up interval for colonoscopy not recommended, reason not otherwise specified.
Measure Steward:	American Gastroenterological Association
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to update the measure description, numerator, and numerator options to ensure the time frame for recommended follow up after a normal colonoscopy for the average risk patient accurately reflects current guidelines which states "[n]ew observational and modeling studies of colonoscopy confirm and strengthen the evidence base to support the conclusion that individuals with normal colonoscopy are at lower-than-average risk for CRC. Based on this reduced risk, we recommend CRC screening in average-risk individuals be repeated 10 years after a normal examination complete to the cecum with bowel preparation adequate to detect polyps >5 mm in size."[155] Additionally, we are proposing to add a numerator note to indicate inclusion of documentation that the patient has received counseling and instruction on when a repeat colonoscopy should be scheduled. This change would ensure the patient is aware of clinical recommendations to drive healthy outcomes.

[155] Gupta, S., Lieberman, D., Anderson, J. C., Burke, C. A., Dominitz, J. A., Kaltenbach, T., Robertson, D. J., Shaukat, A., Syngal, S., & Rex, D. K. (2020). Recommendations for Follow-Up After Colonoscopy and Polypectomy: A Consensus Update by the US Multi-Society Task Force on Colorectal Cancer. *Gastrointestinal Endoscopy*, *91*(3), 463–485.e5. https://doi.org/10.1016/j.gie.2020.01.014.

D.30. Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	322
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low-risk surgery patients 18 years or older for preoperative evaluation during the 12-month submission period.
Substantive Change:	**The measure description is revised to read**: Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), multigated acquisition scan (MUGA), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low-risk surgery patients 18 years or older for preoperative evaluation during the 12-month submission period. **Updated instructions: Added:** multigated acquisition scan (MUGA). **Updated denominator: Added:** multigated acquisition scan (MUGA). **Updated denominator criteria: Added:** coding for multigated acquisition scan (MUGA). **Updated numerator: Added:** multigated acquisition scan (MUGA).
Measure Steward:	American College of Cardiology Foundation
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale	We are proposing to update multiple components of the measure to add MUGA. Even though MUGA scanning allows a clinician to evaluate many heart parameters and can be done while resting or under stress, this diagnostic imaging test would ensure this type of imaging isn't performed on low-risk surgery patients since the risks of the procedure exceed the expected clinical benefit for the denominator eligible patient population.[156] The MUGA scan is primarily used for assessing myocardial function in patients on cardiotoxic chemotherapy.[157]

[156] Winchester, D. E., Maron, D. J., Blankstein, R., Chang, I. C., Kirtane, A. J., Kwong, R. Y., Pellikka, P. A., Prutkin, J. M., Russell, R., & Sandhu, A. T. (2023). ACC/AHA/ASE/ASNC/ASPC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2023 Multimodality Appropriate Use Criteria for the Detection and Risk Assessment of Chronic Coronary Disease. *Journal of Cardiovascular Magnetic Resonance: Official Journal of the Society for Cardiovascular Magnetic Resonance*, *25*(1), 58. https://doi.org/10.1186/s12968-023-00958-5.

[157] Odak, M., & Kayani, W. T. (2023). MUGA Scan. In *StatPearls*. StatPearls Publishing. https://www.ncbi.nlm.nih.gov/books/NBK564365/.

D.31. Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	331
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.
Substantive Change:	**Updated the instructions: Revised:** This measure is to be submitted once for each occurrence of acute viral sinusitis (AVS) during the performance period. Each unique occurrence starts with the onset of AVS symptoms and concludes with the resolution of AVS symptoms or after 90 days if a resolution of AVS symptoms is not documented. If multiple encounters are documented within an occurrence, Merit-based Incentive Payment System (MIPS) eligible clinicians should submit the most recent encounter during that occurrence. A new occurrence of AVS cannot start until the previous occurrence during the performance period has concluded.
Measure Steward:	American Academy of Otolaryngology – Head and Neck Surgery Foundation
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to update the measure instructions to clarify what constitutes an occurrence for the purposes of this measure. This additional guidance would further clarify how patients are attributed to the denominator of this measure for each eligible occurrence. This change would ensure consistency in the abstraction of the measure's elements that support rigorous data for the calculation of MIPS performance rates.

D.32. Maternity Care: Postpartum Follow-up and Care Coordination

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	336
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.
Substantive Change:	**The measure description is revised to read:** Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breastfeeding evaluation and education, postpartum depression screening, intimate partner violence screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update. **Updated numerator: Added:** intimate partner violence screening. **Updated numerator definition: Added:** Intimate Partner Violence Screening – Patients who were screened for intimate partner violence before or at 12 weeks postpartum. Questions may be asked either directly by a health care provider or in the form of self-completed paper-or computer-administered questionnaires, and results should be documented in the medical record. Intimate partner violence screening should include a self-reported validated intimate partner violence screening tool (e.g., Abuse Assessment Screen (AAS), Extended – Hurt, Insult, Threaten, Scream (E-HITS), Humiliation, Afraid, Rape, Kick (HARK)). **Updated numerator instructions: Added:** intimate partner violence screening.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to update multiple measure components to include intimate partner violence screening. "The effects of intimate partner violence (IPV) on maternal and neonatal outcomes are multifaceted and largely preventable."[158] This type of abuse has maternal and neonatal consequences on mental and physical health that could be far reaching beyond the perinatal period;[159] therefore, intimate partner violence screening is being proposed for inclusion. This revision would support clinicians currently screening and would encourage others to begin screening for this risk within this patient population as IPV may escalate during the postpartum period.[160] The American College of Obstetricians and Gynecologists recommend including screening for IPV at the postpartum checkup to help identify patients experiencing IPV so that support may be offered to break this cycle, leading to positive outcomes for both maternal and neonatal health.[161]

[158] Alhusen, J. L., Ray, E., Sharps, P., & Bullock, L. (2015). Intimate Partner Violence During Pregnancy: Maternal and Neonatal Outcomes. *Journal of Women's Health (2002)*, *24*(1), 100–106. https://doi.org/10.1089/jwh.2014.4872.

[159] Chisholm, C. A., Bullock, L., & Ferguson, J. E. J., 2nd (2017). Intimate Partner Violence and Pregnancy: Epidemiology and Impact. *American Journal of Obstetrics and Gynecology*, *217*(2), 141–144. https://doi.org/10.1016/j.ajog.2017.05.042.

[160] American College of Obstetricians and Gynecologists (ACOG). (2012). Committee on Health Care for Underserved Women Opinion: Intimate Partner Violence. https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2012/02/intimate-partner-violence.pdf.

[161] See footnote ACOG, 2012.

D.33. HIV Medical Visit Frequency

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	340
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.
Substantive Change:	**Modified collection type:** eCQM Specifications, MIPS CQM Specifications collection type. **The measure title is revised from "HIV Medical Visit Frequency" to:** HIV Annual Retention in Care. **The measure description is revised to read:** Percentage of patients, regardless of age, with a diagnosis of Human Immunodeficiency Virus (HIV) before or during the first 240 days of the performance period who had at least two eligible encounters or at least one eligible encounter and one HIV viral load test that were at least 90 days apart within the measurement period. **The measure denominator is revised to read:** Patients, regardless of age, with a diagnosis of HIV before or during the first 240 days of the performance period who had at least one eligible encounter during the first 240 days of the performance period. **The measure denominator note is revised to read:** Only patients with an eligible encounter in the first 240 days are included in this measure to allow for sufficient time to complete a second eligible encounter or viral load laboratory at least 90 days after the initial encounter during the performance period. **Updated denominator criteria: Added:** coding for telephone and home visit patient encounters. **Updated denominator exclusion: Removed:** Patient died at any time during the 24-month measurement period. **The measure numerator is revised to read**: Number of patients who had at least one eligible encounter and one HIV viral load test at least 90 days apart during the performance period, or who had at least two eligible encounters at least 90 days apart during the performance period. **Updated numerator note: Added:** A patient would be included in the measure numerator if they have either 1) two eligible encounters at least 90 days apart, or 2) one eligible encounter and one viral load test at least 90 days apart from each other. The encounter or encounters that cause a patient to be included in the numerator do not need to include the encounter that caused the patient to be included in the denominator. **The measure numerator options are revised to read:** **Performance Met:** Patient had two eligible encounters at least 90 days apart or one eligible encounter and one HIV viral load test at least 90 days apart **Performance Not Met:** Patient did not have two eligible encounters at least 90 days apart or one eligible encounter and one HIV viral load test at least 90 days apart
Measure Steward:	Health Resources and Services Administration
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to update the collection types available for this measure to include the eCQM Specifications collection type to allow choice in submission method. We are also proposing to revise multiple components of the measure allowing for improved quality outcome which is to engage persons who are infected with HIV in regular HIV care that promote test-and-treat strategies.[162] In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark would be used for scoring.

D.34. Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A

[162] Gardner, E. M., McLees, M. P., Steiner, J. F., Del Rio, C., & Burman, W. J. (2011). The Spectrum of Engagement in HIV Care and its Relevance to Test-and-treat Strategies for Prevention of HIV Infection. *Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America*, *52*(6), 793–800. https://doi.org/10.1093/cid/ciq243.

Category	Description
Quality #:	344
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.
Substantive Change:	**The measure title is revised from Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) to:** Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) **The measure description is revised to read:** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) without major complication who are discharged to home no later than post-operative day #2. **Updated instructions: Added:** CEA. **Updated denominator: Added:** CEA. **Updated denominator criteria: Added:** coding for carotid endarterectomy. **Updated numerator: Added:** CEA. **Updated numerator definition: Added:** procedure for CEA or CAS. **Updated numerator options: Added:** CEA.
Measure Steward:	Society for Vascular Surgeons
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale	We are proposing to revise this measure to include Carotid Endarterectomy (CEA) to assess for post-operative complications for asymptomatic patients who had CEA. CEA for asymptomatic carotid stenosis reduces the risk of ipsilateral stroke, and any stroke, by approximately 30% over 3 years.[163] Previously, assessment of outcomes for CEA procedures was a separate measure. As both procedures are appropriate for treating asymptomatic carotid artery stenosis, these measures are being combined so that a full picture of positive outcomes can be captured for this patient population.[164] Additionally, by combining these measures the denominator eligible patient population may increase allowing for more robust data for participating MIPS clinicians. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark would be used for scoring.

[163] Chambers, B. R., & Donnan, G. A. (2005). Carotid Endarterectomy for Asymptomatic Carotid Stenosis. *The Cochrane Database of Systematic Reviews*, *2005*(4), CD001923. https://doi.org/10.1002/14651858.CD001923.pub2.

[164] Wang, J., Bai, X., Wang, T., Dmytriw, A. A., Patel, A. B., & Jiao, L. (2022). Carotid Stenting Versus Endarterectomy for Asymptomatic Carotid Artery Stenosis: A Systematic Review and Meta-Analysis. *Stroke*, *53*(10), 3047–3054. https://doi.org/10.1161/STROKEAHA.122.038994.

D.35. Unplanned Reoperation within the 30-Day Postoperative Period

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	355
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.
Substantive Change:	**Updated denominator criteria: Revised:** coding for fissurectomy, including sphincterotomy.
Measure Steward:	American College of Surgeons
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale	We are proposing to update denominator criteria to revise coding for fissurectomy, including sphincterotomy as this is an operative procedure that could have complications requiring unplanned reoperation within 30 days postoperatively.

D.36. Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	360
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study.
Substantive Change:	**The measure description is revised to read:** Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion or infarct avid imaging) reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion or infarct avid imaging) studies that the patient has received in the 12-month period prior to the current study. **The measure denominator is revised to read:** All final reports for patients, regardless of age, undergoing a CT or cardiac nuclear medicine (myocardial perfusion or infarct avid imaging) procedure. **Updated denominator criteria: Added:** coding for cardiology infarct imaging. **The measure numerator is revised to read:** CT and cardiac nuclear medicine (myocardial perfusion or infarct avid imaging) reports that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion or infarct avid imaging) studies that the patient has received in the 12-month period prior to the current study. **Updated numerator instructions: Added:** infarct avid imaging. **The measure numerator options are revised to read:** **Performance Met:** Count of previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion or infarct avid imaging) studies documented in the 12-month period prior to the current study. **Performance Not Met:** Count of previous CT and cardiac nuclear medicine (myocardial perfusion or infarct avid imaging) studies not documented in the 12-month period prior to the current study, reason not given.
Measure Steward:	American College of Radiology
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to revise multiple components of this measure to include infarct avid imaging in the cardiac nuclear medicine imaging study that involves the use of radiation, including a radiotracer or contrast agent and/or Imaging modalities, such as positron emission tomography (PET), single-photon emission computed tomography (SPECT), or magnetic resonance imaging (MRI).[165] Given that this imaging can expose a patient to potentially high doses of radiation,[166] including it in the denominator of this measure requires the clinician to document a more complete count of previous cardiac nuclear medicine imaging studies, increasing patient safety by preventing continued exposure to radiation.

[165] Enabnit, A. & Warren, A. (2023). Infarct Avid Imaging Study: Purpose, Procedure, and Applications. https://www.dovemed.com/health-topics/focused-health-topics/infarct-avid-imaging-study-purpose-procedure-and-applications.

[166] Salah, H., Alkhorayef, M., Jambi, L., Almuwannis, M., & Sulieman, A. (2023). Radiation Dose to Patients and Public Exposure in Cardiac Rest and Stress Single Photon Emission Computed Tomography Examinations. *Radiation Physics and Chemistry*. https://doi.org/10.1016/j.radphyschem.2023.111383.

D.37. Closing the Referral Loop: Receipt of Specialist Report

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	374
CMS eCQM ID:	CMS50v13
Current Collection Type:	eCQM Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.
Substantive Change:	**Updated denominator criteria: For all collection types: Added:** coding for psychology and neuropsychology. **The measure numerator definition is revised to read: For the MIPS CQM Specifications collection type: Revised:** A written document prepared by the eligible clinician (and staff) to whom the patient was referred and that accounts for their findings, provides summary of care information about findings, diagnostics, assessments and/or plans of care, or states the patient did not attend the appointment, and is provided to the referring eligible clinician.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to add psychology and neuropsychology encounter codes to the denominator criteria as this measure is applicable to their scope of care. This expansion of the denominator would allow more clinician types to submit the measure leading to an increase in denominator eligibility, capturing a more complete patient population, as it is clinically appropriate for these clinician types to complete the quality action for a patient referred to a specialist. We are proposing to revise the numerator definitions for the MIPS CQM Specifications collection type to clarify which information should be included in the referring clinician's report to successfully close the referral loop. This revision increases clarity of this element and ensures consistent implementation allowing for more comparable data.

D.38. Functional Status Assessment for Total Hip Replacement

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	376
CMS eCQM ID:	CMS56v13
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 19 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 300 – 425 days after the surgery.
Substantive Change:	**Updated initial patient population: Revised:** encounter timeframe from November of the year prior to August of the year prior.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to revise initial patient population by changing the timing of the encounter to better align with the post-surgical assessment timeframe of 300 to 425 days after the original THA surgery. This would also harmonize the timeframe of the patient encounter with the administrative claims measure "Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)" available for Hospital Inpatient Quality Reporting (88 FR 59067 through 59070), thereby aligning timing specificity and patterns across similar measures. Measure alignment, in accordance with clinical recommendations, guidelines, and best practices, allows for consistent and comparable data points, which leads to actionable data to drive quality care, through understanding where the gaps in care are within a patient population or along the continuum of care.

D.39. Adherence to Antipsychotic Medications For Individuals with Schizophrenia

Category	Description
CBE # / eCQM CBE #:	1879 / N/A
Quality #:	383
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.
Substantive Change:	**Updated denominator note: Removed:** distinction of typical versus atypical, 'days' supply' notation, and medication HCPCS codes. **Updated denominator criteria: Removed:** HCPCS coding from prescription criteria.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale	We are proposing to remove "days' supply" and HCPCS (J codes) from the list of antipsychotic medications in the measure. This revision would ensure inclusion for any duration of the listed long acting injectables permitting the clinician, or site, to obtain days' supply information from any appropriate clinical or administrative source, thus aligning the calculation of PDC with all appropriate medications listed in the measure. This revision reduces the burden of collecting this aspect of the measure from medical records. Decreasing complexity and burden of this element ensures consistent implementation allowing for more comparable data. Finally, we are proposing to remove "typical" and "atypical" as part of the subheadings of the lists of antipsychotic medications as this distinction does not apply to the list of oral and long-acting injectable antipsychotic medications listed under each of the categories which include both typical and atypical medications.[167]

[167] Cleveland Clinic. (2023). Antipsychotic Medications. https://my.clevelandclinic.org/health/treatments/24692-antipsychotic-medications.

D.40. Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	384
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.
Substantive Change:	**Updated instructions: Revised**: timeframe for when surgery for primary rhegmatogenous retinal detachment must have occurred to meet the denominator criteria. **Updated numerator note: Added:** For the purposes of meeting the numerator, complications are only those related to the following procedures: 67107, 67108, 67110.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale	We are proposing to update the instructions to clarify that surgery for primary rhegmatogenous retinal detachment must occur between January 1st and September 30th of the performance period to allow 90 days after the surgery to assess for the numerator action for patients who have surgeries performed by September 30th. We are also proposing to add a numerator note to clarify that the numerator is not required to capture only procedures covered by the three original procedure codes in the denominator, but rather any procedure that is related to complications arising from the original procedures listed.

D.41. Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	386
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, lawful physician-hastened death, or hospice) or whose existing end of life plan was reviewed or updated at least once annually or more frequency as clinically indicated (i.e., rapid progression)
Substantive Change:	**Updated denominator criteria: Added:** coding for speech language pathology.
Measure Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to update the denominator criteria to include coding for speech language pathology and nuclear medicine as this measure is applicable to their scope of care.

D.42. Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	393
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Infection rate following CIED device implantation, replacement, or revision.
Substantive Change:	**Updated instructions: Added:** A new device would be either the first device OR a device implanted with new functionality.
Measure Steward:	American College of Cardiology Foundation
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale	We are proposing to update the measure instructions to clarify the definition of a new device. This change would ensure alignment and consistency in the abstraction of the measure's elements that support rigorous data for the calculation of MIPS performance rates.

D.43. Door to Puncture Time for Endovascular Stroke Treatment

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	413
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of 90 minutes or less.
Substantive Change:	**Updated denominator exclusion: Added:** Patients with secondary stroke within 5 days of the initial procedure.
Measure Steward:	Society of Interventional Radiology
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale	We are proposing to add a denominator exclusion to remove patients with secondary stroke, such as those which may occur with vasospasm in the setting of subarachnoid hemorrhage. Treatment for an initial stroke is most effective when administered very shortly after the onset of symptoms.[168] However, the same is not the case for secondary stroke which is more challenging to manage as patients with secondary stroke may already be on "blood thinners or aspirin, medication to control cholesterol, or drugs to lower blood pressure" as a result of the initial stroke and "experience more severe and long-lasting disability."[169] This additional exclusion would more precisely reflect the time to reperfusion for obtaining favorable outcomes in cerebral revascularization within the target patient population.

[168] Esenwa, C., & Gutierrez, J. (2015). Secondary Stroke Prevention: Challenges and Solutions. *Vascular Health and Risk Management*, *11*, 437–450. https://doi.org/10.2147/VHRM.S63791.

[169] Medical News Today. (2023). Recurrent Strokes: What to Know. https://www.medicalnewstoday.com/articles/recurrent-strokes.

D.44. Osteoporosis Management in Women Who Had a Fracture

Category	Description
CBE # / eCQM CBE #:	0053 / N/A
Quality #:	418
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure Specifications / MIPS CQM Specifications
Current Measure Description:	The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.
Substantive Change:	**The measure description is revised to read: For all collection types:** The percentage of women 50-85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 180 days after the fracture. **Updated instructions: For all collection types: Revised:** from six months to 180 days. **Updated denominator exclusion: For all collection types: Removed:** specific encounter requirements from the frailty/advanced illness exclusion. **The measure numerator is revised to read: For all collection types:** Patients who received either a bone mineral density test or a prescription for a drug to treat osteoporosis in the 180 days after the fracture.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale	We are proposing to use both 6 months and 180 days within the measure denominator and numerator to allow for the appropriate time anchors. In the denominator, 6 months is used so that the measurement period to identify a fracture is always July 1 – June 30 (during the 6 months prior to the performance period through June 30 of the performance period). The numerator action of administration of a bone mineral density test or a prescription for a drug to treat osteoporosis within a specific number of days (180 days after the date of a fracture) rather than months with varying number of days (e.g., 28 – 31 days). We are proposing to update the denominator exclusion by removing the requirement for patients to have had at least one inpatient or two outpatient encounters to recognize a diagnosis of advanced illness. The removal of this requirement within the denominator exclusion reduces the burden of identifying applicable encounters, while still identifying patients with an indication of frailty. This is particularly applicable for those patients seen outside of their reporting clinician's medical record. This revision would update the denominator exclusion to remove any patient 66-80 years of age and older who has a diagnosis of advanced illness during the measurement period or the year prior from the denominator of measure Q418. Decreasing complexity and burden of this element ensures consistent implementation allowing for more comparable data.

D.45. Varicose Vein Treatment with Saphenous Ablation: Outcome Survey

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	420
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.
Substantive Change:	**Updated numerator definition: Added:** Varicose Veins Symptom Questionnaire (VVSymQ) and Venous Clinical Severity Score (VCSS).
Measure Steward:	Society of Interventional Radiology
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale	We are proposing to revise the definition of an 'Outcome Survey' to include the VVSymQ and VCSS. These outcome surveys measure improvement for saphenous vein ablation and would allow clinicians more choices for meeting the numerator, which may encourage further adoption of this measure.[170]

[170] Paty, J., Turner-Bowker, D. M., Elash, C. A., & Wright, D. (2016). The VVSymQ® Instrument: Use of a New Patient-Reported Outcome Measure for Assessment of Varicose Vein Symptoms. *Phlebology*, *31*(7), 481–488. https://doi.org/10.1177/0268355515595193.

D.46. Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	432
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the bladder recognized either during or within 30 days after surgery.

Substantive Change:	**The measure title is revised from Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair to:** Proportion of Patients Sustaining a Bladder or Bowel Injury at the time of any Pelvic Organ Prolapse Repair. **The measure description is revised to read:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bladder or bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery. **The measure instructions are revised to read:** This measure is to be submitted each time an anterior, posterior, or apical prolapse repair surgery is performed from December 1st of the previous performance period through November 30th of the current performance period. There is no diagnosis associated with this measure. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding. This measure will be calculated with 2 performance rates: 1) Percentage of patients undergoing prolapse repair who sustain a bladder injury that necessitates repair either intraoperatively or within 30 days after surgery. 2) Percentage of patients undergoing prolapse repair who sustain a bowel injury that necessitates repair either intraoperatively or within 30 days after surgery. Submission of the two performance rates is required for this measure. A simple average, which is the sum of the performance rates divided by the number of the performance rates will be used to calculate performance. THERE ARE TWO SUBMISSION CRITERIA FOR THIS MEASURE: 1) All patients undergoing anterior or apical pelvic organ prolapse (POP) surgery who sustain a bladder injury. 2) All patients undergoing anterior, posterior, or apical pelvic organ prolapse (POP) surgery who sustain a bowel injury. This measure contains two submission criteria which together ensure that the proper evaluation and treatment is provided for patients who undergo pelvic organ prolapse repair. Submission Criteria 1 evaluates whether patients sustained a bladder injury intraoperatively or within 30 days after surgery. Submission Criteria 2 evaluates whether patients sustained a bowel injury intraoperatively or within 30 days after surgery. Patients who undergo a procedure that meets the denominator of both submission criteria should be included in both and assessed for each clinical outcome. **Updated denominator: Added:** SUBMISSION CRITERIA 2: All patients undergoing anterior, posterior, or apical pelvic organ prolapse (POP) surgery. **Updated denominator criteria: Added:** SUBMISSION CRITERIA 2: All patients, regardless of age AND Patient procedure during the denominator identification period WITHOUT Telehealth Modifier **Updated definition: Added:** SUBMISSION CRITERIA 1 & 2: Denominator identification period – the twelve month period in which eligible patients have a procedure, which December 1st of the previous performance period through November 30th of the current performance period. **Updated numerator:** **Revised:** SUBMISSION CRITERIA 1: Percentage of patients undergoing prolapse repair who sustain a bladder injury that necessitates repair either intraoperatively or within 30 days after surgery. **Added:** SUBMISSION CRITERIA 2: Percentage of patients undergoing prolapse repair who sustain a bowel injury that necessitates repair either intraoperatively or within 30 days after surgery. Update numerator instructions: Added: SUBMISSION CRITERIA 2: INVERSE MEASURE – A lower calculated performance rate for this measure indicates better clinical care or control. The "Performance Not Met" numerator option for this measure is the representation of the better clinical quality or control. Submitting that numerator option will produce a performance rate that trends closer to 0%, as quality increases. For inverse measures, a rate of 100% means all of the denominator eligible patients did not receive the appropriate care or were not in proper control. **Updated numerator note: Added:** SUBMISSION CRITERIA 2: In order to meet the measure, bowel injury is sustained as a result of the prolapse surgery. **Updated numerator options: Added:** SUBMISSION CRITERIA 2: Performance Met: Patient sustained bowel injury at the time of surgery or discovered subsequently up to 30 days post-surgery OR

Category	Description
	Denominator Exception: Documented medical reasons for not reporting bowel injury (e.g. gynecologic or other pelvic malignancy documented, planned (e.g. not due to an unexpected bowel injury) resection and/or re-anastomosis of bowel, or patient death from non-medical causes not related to surgery, patient died during procedure without evidence of bowel injury) OR Performance Not Met:Patient did not sustain a bowel injury at the time of surgery nor discovered subsequently up to 30 days post-surgery
Measure Steward:	American Urogynecologic Society
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale	We are proposing to revise this measure to add a submission criteria and performance rate for patients who retain a bowel injury at the time of any pelvic organ prolapse repair. We are proposing to add submission criteria two to evaluate all patients undergoing anterior, posterior, or apical pelvic organ prolapse surgery who sustain a bowel injury. Previously, assessment of bowel injury outcomes for POP procedures was a separate measure. As both measures are assessing for adverse outcomes following POP procedures, these measures are being combined so that a full picture of adverse outcomes can be captured for this patient population. Additionally, by combining these measures, the denominator eligible patient population may increase allowing for more robust data for participating MIPS clinicians. We are also proposing to add a definition for the denominator identification period of December 1st of the previous performance period through November 30th of the current performance period. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark would be used for scoring.

D.47. Appropriate Workup Prior to Endometrial Ablation

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	448
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results are documented before undergoing an endometrial ablation.
Substantive Change:	**Updated the instructions: Revised:** submission of the measure to once per performance period.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to change the frequency of this measure from each time a procedure for endometrial ablation is performed to once per performance period, as this is more aligned with the clinical action being assessed for this measure.

D.48. Appropriate Treatment for Patients with Stage I (T1c) - III HER2 Positive Breast Cancer

Category	Description
CBE # / eCQM CBE #:	1858 / N/A
Quality #:	450
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of female patients aged 18 to 70 with stage I (T1c) - III HER2 positive breast cancer for whom appropriate treatment is initiated.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 18 to 70 with stage I (T1c) – III HER2 positive breast cancer for whom appropriate treatment is initiated. **The measure denominator is revised to read:** All breast cancer patients aged 18 to 70 with pathologic stage I (T1c) – III HER2 positive breast cancer diagnosed between July 1st of the previous performance period through June 30th of the current performance period. **Updated denominator instructions: Added:** For the purposes of this measure, only pathologic staging and HER-2 testing performed between July 1st of the previous performance period through June 30th of the current performance period will be included in the denominator of this measure. **Updated denominator note: Added:** This measure includes both female and male breast cancers. While treatment recommendations for males have largely been extrapolated from results of clinical trials focused on breast cancer in females, management of breast cancer in males is similar in overall management to breast cancer in females. Consistent with guidance in NCCN guideline recommendations for adjuvant systemic therapy, chemotherapy with/without HER2-targeted therapy should be recommended for males with breast cancer according to guidelines for females with breast cancer. **Updated denominator criteria: Revised:** Patients age 18-70 years on date of encounter **Added:** diagnosis codes for male breast cancer. **Added:** Diagnosis of breast cancer between July 1st of the previous performance period through June 30th of the current performance period. **Updated numerator note: Added:** The timeframe to identify the adjuvant treatment course is within six months of breast cancer pathologic staging. To satisfy the numerator, both chemotherapy and HER2-targeted therapy must occur within six months of pathologic staging.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to update multiple components of this measure to ensure that all patients diagnosed with breast cancer are included in the measure's denominator. While treatment recommendations for males have largely been extrapolated from results of clinical trials focused on breast cancer in females,[171] management of breast cancer in males is similar in overall management to breast cancer in females. Consistent with guidance in NCCN recommendations for adjuvant systemic therapy, chemotherapy with/without HER2-targeted therapy should be recommended for males with breast cancer according to guidelines for females with breast cancer.[172] Additionally, revisions to the denominator definition would clarify the timeframe in which pathologic staging and HER-2 testing should be performed for patient to be included in the denominator. We are also proposing revisions to the numerator note to further clarify definition of and timeframe for when adjuvant treatment, for the purposes of this measure, should occur relative to pathologic staging.

[171] Hassett, M. J., Somerfield, M. R., & Giordano, S. H. (2020). Management of Male Breast Cancer: ASCO Guideline Summary. *JCO Oncology Practice*, *16*(8), e839–e843. https://doi.org/10.1200/JOP.19.00792.

[172] Gradishar, W. J., Moran, M. S., Abraham, J., Abramson, V., Aft, R., Agnese, D., Allison, K. H., Anderson, B., Burstein, H. J., Chew, H., Dang, C., Elias, A. D., Giordano, S. H., Goetz, M. P., Goldstein, L. J., Hurvitz, S. A., Jankowitz, R. C., Javid, S. H., Krishnamurthy, J., Leitch, A. M., … Kumar, R. (2023). NCCN Guidelines® Insights: Breast Cancer, Version 4.2023. *Journal of the National Comprehensive Cancer Network: JNCCN*, *21*(6), 594–608. https://doi.org/10.6004/jnccn.2023.0031.

D.49. RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who Receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy

Category	Description
CBE # / eCQM CBE #:	1859 / N/A
Quality #:	451
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed.
Substantive Change:	**Updated denominator instructions: Added:** The denominator of this measure is intended to capture newly diagnosed stage IV patients or patients who have distant metastases at the time of colon cancer diagnosis. For the purposes of this measure, the patient's initial diagnosis may occur between December 1 of the prior year through November 30 of the performance period, and anti-EGFR monoclonal antibody therapy may occur between December 1 of the prior year through December 31 of the performance period.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	No
Measure Type:	Process
Rationale	We are proposing to add denominator instructions to clarify that only patients who have been newly diagnosed with Stage IV colorectal cancer or patients who have distant metastases at the time of colon cancer diagnosis are to be captured in the denominator of the measure. This would ensure that the appropriate patient population is assessed for the numerator action.

D.50. Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	462
CMS eCQM ID:	CMS645v8
Current Collection Type:	eCQM Specifications
Current Measure Description:	Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.
Substantive Change:	**The measure denominator is revised to read:** Patients with a qualifying encounter in the measurement period AND with a diagnosis of prostate cancer AND with an order for ADT or an active medication of ADT with an intent for treatment greater than or equal to 12 months during the measurement period AND order for ADT in 3 months before to 9 months after the start of the measurement period.
Measure Steward:	Oregon Urology Institute
High Priority Measure:	No
Measure Type:	Process
Rationale	We are proposing to expand the denominator to include all patients regardless of gender. This revision broadens the denominator population to capture all patients with a diagnosis of prostate cancer who are receiving androgen deprivation therapy and ensure a bone density evaluation is completed prior to the start of treatment. As significantly lower PSA screening rates were seen among transgender individuals for ages 40-54 and 55-69, but higher rates within the age group 70-80 (P.ß<.ß.001 for all),[173] broadening the denominator would ensure these patient populations are being screened in accordance with current clinical guidelines.

[173] Premo, H., Gordee, A., Lee, H. J., Scales, C. D., Moul, J. W., & Peterson, A. (2023). Disparities in Prostate Cancer Screening for Transgender Women: An Analysis of the MarketScan Database. *Urology*, *176*, 237–242. https://doi.org/10.1016/j.urology.2023.03.016.

D.51. Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use

Category	Description
CBE # / eCQM CBE #:	0657 / N/A
Quality #:	464
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.
Substantive Change:	**The measure instructions are revised to read:** This measure is to be submitted once for each occurrence of otitis media with effusion (OME) in children seen during the performance period. Each unique occurrence starts with the onset of OME symptoms and concludes with the resolution of OME or after 90 days if a resolution of OME symptoms is not documented. If multiple encounters are documented within an occurrence, Merit-based Incentive Payment System (MIPS) eligible clinicians should submit the most recent encounter during that occurrence. A new occurrence of OME cannot start until the previous occurrence during the performance period has concluded.
Measure Steward:	American Academy of Otolaryngology – Head and Neck Surgery Foundation
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to update the measure instructions to clarify what constitutes an occurrence for the purposes of this measure. This additional guidance would further clarify how patients are attributed to the denominator of this measure for each eligible occurrence. This change would ensure consistency in the abstraction of the measure's elements that support rigorous data for the calculation of MIPS performance rates.

D.52. Functional Status After Primary Total Knee Replacement

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	470
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) or a 71 or greater on the KOOS, JR. tool at one year (9 to 15 months) postoperatively.
Substantive Change:	**Updated numerator note: Revised:** list of situations that denote performance not met.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale	We are proposing to revise the numerator note by clarifying that if a tool other than the Oxford Knee Score (OKS) or Knee injury/Osteoarthritis Outcome Score Joint Replacement (KOOS, JR.) is used to assess a patient's functional status for this measure, it would result in a performance not met. The requirements for meeting this measure require use of the specific tools referenced in the measure specification, as they have been tested, validated, and determined to be most appropriate for capturing the numerator action.

D.53. Psoriasis – Improvement in Patient-Reported Itch Severity

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	485
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	The percentage of patients aged 8 years and older, with a diagnosis of psoriasis where at an initial (index) visit have a patient-reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 3 or more points at a follow-up visit.
Substantive Change:	**Updated denominator note: Added:** The initial (index) visit assessment and the follow-up visit for assessment must occur during the performance period. The initial (index) visit is the first encounter with the patient during the performance period. Every visit after the initial (index) visit during the performance period is a follow-up visit. An assessment should be completed at each visit. **Updated numerator instructions: Removed:** If a patient has multiple follow-up visits within the measurement period, the last (most recent) visit should be used.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Patient-reported Outcome-based Performance Measure
Rationale	We are proposing to update the denominator note to clarify encounter timing by including language outlining that a patient's first visit during the measurement period is considered the initial (index) encounter. Each visit after the initial (index) visit during the measurement period would be deemed a follow-up visit used to determine the outcome of the measure. This change would ensure consistency in the abstraction of the measure's elements that support rigorous data for the calculation of MIPS performance rates.

D.54. Dermatitis – Improvement in Patient-Reported Itch Severity

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	486
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	The percentage of patients aged 8 years and older, with a diagnosis of dermatitis where at an initial (index) visit have a patient-reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 3 or more points at a follow-up visit.
Substantive Change:	**Updated denominator note: Added:** The initial (index) assessment and the follow-up visit for assessment must occur during the performance period. The initial (index) visit is the first encounter with the patient during the performance period. Every visit after the initial (index) visit during the performance period is a follow-up visit. An assessment should be completed at each visit. **Updated numerator instructions: Removed**: If a patient has multiple follow-up visits within the measurement period, the last (most recent) visit should be used.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-based Performance Measure
Rationale	We are proposing to update the denominator note to clarify encounter timing by including language outlining that a patient's first visit during the measurement period is considered the initial (index) encounter. Each visit after the initial (index) visit during the measurement period would be deemed a follow-up visit used to determine the outcome of the measure. This change would ensure consistency in the abstraction of the measure's elements that support rigorous data for the calculation of MIPS performance rates.

D.55. Kidney Health Evaluation

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	488
CMS eCQM ID:	CMS951v3
Current Collection Type:	eCQM Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period
Substantive Change:	**Updated description: For all collection types: Revised:** patients aged 18-85 years. **Updated denominator: For all collection types: Revised:** patients aged 18-85 years. **Updated denominator criteria: For the MIPS CQM Specifications collection type: Revised:** patients aged 18-85 years.
Measure Steward:	National Kidney Foundation
High Priority Measure:	No
Measure Type:	Process
Rationale	We are proposing to update the age from 18-75 to 18-85 years of age for denominator eligibility. Based on information from National Institutes of Health states, "A high proportion of older CKD patients are usually affected by multimorbidity, polypharmacy, frailty, functional and cognitive impairment, and disability."[174] "The benefits of preventing/slowing the progression of CKD has the potential to impact different social and health domains, for example, reducing the need for long-term care and the cost related to caregiving."[175] Increasing the denominator age criteria support the reporting of clinicians currently screening a broader elderly population for this preventable disease.

[174] Corsonello, A., Freiberger, E., & Lattanzio, F. (2020). The Screening for Chronic Kidney Disease Among Older People across Europe (SCOPE) Project: Findings from Cross-Sectional Analysis. *BMC Geriatrics*, *20*(Suppl 1), 316. https://doi.org/10.1186/s12877-020-01701-w.

[175] See footnote Corsonello et al., 2020.

D.56. Appropriate Intervention of Immune-Related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	490
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients, aged 18 years and older, with a diagnosis of cancer, on immune checkpoint inhibitor therapy, and grade 2 or above diarrhea and/or grade 2 or above colitis, who have immune checkpoint inhibitor therapy held and corticosteroids or immunosuppressants prescribed or administered.
Substantive Change:	**Updated denominator definition: For the MIPS CQM Specifications collection type: Added:** immune checkpoint inhibitors Lag-3 inhibitor drug: Relatlimab; and Tremelimumab to CTLA-4 inhibitor drugs.
Measure Steward:	Society for Immunotherapy of Cancer (SITC)
High Priority Measure:	No
Measure Type:	Process
Rationale	We are proposing to update the denominator definition to add new Food and Drug Administration (FDA) approved checkpoint inhibitors, Relatlimab and Tremelimumab. These inhibitors are clinically appropriate to include in the denominator of this measure.[176] [177]

[176] FDA. (2022). FDA Approves Tremelimumab in Combination with Durvalumab and Platinum-based Chemotherapy for Metastatic Non-small Cell Lung Cancer. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-tremelimumab-combination-durvalumab-and-platinum-based-chemotherapy-metastatic-non.

[177] FDA. (2022). FDA Approves Opdualag for Unresectable or Metastatic Melanoma. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-opdualag-unresectable-or-metastatic-melanoma.

D.57. Risk-Standardized Acute Cardiovascular-Related Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	492
CMS eCQM ID:	N/A
Current Collection Type:	Administrative Claims
Current Measure Description:	Annual risk-standardized rate of acute, unplanned cardiovascular-related admissions among Medicare Fee-for-Service (FFS) patients aged 65 years and older with heart failure (HF) or cardiomyopathy.
Substantive Change:	**Updated: Reporting Requirements: Removed:** individual reporting.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale	We are proposing a substantive change to this measure that would be applied retroactively starting with the CY 2023 performance period/2025 MIPS payment year. In the CY 2023 PFS final rule, we inadvertently specified the measure was availability at the individual clinician level. The inclusion of the availability of the measure at the individual clinician level is a misrepresentation and erroneously conveys to MIPS eligible clinicians reporting at the individual clinician level that the measure is available to meet the minimum required number of measures to report under traditional MIPS or an MVP. The measure was tested and developed for implementation at the group, virtual group, subgroup via an MVP, and APM Entity levels. Thus, the measure is limited to groups, virtual groups, subgroups via an MVP, and APM Entities participating in MIPS. We believe that a failure to apply this substantive change retroactively would be contrary to the public interest. Prior to the finalization of this measure as a new measure available within the MIPS quality measure inventory in the CY 2023 PFS final rule, the measure was initially proposed as a new measure in the CY 2022 PFS proposed rule. Based on the public comments received in response to the initial proposal of this measure in the CY 2022 PFS proposed rule, there were concerns regarding the attribution of certain patients to clinicians, particularly the risk adjustment for clinicians with higher caseloads of patients with more complicated or severe heart failure. As a result, the measure was not finalized as part of the CY 2022 PFS final rule; however, we noted that we would continue to consider how to implement condition-specific measures such as this measure under MIPS (86 FR 65692 through 65694). In the CY 2023 PFS proposed rule, we re-proposed this measure, which mitigated the concerns regarding the attribution of such patients to clinicians by excluding patients at advanced stages of heart failure and requiring that a group, virtual group, subgroup via an MVP, and APM Entity to include at least 1 cardiologist (and a 21-patient case minimum); and subsequently, the measure was finalized in the CY 2023 PFS final rule (87 FR 70266) through 70271). The intent of the measure is for assessment of performance to be conducted at the group, virtual group, subgroup via an MVP, and APM Entity levels. The measure was not tested, developed, or implemented at the individual clinician level. In order for this measure to be available at the individual clinician level, the measure would need to be tested at the individual clinician level to establish validity, reliability, and risk adjustments at the individual clinician level. It is not appropriate for the measure to be available at the individual clinician level without further testing. Consequently, any assessment of data for this measure at the individual clinician level would produce invalid and unreliable results. By retroactively applying the substantive change to this measure (modifying the measure to remove the individual clinician level as an option) effective starting with the CY 2023 performance period/2025 MIPS payment year, the level of reporting available for the measure would align with the intent, implementation, and operationalization of the measure, and clarify that the measure is not available at the individual clinician level.

D.58. Adult Immunization Status

Category	Description
CBE # / eCQM CBE #:	3620 / N/A
Quality #:	493
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.
Substantive Change:	**Updated instructions: Revised:** pneumococcal vaccine on or after their 19th birthday. **Updated numerator: Revised:** Submission Criteria 4: pneumococcal vaccine on or after their 19th birthday.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale	We are proposing to update the measure instructions and numerator to lower the minimum age from 60 years of age to 19 years of age. This revision aligns with the updated ACIP pneumococcal vaccination guidelines[178] that recommend administering conjugate vaccines to all adults with certain underlying medical conditions. In the CY 2023 PFS final rule, this measure was finalized, and it was noted that the scoring of the measure would use a weighted average for the first 2 years of implementation; and starting with the CY 2025 performance period/2027 MIPS payment year, the measure would be scored as an all-or-none composite measure to ensure a more thorough assessment of a patient's vaccination status (87 FR 70272 through 70274). However, based upon an analysis of preliminary data submitted for the CY 2023 performance period, low measure adoption, and feedback received through Quality Payment Program Service Now tickets regarding burden of implementation and ability to meet performance on all four components, we are proposing to maintain the weighted average analytic for the CY 2025 performance period and subsequent years as determined by CMS. The utilization of the weighted average metric/analytic beyond 2 years would provide clinicians with more time to prepare for the transition to a more stringent all-or-none metric/analytic, which would require a complete vaccination history to meet numerator compliance.

[178] Kobayashi, M., Pilishvili, T., Farrar, J. L., Leidner, A. J., Gierke, R., Prasad, N., Moro, P., Campos-Outcalt, D., Morgan, R. L., Long, S. S., Poehling, K. A., & Cohen, A. L. (2023). Pneumococcal Vaccine for Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices, United States, 2023. *MMWR. Recommendations and Reports: Morbidity and Mortality Weekly Report. Recommendations and Reports*, *72*(3), 1–39. https://doi.org/10.15585/mmwr.rr7203a1.

D.59. Preventive Care and Wellness (composite)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	497
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).
Substantive Change:	**Updated instructions: Updated:** Percentage of patients 65 years of age or older who received a pneumococcal vaccination on or after their 19th birthday. **Updated denominator exclusion: Removed:** (Submission Criteria 3 and Submission Criteria 4): specific encounter requirements from the frailty/advanced illness exclusion. **Updated denominator criteria: Added:** (Submission Criteria 7) coding for nutrition/dietitian clinician type. **Updated numerator definition: Revised:** intervals for rescreening for first and second hypertensive BP readings.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale	We are proposing to update the measure instructions for patients 65 years of age and older who have received a pneumococcal vaccination on or after their 19th birthday. This update would allow for the identification of patients 65 years of age and older who may have a clinical condition that would make them a candidate to receive the pneumococcal vaccine prior to 65 years of age.[179] We are proposing to add encounter codes for nutrition therapy to the denominator criteria as this is an appropriate setting to identify people who may have elevated blood pressure (BP) readings. Nutritional approaches play a pivotal role in helping to reduce the risk of hypertension or control blood pressure in people with hypertension.[180] We are proposing to remove the minimum timeframe for follow-up screenings for patients with elevated BP readings. This change allows clinician discretion to recommend a follow-up plan based on the patient's current health status. Additionally, this supports stability of this measure component, as the frequency is each visit, within the specification over time, while still maintaining consistency with the current guidelines.[181] We are proposing to update the denominator exclusion by removing the requirement for patients to have had at least one inpatient or two outpatient encounters to recognize a diagnosis of advanced illness. The removal of this requirement within the denominator exclusion reduces the burden of identifying applicable encounters, while still identifying patients with an indication of frailty. This is particularly applicable for those patients seen outside of their reporting clinician's medical record. This revision would update the denominator exclusion to remove any patient 66 years of age and older who has a diagnosis of advanced illness during the measurement period or the year prior from the denominator for submission criteria 3 and submission criteria 4 of measure Q497.

[179] See footnote Kobayashi et al., 2023 in Table D.58 of this Appendix.

[180] See footnote Physicians Committee for Responsible Medicine, 2023 in Table D.28 of this Appendix.

[181] See footnote Whelton et. al., 2018 in Table D.28 of this Appendix.

D.60. Connection to Community Service Provider

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	498
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.
Substantive Change:	**Updated denominator criteria: Added:** coding for Dentistry, Emergency Medicine, Inpatient, Nuclear Medicine, Interventional Radiology, Psychiatry, Mental and Behavioral Health, Nephrology, Nutrition, Dietician, Obstetrics/Gynecology, Ophthalmology, Otolaryngology, Physical Therapy/Occupational Therapy, Home Care and Skilled Nursing.
Measure Steward:	OCHIN
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to update the denominator criteria to include coding for multiple patient services as this measure is applicable to the scope of care associated with these services. Clinicians treating patients within these services have an opportunity for screening for HRSNs and connecting with an appropriate CSP. Addressing the social determinants is an important and emerging area of practice that entails starting earlier and broadening the scope of interventions, thus making entire families and communities healthier.[182]

[182] Andermann, A., & CLEAR Collaboration (2016). Taking Action on the Social Determinants of Health in Clinical Practice: A Framework for Health Professionals. *CMAJ: Canadian Medical Association Journal*, *188*(17-18), E474–E483. https://doi.org/10.1503/cmaj.160177.

D.61. Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	500
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 8 weeks.
Substantive Change:	**Updated denominator criteria: Added:** acute PVD. **Removed:** coding for non-acute disorders related to PVD.
Measure Steward:	American Society of Retina Specialists
High Priority Measure:	No
Measure Type:	Process
Rationale	We are proposing to revise the denominator criteria by removing diagnosis codes for non-acute PVD and adding acute PVD within the criteria of the denominator. The ICD-10-CM PVD diagnosis codes do not differentiate between acute and non-acute disorders of vitreous detachment; therefore, to ensure the intended patient population is identified, the denominator criteria must be specific to acute PVD.

D.62. Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	501
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) and acute vitreous hemorrhage in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 2 weeks
Substantive Change:	**Updated denominator criteria: Removed:** coding for non-acute disorders related to PVD.
Measure Steward:	American Society of Retina Specialists
High Priority Measure:	No
Measure Type:	Process
Rationale	We are proposing to revise the denominator criteria by removing diagnosis codes for non-acute PVD and adding acute PVD within the criteria of the denominator. The ICD-10-CM PVD diagnosis codes do not differentiate between acute and non-acute disorders of vitreous detachment; therefore, to ensure the intended patient population is identified, the denominator criteria must be specific to acute PVD.

D.63. Gains in Patient Activation Measure (PAM®) Scores at 12 Months

Category	Description
CBE # / eCQM CBE #:	2483 / N/A
Quality #:	503
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	The Patient Activation Measure® (PAM®) is a 10- or 13- item questionnaire that assesses an individual's knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.
Substantive Change:	**Updated instructions: Revised:** follow-up PAM® survey collected on at least 25% of all eligible patients within 4 to 12 months of the baseline during the performance period. **The measure denominator is revised to read:** **For Submission Criteria 1:** Patients aged 14 years and older with at least two qualifying visits during the performance period. **For Submission Criteria 2, 3 & 4:** Patients aged 14 years and older with Performance Met for Submission Criteria 1 who had a baseline PAM® score and a second score within 4 to 12 month of baseline PAM® score and who were seen for a qualifying visit at least twice during the performance period. **Updated denominator criteria: Revised:** For Submission Criteria 2, 3, & 4: follow-up PAM® survey collected on at least 25% of all eligible patients within 4 to 12 months of the baseline during the performance period. **Updated denominator exception: Revised:** For Submission Criteria 1: to remove patients with excessive missing responses or patients who were not seen for the second PAM survey within 4 months of the baseline. **Updated denominator exclusion: Added:** For ALL Submission Criteria: Patients who died during the performance period. **Updated numerator: Revised:** for ALL Submission Criteria: timing of follow-up PAM® survey to occur 4 to 12 months after baseline. **Updated numerator definition: Added**: For Submission Criteria 1: clarification as to what denotes excessive missing responses for each PAM survey.
Measure Steward:	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale	We are proposing to revise multiple components of this measure to allow re-administration of the PAM® survey no less than 4 months after the baseline survey is administered as opposed to 6 months. This change would allow a higher percentage of patients to complete the survey and be included in the measure denominator. In addition, we are proposing to lower the minimum performance threshold for collected follow-up PAM® surveys from 50 percent to 25 percent and remove patients who were missing more than 3 responses on the PAM-10® surveys or more than 4 responses on the PAM-13® surveys. Revising the threshold for the collected follow-up PAM® survey reduces clinician burden by lowering the number of survey responses that need to be collected to meet the measure denominator. We are also proposing to add a definition to clarify what denotes excessive for missing responses. Removing patients with excessive missing responses allows for a more complete assessment of an individual's knowledge, skills, and confidence for managing their health and health care. We are also proposing to increase the number of qualifying visits to two during the performance period and add an exclusion to remove patients who may have died during the performance period. These revisions to the denominator ensure a patient is established within that clinician's patient population which supports the completion of the baseline and follow-up of the survey.

D.64. Initiation, Review, and/or Update to Suicide Safety Plan for Individuals with Suicidal Thoughts, Behavior, or Suicide Risk

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	504
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 12 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician. **The measure denominator is revised to read:** For denominator submission criteria 1 & 2: Patients aged 12 years and older with a mental and/or substance use disorder with suicidal ideation and/or behavior symptoms or suicide risk at a clinical encounter during the denominator identification period.
Measure Steward:	American Psychiatric Association
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We are proposing to revise the age from 18 years and older to 12 years and older for denominator eligibility as suicide risk assessment is an important part of child and adolescent mental health. As noted in an American Academy of Pediatrics publication.[183] "Suicide is the second leading cause of death for 10- to 24-year-olds in the United States and is a global public health issue, with a recent declaration of a National State of Emergency in Children's Mental Health by the American Academy of Pediatrics, American Academy of Child and Adolescent Psychiatry, and Children's Hospital Association."[184]

[183] Hua, L. L., Lee, J., Rahmandar, M. H., Sigel, E. J., Committee on Adolescence, & Council on Injury, Violence, and Poison Prevention. (2024). Suicide and Suicide Risk in Adolescents. *Pediatrics*, *153*(1), e2023064800. https://doi.org/10.1542/peds.2023-064800.

[184] See footnote Hua et al., 2024.

Table Group DD: Proposed Substantive Changes to Previously Finalized MIPS Quality Measures Available Only for Use in Relevant MVPs for the CY 2025 Performance Period/2027 MIPS Payment Year and Future Years

As finalized for the CY 2024 performance period/2026 MIPS payment year and future years, the following three MIPS quality measures were retained for utilization in MVPs only while removed from traditional MIPS: Q112: Breast Cancer Screening, Q113: Colorectal Cancer Screening, and Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (88 FR 79897 through 79902). We note that some MIPS quality measures available only in MVPs are adopted by the Medicare Shared Savings Program for utilization in the Alternative Payment Model (APM) Performance Pathway (APP) and/or APP Plus, as proposed in section XX of this proposed rule. For such measures, the collection type applicable for purposes of the APP and/or APP Plus (Medicare CQM for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQM)) is also specified as a collection type available for such measures described in Table Group DD.

Table Group DD within this proposed rule provides substantive changes proposed for the CY 2025 performance period/2027 MIPS payment year for MIPS quality measures available only in a relevant MVP. Two of the aforementioned MIPS quality measures, Q112 and Q113, have proposed substantive changes under Table Group DD. The changes that are made to the denominator codes sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2025 may not be identified within this proposed rule due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2025 CPT and ICD-10 updates and assessment of these codes inclusion by the Measure Steward, these changes may be postponed until CY 2026. The 2025 Quality Measure Release Notes provide a comprehensive, detailed reference of exact codes changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types in the Quality Payment Program website at *https://qpp.cms.gov*.

Note: Electronic clinical quality measures (eCQMs) that are endorsed by a CBE are shown in Table DD of this Appendix as follows: CBE # / eCQM CBE #.

In addition to the proposed substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but they are important to communicate to interested parties. These changes align with the scope of the current coding; however, though not substantive in nature, these changes would expand or contract the measure's current eligible patient population. Therefore, please refer to the current year measure specification and the 2025 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes to ensure correct implementation.

The eCQM Technical Release Notes should also be carefully reviewed for revisions within the logic portion of the measure. In addition to the proposed substantive changes, there may be revisions within the logic that are not considered substantive in nature, however, it is important to review to ensure proper implementation of the measure. As not all systems and clinical workflows are the same, it is important to review these changes in the context of a specific system and/or clinical workflow.

We request comments on these substantive changes.

DD.1. Breast Cancer Screening

Category	Description
CBE # / eCQM CBE #:	2372 / N/A
Quality #:	112
CMS eCQM ID:	CMS125v13
Current Collection Type:	Medicare Part B Claims Measure Specifications / eCQM Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of women 40 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications, and Medicare CQM Specifications (collection type available only in the APP and/or APP Plus). **Updated denominator exclusion: For all collection types: Removed:** specific encounter requirements from the frailty/advanced illness exclusion.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale	We are proposing to update the denominator exclusion by removing the requirement for patients to have had at least one inpatient or two outpatient encounters to recognize a diagnosis of advanced illness. The removal of this requirement within the denominator exclusion reduces the burden of identifying applicable encounters, while still identifying patients with an indication of frailty. This is particularly applicable for those patients seen outside of their reporting clinician's medical record. This revision would update the denominator exclusion to remove any patient 66 years of age and older who has a diagnosis of advanced illness during the measurement period or the year prior from the denominator of measure Q112. Decreasing complexity and burden of this element ensures consistent implementation allowing for more comparable data.

DD.2. Colorectal Cancer Screening

Category	Description
CBE # / eCQM CBE #:	0034 / N/A
Quality #:	113
CMS eCQM ID:	CMS130v13
Current Collection Type:	Medicare Part B Claims Measure Specifications / eCQM Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of patients 45-75 years of age who had appropriate screening for colorectal cancer.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications, and Medicare CQM Specifications (collection type available only in the APP and/or APP Plus) **Updated denominator exclusion: For all collection types: Removed:** specific encounter requirements from the frailty/advanced illness exclusion.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale	We are proposing to update the denominator exclusion by removing the requirement for patients to have had at least one inpatient or two outpatient encounters to recognize a diagnosis of advanced illness. The removal of this requirement within the denominator exclusion reduces the burden of identifying applicable encounters, while still identifying patients with an indication of frailty. This is particularly applicable for those patients seen outside of their reporting clinician's medical record. This revision would update the denominator exclusion to remove any patient 66 years of age and older who has a diagnosis of advanced illness during the measurement period or the year prior from the denominator of measure Q113. Decreasing complexity and burden of this element ensures consistent implementation allowing for more comparable data.

APPENDIX 2: IMPROVEMENT ACTIVITIES

In this proposed rule, for the CY 2025 performance period/2027 MIPS payment year and future years, we are proposing to add **two** new improvement activities, modify **two** previously adopted improvement activities, and remove **eight** previously adopted improvement activities. These proposals are discussed in section IV.A.4.e.(3)(b)(iii) of this proposed rule and in more detail below. We request comment on our proposals.

TABLE A: New Improvement Activities for the CY 2025 Performance Period/2027 MIPS Payment Year and for Future Years

New Improvement Activity	
Proposed Activity ID:	**IA_PM_XX**
Proposed Subcategory:	Population Management
Proposed Activity Title:	Implementation of Protocols and Provision of Resources to Increase Lung Cancer Screening Uptake
Proposed Activity Description:	Establish a process or procedure to increase rates of lung cancer screening through one or more of the following interventions: • Implementation of protocols that support enhanced documentation methods to identify eligible patients for lung cancer screening. ++ Example: A practice could embed electronic health record (EHR) prompts to flag insufficient patient smoking history (for example, total pack-years) and increase practice awareness around patient eligibility for screening ++ Example: A practice could implement documentation processes or procedures (for example, retrospective chart review, lung cancer screening eligibility questionnaire) to improve patient lung cancer screening eligibility data in the medical record • Development of a patient outreach and activation plan consisting of educational materials and resources for patients at high-risk of lung cancer for improved patient engagement and decision-making. ++ Example: Providers or clinic staff could provide culturally and linguistically appropriate patient-directed educational or care navigation materials related to lung cancer screening, eligibility criteria for low-dose computed tomography (LDCT), and the purpose and benefits of screening ++ Example: Providers or clinic staff could provide tools to prepare patients for shared decision-making (SDM) clinical encounters and promote patient/provider communication on lung cancer screening decision-making • Establishment of a navigation program to improve uptake and adherence of lung cancer screening and increase rates of LDCT referral completion. ++ Example: A practice could designate and train existing clinic staff or hire an additional staff member to counsel patients on the importance of lung cancer screening and refer them to existing resources (for example, transportation assistance, translator, financial services, appointment scheduling) to support ability to obtain LDCT ++ Example: A practice could create a process to follow up with referred patients via telephone reminders or virtual notifications (for example, email, patient charts)
Rationale:	Lung cancer is a leading cause of cancer-related deaths (21%) in the U.S., more than colon and breast cancers combined.[1,2] While there are established guidelines for the targeted use of LDCT for eligible patients, including particular criteria for age and smoking history[3,4], national lung cancer screening (LCS) rates are estimated at only 6.5% as of 2020, compared to 63% for colon and 64% for breast cancer screening in 2019.[5,6] Evidence demonstrates that screening for lung cancer can improve patient outcomes. The implementation of protocols that support enhanced documentation methods to identify

eligible patients for LCS has been found to increase early-stage lung cancer detection, in one study by 24 percent (Russel et al., 2022).[7] Other studies have also shown benefits from enhancing documentation to allow for more appropriate LCS:

- Following a retrospective chart review of existing patient smoking history and implementation of a notification system for primary care providers (PCPs), a community hospital identified 82 percent of patients who were eligible for LCS not yet referred for screening, and of that, 31 percent completed an LDCT referral.[8]
- Implementation of a clinical reminder system in an EHR to refer eligible patients to an LCS program, increased the number of LDCTs performed from 54 percent to 79 percent in one Veterans Affairs (VA) medical center.[9]
- EHR prompts generating a notification for providers to order LDCT screening for eligible patients, increased documentation of complete patient smoking history by 31 percent.[10]
- Updating patient pack-year data in the EHR through a patient questionnaire on smoking history and implementation of an EHR screen assessing pack-year data in alignment with evidence-based guidelines; development of a patient outreach and activation plan consisting of educational materials and resources for patients at high-risk of lung cancer for improved patient engagement and decision-making: among patients from a tobacco quit-line utilizing a video-based LCS decision aid, 50 percent reported feeling well-prepared to make screening decisions than with traditional materials and 68 percent reported being clear about their values related to the harms and benefits of screening. Additionally, patients using the decision-aid were more knowledgeable about LCS than participants using standard educational materials at each follow-up assessment.[11]
- A web-based tool developed for SDM led to improved patient engagement, knowledge of LDCT, and preparation for SDM discussions among veterans in a primary care setting.[12]
- A computer tailored decision-support tool developed in alignment with the U.S. Preventive Services Task Force (USPSTF) LCS guidelines, increased LCS knowledge scores (2.33 mean change) and patient-perceived self-efficacy and benefits of LCS in a community-based clinic.[13]

Evidence also demonstrates the outcomes-improvement potential of the establishment of a navigation program to improve uptake and adherence of LCS and to increase rates of LDCT referral completion:

- In a patient navigator-led program including patient outreach to determine LCS eligibility, SDM discussions, and appointment-scheduling with patient's PCPs, 23.5 percent of LDCTs were performed in the intervention group compared to 8.6 percent in the control group among high-risk current smokers across 5 community health centers.[14]
- An oncology nurse navigator-led provider education program resulted in improved provider knowledge of LDCT and documented tobacco cessation discussions, as well as increased LDCT ordering for eligible patients.[15]
- A nurse-practitioner-led LCS clinic observed a 60 percent increase in the total number of LDCTs conducted and 85 percent of stakeholder participants noted the clinic was effective at addressing barriers to LCS.[16]

Exemplifying the importance of efforts seeking to increase LCS and follow up, guidelines and recommendations on expanded LCS eligibility criteria and SDM requirements by the Centers for Medicare & Medicaid Services (CMS) have recently been implemented:

- In 2021, leading LCS clinical guideline developers, including USPSTF and the AAFP lowered the starting age of LCS with LDCT from 55 to 50 years and patient pack-year history from 30 to 20 years, resulting in a larger eligible screening population.[17,3]
- In 2022, under the Medicare National Coverage Determination, CMS expanded LCS eligibility criteria for age and pack-year history for beneficiaries receiving LDCT in alignment with clinical guidelines (for example, USPSTF, AAFP).

	• In addition to the expanded eligibility criteria, CMS requires a counseling and SDM visit to be appropriately documented in a patient's medical record and be inclusive of determination of beneficiary eligibility and the use of one or more decision-aids.[18] There is also published evidence that cost-effectiveness of care can improve as a result of expanded eligibility screening. Research has found downstream effects linked to early detection and prevention in LCS to be associated with long-term cost-effectiveness in LCS care delivery: • In 2021, the USPSTF expanded screening recommendations to include individuals at an earlier age of 50 from 55 years, and minimum cumulative smoking exposure from 30 to 20 pack-years. An economic evaluation of this guideline change indicated that the updated recommendations were cost effective compared to the earlier recommendations, with a mean incremental cost-effectiveness ratio of $72,564 per quality-adjusted life-year (QALY) gained.[19] • One study demonstrates the cost-savings of earlier diagnosis of lung cancer. In a review of patients with non-small cell lung cancer (NSCLC), it was revealed that the total per-patient per-month health care costs after diagnosis were significantly higher among those diagnosed at a Stage IV and lower among those diagnosed at Stage I ($7,239 Stage I, $9,484 Stage II, $11,193 Stage IIIa, $17,415 Stage IIIb, and $21,441 Stage IV).[20] • One modeling study of costs and outcomes associated with lung cancer found that implementation of a patient navigation program is cost-effective for lung cancer patients in Medicare, including that the program was cost-effective at a probability of 0.91 at $100,000/QALY.[21] • Given the significant impact of lung cancer in the U.S.--and the effectiveness of LCS and related interventions--as noted above, this activity has a high likelihood of making a positive impact on outcomes for eligible clinicians' patients.
New Improvement Activity	
Proposed Activity ID:	**IA_PM_XX**
Proposed Subcategory:	Population Management
Proposed Activity Title:	Save a Million Hearts: Standardization of Approach to Screening and Treatment for Cardiovascular Disease Risk
Proposed Activity Description:	Implement standardized, evidence-based cardiovascular disease risk assessment and care management for a defined population in the clinician's practice. The clinician or clinician group will apply standardized risk assessment and care management to a broad, clinician-defined patient population in the practice. The population can be defined by 1) patient age and/or atherosclerotic cardiovascular disease (ASCVD) risk factors; or 2) the constraints of the risk assessment tool (for example, the American College of Cardiology (ACC)/American Heart Association (AHA) ASCVD Risk Calculator is validated for patients over age 40). The results of screening and the plan for treatment and follow up will be documented using a standardized method in the patient's medical record. Care management plan and follow up intervals will be influenced by the degree of patient risk. Cardiovascular care management should be defined by risk assessment and lead to the development of individualized care plans with specific goals. Shared decision making should be part of the development of every patient care plan.
Rationale:	Heart disease is the leading cause of death in the United States. Stroke is the fifth most common cause of death in the United States.[22]This activity is informed by the results of the CMS Innovation Center Million Hearts Model, which included initial ASCVD assessment as well as cardiovascular care management. [23] The Million Hearts Model used the ACC/AHA ASCVD Risk Calculator: ASCVD Risk Estimator (acc.org). [24]

	The proposed new activity supports improved identification and treatment of patients at risk for ASCVD, and would expand on the work of the model in two ways: (1) increasing flexibility in requirements, allowing more clinician specialties to participate, along with increased flexibility in risk assessment to fit the needs of attesting clinicians and their patient populations; (2) requiring the use of structured documentation of risk factors and associated treatment plans with the aim of addressing all risk factors directly. This activity accommodates the use of any evidence-based approach to risk evaluation and patient care management that is implemented using standardized methods and across an entire patient population. The ASCVD Risk Estimator used by the Million Hearts Model is evidence based and simple to implement but may not be appropriate for every practice scenario or patient population. There is strong published evidence validating the ACC/AHA ASCVD Risk Calculator; describing optimal care for coronary artery disease (including making comparisons to European Union best practices); and providing guidelines for primary prevention of coronary artery disease.[25,26,27,28]

[1] American Cancer Society. (2021) Can Lung Cancer Be Found Early?, https://www.cancer.org/cancer/lung-cancer/detection-diagnosis-staging/detection.html.

[2] NIH National Cancer Institute. Cancer Stat Facts: Lung and Bronchus Cancer. (2022). https://seer.cancer.gov/statfacts/html/lungb.html.

[3] American Academy of Family Physicians (AAFP). AAFP Updates Recommendation on Lung Cancer Screening. (2021). https://www.aafp.org/news/health-of-the-public/20210406lungcancer.html.

[4] National Comprehensive Cancer Network. NCCN Guidelines for Patients. (2020) Lung Cancer Screening. https://www.nccn.org/patients/guidelines/content/PDF/lung_screening-patient.pdf.

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[6] National Cancer Institute (2023). Lung Cancer Screening. *https://progressreport.cancer.gov/detection/lung_cancer*; accessed May 2023, last updated March 2024.

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TABLE B: Changes to Previously Adopted Improvement Activities for the CY 2025 Performance Period/2027 MIPS Payment Year and for Future Years

In this proposed rule, we are proposing to modify **two** previously finalized improvement activities for the CY 2025 performance period/2027 MIPS payment year and future years. These proposals are discussed in section IV.A.4.e.(3)(b)(iii) of this proposed rule and in more detail below.

Current Improvement Activity	
Current Activity ID:	**IA_ERP_6**
Current Subcategory:	Emergency Response & Preparedness
Current Activity Title:	COVID-19 Vaccine Achievement for Practice Staff
Current Activity Description:	Demonstrate that the MIPS eligible clinician's practice has maintained or achieved a rate of 100 percent of office staff staying up to date with COVID vaccines according to the Centers for Disease Control and Prevention.[29] Please note that those who are determined to have a medical contraindication specified by CDC recommendations are excluded from this activity.
Current Weighting:	Medium
Proposed Activity ID:	**IA_PM_XX**
Proposed Subcategory:	Population Management
Proposed Revised Activity Title:	Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B
Proposed Revised Activity Description:	Demonstrate that the MIPS eligible clinician's practice has achieved and/or maintained a vaccination rate of 60 percent of clinical practice staff for COVID-19, and 80 percent for influenza. Demonstrate vaccination, immunity, or non-responder status to hepatitis B for 95 percent of clinical practice staff. Vaccination recommendations are from Centers for Disease Control and Prevention; staff with contraindications to the vaccinations, as determined by the CDC, are excluded from the requirements. Vaccines and Immunizations | CDC.
Proposed Change and Rationale:	Adjusting the target goals for this activity would align with the latest CDC recommendations and feedback received indicates that the proposal could increase the activity's utilization. Additionally, we are expanding the focus of this activity to include influenza and hepatitis B to highlight the importance of staff vaccination for vaccine-preventable diseases prevalent today. We are also proposing a change in this activity's subcategory, from Emergency Response & Preparedness to Population Management, to emphasize that staff vaccination is a long-term strategy in reducing morbidity and mortality rates for these diseases.
Current Improvement Activity	
Current Activity ID:	**IA_BE_4**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Engagement of patients through implementation of improvements in patient portal
Current Activity Description:	To receive credit for this activity, MIPS eligible clinicians must provide access to an enhanced patient/caregiver portal that allows users (patients or caregivers and their clinicians) to engage in bidirectional information exchange. The primary use of this portal should be clinical and not administrative. Examples of the use of such a portal include but are not limited to: brief patient reevaluation by messaging; communication about test results and follow up; communication about medication adherence, side effects, and refills; blood pressure management for a patient with hypertension; blood sugar management for a patient with diabetes; or any relevant acute or chronic disease management.
Current Weighting:	Medium
Proposed Activity ID:	**IA_BE_4**

Proposed Subcategory:	Beneficiary Engagement
Proposed Revised Activity Title:	Engagement of Patients through Implementation of New Patient Portal
Proposed Revised Activity Description:	To receive credit for this activity, MIPS eligible clinicians must implement and provide access to a new patient/caregiver portal that allows users (patients or caregivers and their clinicians) to engage in bidirectional information exchange. The primary use of this portal should be clinical and not administrative. Examples of the use of such a portal include, but are not limited to, the following: brief patient reevaluation by messaging; communication about test results and follow up; communication about medication adherence, side effects, and refills; blood pressure management for a patient with hypertension; blood sugar management for a patient with diabetes; and/or any relevant acute or chronic disease management.
Proposed Change and Rationale:	We are proposing to modify this activity's description and its validation criteria to specify the implementation of a new patient/caregiver portal by clinicians who were not previously using a patient portal. This activity was originally created during a time of transition to EHRs to encourage electronic information exchange. It has become standard practice to use patient portals; therefore, the activity is likely no longer driving improvement among clinicians who have already implemented a patient portal. This activity has been highly utilized year over year and continues to be in the top ten activities reported. Limiting the activity to clinicians that implement new patient portals in practices that previously did not use them would refocus the measure on its original purpose and encourage clinicians who have previously implemented patient portals to report other improvement activities that may offer meaningful opportunities for improvement.

[29]Centers for Disease Control and Prevention (2024). Stay Up to Date with COVID-19 Vaccines. Last Updated April 25, 2024. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html

TABLE C: Improvement Activities Proposed for Removal for the CY 2025 Performance Period/20267MIPS Payment Year and for Future Years

In this proposed rule, we are proposing to remove **eight** previously finalized improvement activities beginning with the CY 2025 performance period/2027 MIPS payment year. These proposals are discussed in section IV.A.4.e.(3)(b)(iii) of this proposed rule and in more detail below; activity removal factors are discussed in the CY 2020 PFS final rule (84 FR 62568 through 63563).

Current Improvement Activity	
Current Activity ID:	**IA_EPA_1**
Current Subcategory:	Expanded Practice Access
Current Activity Title:	Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
Current Activity Description:	Provide 24/7 access to MIPS eligible clinicians, groups, or care teams for advice about urgent care (for example, MIPS eligible clinician and care team access to medical record, cross-coverage with access to medical record, or protocol-driven nurse line with access to medical record) that could include one or more of the following: • Expanded hours in evenings and weekends with access to the patient medical record for example, coordinate with small practices to provide alternate hour office visits and urgent care); • Use of alternatives to increase access to care team by MIPS eligible clinicians and groups, such as e-visits, phone visits, group visits, home visits and alternate locations (for example, senior centers and assisted living centers); and/or • Provision of same-day or next-day access to a MIPS eligible clinician, group or care team when needed for urgent care or transition management.
Current Weighting:	High
Removal Rationale:	We are proposing to remove this activity under removal factor seven, activity is obsolete; this activity was created, in part, to incentivize utilization of EHRs to increase access to clinicians in off hours and decrease emergency room (ER) visits. Today, EHRs are highly utilized, and this activity has become standard of care. This is supported by the fact that this activity continues to be in the top ten activities reported, indicating that it is overutilized and that the clinical practice improvement promoted by the activity has been achieved. We are proposing the removal of this activity in the context of our regular review of the Inventory. In conducting this review recently, we concluded that the goal of this activity has been widely achieved by eligible clinicians and practices.
Current Improvement Activity	
Current Activity ID:	**IA_PM_12**
Current Subcategory:	Population Management
Current Activity Title:	Population empanelment
Current Activity Description:	Empanel (assign responsibility for) the total population, linking each patient to a MIPS eligible clinician or group or care team. Empanelment is a series of processes that assign each active patient to a MIPS eligible clinician or group and/or care team, confirm assignment with patients and clinicians, and use the resultant patient panels as a foundation for individual patient and population health management. Empanelment identifies the patients and population for whom the MIPS eligible clinician or group and/or care team is responsible and is the foundation for the relationship continuity between patient and MIPS eligible clinician or group /care team that is at the heart of comprehensive primary care. Effective empanelment requires identification of the "active population" of the practice: those patients who identify and use your practice as a source for primary care. There are many ways to define "active patients" operationally, but generally, the definition of "active patients" includes

	patients who have sought care within the last 24 to 36 months, allowing inclusion of younger patients who have minimal acute or preventive health care.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under removal factor seven, activity is obsolete; this activity was designed in the early years of the MIPS program to highlight the importance of patient population empanelment to drive patient-centered care and, over time, to drive quality improvement. Empanelment is now more widely accepted and/or used as an option to drive and/or measure comprehensive care, and this activity has no requirement for implementation or improvement beyond the empanelment; therefore, we are recommending its removal.
Current Improvement Activity	
Current Activity ID:	**IA_CC_1**
Current Subcategory:	Care Coordination
Current Activity Title:	Implementation of use of specialist reports back to referring clinician or group to close referral loop
Current Activity Description:	Performance of regular practices that include providing specialist reports back to the referring individual MIPS eligible clinician or group to close the referral loop or where the referring individual MIPS eligible clinician or group initiates regular inquiries to specialist for specialist reports which could be documented or noted in the EHR technology.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under removal factor one, this activity is duplicative, and factor five, this activity does not align with the quality, cost, or Promoting Interoperability performance categories. This activity provides credit for ensuring that consultation reports are communicated between an ordering and a consulting provider, and this is now standard of care. Also, this concept is redundant with some quality and Quality Clinical Data Registry (QCDR) measures, including QM#374. Our recommendation for removal is supported by the fact that this activity continues to be in the top ten activities reported, indicating that it is overutilized and that the clinical practice improvement promoted by the activity has been achieved. We are proposing the removal of this activity in the context of our regular review of the Inventory. In conducting this review recently, we concluded that the goal of this activity has been widely achieved by eligible clinicians and practices.
Current Improvement Activity	
Current Activity ID:	**IA_CC_2**
Current Subcategory:	Care Coordination
Current Activity Title:	Implementation of improvements that contribute to more timely communication of test results
Current Activity Description:	Timely communication of test results defined as timely identification of abnormal test results with timely follow-up.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under removal factor seven, activity is obsolete. This activity was created, in part, to encourage strategies for timely communication and to improve upon those strategies. This process has become widely used with the use of EHRs and the adoption of patient portals, and is now standard of care. This is supported by the fact that this activity continues to be in the top ten activities reported, indicating that it is overutilized. We are proposing the removal of this activity in the context of our regular review of the Inventory. In conducting this review recently, we concluded that the goal of this activity has been widely achieved by eligible clinicians and practices.
Current Improvement Activity	
Current Activity ID:	**IA_ERP_4**
Current Subcategory:	Emergency Response and Preparedness
Current Activity Title:	Implementation of a Personal Protective Equipment (PPE) Plan
Current Activity Description:	Implement a plan to acquire, store, maintain, and replenish supplies of personal protective equipment (PPE) for all clinicians or other staff who are in physical proximity to patients. In accordance with guidance from the Centers for Disease Control and Prevention (CDC) the PPE plan should address:

	• Conventional capacity: PPE controls that should be implemented in general infection prevention and control plans in healthcare settings, including training in proper PPE use. • Contingency capacity: actions that may be used temporarily during periods of expected PPE shortages. • Crisis capacity: strategies that may need to be considered during periods of known PPE shortages. The PPE plan should address all of the following types of PPE: • Standard precautions (for example, hand hygiene, prevention of needle-stick or sharps injuries, safe waste management, cleaning and disinfection of the environment) • Eye protection • Gowns (including coveralls or aprons) • Gloves • Facemasks • Respirators (including N95 respirators)
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under removal factor seven, activity is obsolete; since the COVID-19 pandemic, most clinicians are well prepared in PPE safety, as PPE enhancements have been made throughout patient care settings. It is unlikely that this activity will drive new improvements. We acknowledge the ongoing importance of PPE, and will work to ensure that, going forward, improvement activities that support continued enhancement and maintenance of PPE protocols are reflected in MIPS.
Current Improvement Activity	
Current Activity ID:	**IA_ERP_5**
Current Subcategory:	Emergency Response and Preparedness
Current Activity Title:	Implementation of a Laboratory Preparedness Plan
Current Activity Description:	Develop, implement, update, and maintain a preparedness plan for a laboratory intended to support continued or expanded patient care during COVID-19 or another public health emergency. The plan should address how the laboratory would maintain or expand patient access to health care services to improve beneficiary health outcomes and reduce healthcare disparities. For laboratories without a preparedness plan, MIPS eligible clinicians would meet with stakeholders, record minutes, and document a preparedness plan, as needed. The laboratory must then implement the steps identified in the plan and maintain them. For laboratories with existing preparedness plans, MIPS eligible clinicians should review, revise, or update the plan as necessary to meet the needs of the current PHE, implement new procedures, and maintain the plan. Maintenance of the plan in this activity could include additional hazard assessments, drills, training, and/or developing checklists to facilitate execution of the plan. Participation in debriefings to evaluate the effectiveness of plans are additional examples of engagement in this activity.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under removal factor seven, activity is obsolete; since the COVID-19 pandemic, most clinicians are now well prepared in COVID-19-related patient safety and laboratory-preparedness enhancements have been made throughout patient care settings. It is unlikely that this activity will drive new improvements. We acknowledge the ongoing importance of laboratory preparedness, and will work to ensure that, going forward, improvement activities that support continued enhancement and maintenance of lab preparedness protocols are reflected in MIPS.
Current Improvement Activity	
Current Activity ID:	**IA_BMH_8**
Current Subcategory:	Behavioral and Mental Health
Current Activity Title:	Electronic Health Record Enhancements for BH data capture
Current Activity Description:	Enhancements to an electronic health record to capture additional data on behavioral health (BH) populations and use that data for additional decision-making purposes (for

	example, capture of additional BH data results in additional depression screening for at-risk patient not previously identified).
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under removal factor two, there is an alternative activity with a stronger relationship to quality care or improvements in clinical practice. This activity was created, in part, to assist in the transition from paper charts to EHRs. While the use of EHRs is now highly prevalent and has become part of current basic standards of care, there is still much progress to be made in terms of adoption and use of EHRs and other health information technologies in a behavioral health context. This activity, though, allows attestation with a low level of effort and with vague requirements related to clinical outcomes. Because there are other, more potentially impactful, behavioral health activities in the current Inventory, we are recommending that this activity be removed. IA_BMH_7, Implementation of Integrated Patient Centered Behavioral Health Model, which includes 'use of a registry or health information technology functionality to support active care management and outreach to patients in treatment,' is a strong alternative activity. We also intend, in future rulemaking, to develop a new activity (or to modify an existing activity) to promote the effective use of health information technologies in behavioral health.
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_27**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Invasive Procedure or Surgery Anticoagulation Medication Management
Current Activity Description:	For an anticoagulated patient undergoing a planned invasive procedure for which interruption in anticoagulation is anticipated, including patients taking vitamin K antagonists (warfarin), target specific oral anticoagulants (such as apixaban, dabigatran, and rivaroxaban), and heparins/low molecular weight heparins, documentation, including through the use of electronic tools, that the plan for anticoagulation management in the periprocedural period was discussed with the patient and with the clinician responsible for managing the patient's anticoagulation. Elements of the plan should include the following: discontinuation, resumption, and, if applicable, bridging, laboratory monitoring, and management of concomitant antithrombotic medications (such as antiplatelets and nonsteroidal anti-inflammatory drugs (NSAIDs)). An invasive or surgical procedure is defined as a procedure in which skin or mucous membranes and connective tissue are incised, or an instrument is introduced through a natural body orifice.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under removal factor one, this activity is duplicative. We recommend removal of this activity as its focus is duplicative with IA_CC_15: PSH [Perioperative-Surgical Home] Care Coordination. IA_CC_15 requires coordination of patient care through the perioperative period and includes anticoagulant management as one part of its requirements. This activity, IA_PSPA_27, is more tightly focused in an area that is high risk and, therefore, is not likely changing clinical practice widely. We acknowledge the ongoing importance of care coordination and medication management as a patient safety goal, and will work to ensure that, going forward, improvement activities that support enhancement and maintenance of medication management activities (for example, anticoagulation) are reflected in MIPS.

APPENDIX 3: MVP INVENTORY

MVP Development: Background

In the CY 2021 PFS final rule (85 FR 84849 through 84854), the CY 2022 PFS final rule (86 FR 65998 through 66031), and the CY 2023 PFS final rule (87 FR 70210 through 70211) we finalized a set of criteria to use in the development of MVPs, including MVP reporting requirements, MVP maintenance, and the selection of measures and activities within an MVP.

This appendix contains two groups of proposed MVP tables: Group A: proposed new MVPs and Group B: proposed modifications to previously finalized MVPs. Group A includes six new proposed MVPs. Group B includes 16 previously finalized MVPs with proposed modifications.

Each MVP includes measures and activities from the quality performance category, improvement activities performance category, and the cost performance category relevant to the clinical theme of the MVP. Each MVP also includes a foundational layer comprised of population health measures and Promoting Interoperability performance category measures.

MVP Development: Performance Category Sources

The MVP tables contain a set of MIPS quality measures, QCDR measures (as applicable), improvement activities, cost measures, and foundational measures based on clinical topics. For further reference, the sources of the measures and activities in the MVP tables are as follows:

- Existing MIPS quality measures are in the 2024 MIPS Quality Measures List on the Quality Payment Program website.[1017] See Appendix 1: MIPS Quality Measures of this proposed rule for any proposed additions (Table Group A), proposed removals (Table Group B), or proposed modifications to existing quality measures (Table Groups D and DD).
- Existing QCDR measures are based on the most recent publication of the 2024 QCDR Measure Specification file, located on the Quality Payment Program website.[1018] We plan to modify the list of 2025 QCDR measures around December 2024.
- Improvement activities are in the 2024 Improvement Activities Inventory and the 2024 MIPS Data Validation Criteria, located on the Quality Payment Program website.[1019] See Appendix 2: Improvement Activities of this proposed rule for any proposed additions (Table Group A), proposed modifications to existing improvement activities (Table Group B), or proposed removals (Table Group C).
- Existing cost measures are in the 2024 Cost Measures Inventory.[1020] See section IV.A.4.e.(2) of this proposed rule for any proposed removals, additions, or modifications to existing cost measures.
- For further details on the population health measures (attributed to the Quality Performance Category) included in the foundational layer, see the CY 2022 PFS final rule (86 FR 65408 through 65409).
- Existing Promoting Interoperability measures adopted in prior rulemaking and included in the foundational layer are located on the Quality Payment Program website.[1021] There were policy updates to the Promoting Interoperability performance category but no proposed new, modifications, or removed Promoting Interoperability measures for the CY 2025 performance period/2027 MIPS payment year (for policy updates on this category see section IV.A.4.e. of this proposed rule.

MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity

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[1017] See the 2024 MIPS Quality Measures List: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2632/2024%20MIPS%20Quality%20Measures%20List.xlsx.*

[1018] See *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2617/2024%20QCDR%20Measure%20Specifications.xlsx* for QCDR measures.

[1019] See the 2024 Improvement Activities Inventory: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2644/2024ImprovementActivitiesInv.zip* and 2024 MIPS Data Validation Criteria: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2666/2024MIPSDataValidationCriteria.zip.* for improvement activity details.

[1020] See the 2024 Cost Measures Inventory: *https://qpp.cms.gov/mips/explore-measures?tab=costMeasures&py=2024.*

[1021] See the 2024 Promoting Interoperability Measure Specifications: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2223/2024%20MIPS%20Promoting%20Interoperability%20Measure%20Specifications.zip* for Promoting Interoperability measure details.

- We are proposing to eliminate the weighting from improvement activities and provide full credit for the improvement activities performance category when an MVP participant attests to one improvement activity option within the selected MVP. See section IV.A.4.e.(3)(b)(iv)of this proposed rule for detailed information regarding the proposed removal of weighting from improvement activities and for detailed information regarding our proposed reporting requirement changes for improvement activities.
- We are proposing to modify IA_ERP_6: COVID-19 Vaccine Achievement for Practice Staff to expand the focus and importance of vaccination status to drive improvement across the practice. We are proposing to add the proposed modified IA_ERP_6 to all new and previously finalized MVPs because of the importance of vaccination status in practice settings. See Appendix 2, Improvement Activities: Table B of this proposed rule for detailed information regarding the proposed modifications to IA_ERP_6: COVID-19 Vaccine Achievement for Practice Staff, including a proposed activity ID and title update.

MVP Table Symbol Information and Definitions

Please note the following symbols and definitions used within the MVP tables in the Group A and Group B tables below:

• Quality measures, improvement activities, and cost measures proposed for addition to a previously finalized MVP are identified with a plus sign (+) within the Group B MVP tables in this appendix.

• New quality measures, improvement activities, and cost measures proposed for inclusion in MIPS beginning with the CY 2025 performance period/2027 MIPS payment year and future years are identified with a caret symbol (^). See Appendix 1, MIPS Quality Measures: Table Group A of this proposed rule for further information regarding new MIPS quality measures. See Appendix 2: Improvement Activities: Table A of this proposed rule for further information regarding new improvement activities. See section IV.A.4.e.(2)(a)(iii)of this proposed rule for further information regarding new cost measures.

• Existing measures and improvement activities with proposed revisions are identified with a single asterisk (*). See Appendix 1, MIPS Quality Measures: Table Group D of this proposed rule for further information regarding proposed revisions to MIPS quality measures. See Appendix 2: Improvement Activities: Table B of this proposed rule for further information regarding proposed revisions to improvement activities. See section IV.A.4.e.(2)(a)(vi) and IV.A.4.e.(2)(a)(vii)of this proposed rule for further information regarding proposed revisions to cost measures. We intend to include existing measures or activities with proposed revisions in MVPs (as applicable) regardless of whether the proposed revisions are finalized beginning with the CY 2025 performance period/2027 MIPS payment year.

• Quality measures and improvement activities identified with a double asterisk (**) can only be submitted when included in an MVP.

• Quality measures considered high priority (as defined in § 414.1305) are identified with a single exclamation point (!) while outcome measures (as defined in § 414.1305) are identified with a double exclamation point (!!). Further details of these types of measures are in the CMS Measures Management System Hub.[1022]

• QCDR measures identified with a pound sign (#) indicate testing data is still pending and due on or before September 1, 2024. We refer readers to the CY 2022 PFS final rule for additional details regarding requirements for QCDR measures considered for an MVP (86 FR 65407 through 65408).

• Quality measures and improvement activities that include a health equity component are identified with a tilde (~) within the MVP table.

• IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation is identified with a percent (%) to indicate attestation to this improvement activity provides full credit for the improvement activity performance category within an MVP.

• Quality measure collection types are identified in parentheses after each quality measure title, and improvement activity medium/high weight designations are identified in parentheses after each improvement activity

Group A: New MVPs Proposed for the CY 2025 Performance Period/2027 MIPS Payment Year and Future Years

A.1 Complete Ophthalmologic Care MVP

The proposed Complete Ophthalmologic Care MVP assesses meaningful outcomes in cataract, glaucoma, retinal detachment, and broadly applicable ocular care. This MVP would be most applicable to clinicians who treat patients within the practice of ophthalmology and optometry.

[1022] See *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.*

Quality Measures

We are proposing to include 18 MIPS quality measures and 6 QCDR measures within the quality performance category of this MVP, which are specific to the clinical topic of ocular care by assessing ocular health and treatment of disorders attributed to diabetes related disease, glaucoma, retinal detachment, and cataracts. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in ocular care:

- Q012: Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation: This MIPS quality measure evaluates changes in the optic nerve which define the progression and worsening of glaucoma disease status.
- Q019: Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care: This MIPS quality measure focuses on the communication between the primary physician managing ongoing care and the physician performing the dilated macular or fundus exam on patients with diabetic retinopathy.
- Q117: Diabetes: Eye Exam: This MIPS quality measure supports eye screening for diabetic retinal disease.
- Q141: Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care: This MIPS quality measure focuses on glaucoma treatment and follow up, ensuring the IOP is within a range at which visual field loss is unlikely to significantly reduce a patient's health-related quality of life over their lifetime.
- Q191: Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery: This MIPS quality measure evaluates visual acuity as a surgical outcome following cataract surgery.
- Q303: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery: This MIPS quality measure looks for improvement in visual function following cataract surgery.
- Q304: Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery: This MIPS quality measure assesses patient satisfaction following cataract surgery. Patient satisfaction is a valuable performance indicator for measuring quality of care delivered by clinicians providing cataract surgery. Patient satisfaction is an assessment of the patient's experience with the care process delivered by the clinician and health care services.
- Q384: Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery: This MIPS quality measure assesses for successful surgical procedures by evaluating if patients required a return to the operation room or not.
- Q385: Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery: This MIPS quality measure assesses for successful surgical procedures by evaluating if patients showed improvement of visual acuity following surgery as compared to their preoperative level.
- Q389: Cataract Surgery: Difference Between Planned and Final Refraction: This MIPS quality measure evaluates patients for achieving a final refraction within +/- 1.0 diopters of their planned (target) refraction following cataract surgery.
- Q499: Appropriate Screening and Plan of Care for Elevated Intraocular Pressure Following Intravitreal or Periocular Steroid Therapy: This MIPS quality measure focuses on patient safety and ensures appropriate screening and plan of care for elevated intraocular pressure following treatment with intravitreal or periocular steroid.
- Q500: Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up: This MIPS quality measure evaluates patients following acute posterior vitreous detachment to ensure prompt and appropriate care to minimize potential for complications.
- Q501: Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up: This MIPS quality measure evaluates patients following acute posterior vitreous detachment and acute vitreous hemorrhage to ensure prompt and appropriate care to minimize potential for complications.
- IRIS2: Glaucoma – Intraocular Pressure Reduction: This QCDR measure focuses on glaucoma patients to assess management of their IOP by evaluating if it is below a threshold level based on severity of their glaucoma.
- IRIS13: Diabetic Macular Edema – Loss of Visual Acuity: This QCDR measure evaluates outcomes of treatment for diabetic macular edema by assessing for change in visual acuity after treatment.
- IRIS39: Intraocular Pressure Reduction Following Trabeculectomy or an Aqueous Shunt Procedure: This QCDR measure assesses for successful treatment of patients with glaucoma who have undergone trabeculectomy or an aqueous shunt procedure by evaluating for intraocular pressure reduction.
- IRIS54: Complications after Cataract Surgery: This QCDR measure assesses for successful cataract surgeries by reviewing patients for complications within 90 days of the procedure.
- IRIS58: Improved Visual Acuity after Vitrectomy for Complications of Diabetic Retinopathy within 120 Days: This QCDR measure assesses for successful vitrectomy procedure in patients with diabetic retinopathy by reviewing patients for complications within 120 days of the procedure.
- IRIS61: Visual Acuity Improvement Following Cataract Surgery and Minimally Invasive Glaucoma Surgery: This QCDR measure evaluates visual acuity as a surgical outcome following cataract surgery and minimally invasive glaucoma surgery.

The following broadly applicable MIPS quality measures are relevant to clinicians who specialize in ocular care. The quality measures below assess for age-specific screenings and the patients' understanding of engagement in their healthcare:

- Q130: Documentation of Current Medications in the Medical Record: This MIPS quality measure bases performance on clinicians documenting the list of current medications using all immediate resources for capture of this important clinical topic.
- Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure ensures patients are screened for tobacco use and if screened positive receive tobacco cessation intervention.
- Q374: Closing the Referral Loop: Receipt of Specialist Report: This MIPS quality measure is attributable to the clinician referring the patient and ensures report receival from the referred to clinician, closing the communication loop.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
- Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in the clinician's ability to manage their health and be an active partner in the health care journey.

Improvement Activities

We reviewed the Improvement Activities Inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We are proposing to include 14 improvement activities that reflect actions and processes undertaken by clinicians who specialize in ocular care, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_1: Enhance Engagement of Medicaid and Other Underserved Populations
- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BE_25: Drug Cost Transparency
- IA_CC_9: Implementation of practices/processes for developing regular individual care plans
- IA_CC_10: Care transition documentation practice improvements
- IA_CC_13: Practice improvements to align with OpenNotes principles
- IA_ERP_6: COVID-19 Vaccine Achievement for Practice Staff
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_13: Chronic care and preventative care management for empaneled patients
- IA_PM_16: Implementation of medication management practice improvements
- IA_PSPA_7: Use of QCDR data for ongoing practice assessment and improvements

We are proposing to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity, which includes a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this proposed rule for all proposed revisions to this activity.

Cost Measures

We are proposing to include one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of ocular care. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for clinicians who specialize in ocular care, specifically cataract removal, and aligns with other measures and activities within this MVP:

- Routine Cataract Removal with Intraocular Lens (IOL) Implantation: This MIPS episode-based cost measure assesses costs associated with routine cataract removal. The addition of this measure aligns with included quality measures, such as Q191: Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery and Q303: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

We are proposing to modify the Routine Cataract Removal with Intraocular Lens (IOL) Implantation cost measure, which includes a proposed measure title update. Please see section IV.A.4.e(2)(a)(vi) of this proposed rule for all proposed revisions to this measure.

Complete Ophthalmologic Care MVP Tables

As stated in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those we determined best fit the clinical concept of the proposed Complete Ophthalmologic Care MVP. We request comment on the measures and activities included in this MVP.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with proposed revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component
Percent (%): attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category
Pound sign (#): QCDR measures pending testing data

TABLE A.1a: Complete Ophthalmologic Care MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
Q012: Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation (Collection Type: eCQM Specifications) **(*)(!) Q019:** Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*) Q117:** Diabetes: Eye Exam (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*)(!) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(!!) Q141:** Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care (Collection Type: Medicare Part B Claims Specifications, MIPS CQMs Specifications) **(!!) Q191:** Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM Specifications, MIPS CQMs Specifications) **(!!) Q303:** Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (Collection Type: MIPS CQMs Specifications) **(!) Q304:** Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery (Collection Type: MIPS CQMs Specifications) **(*)(!) Q374:** Closing the Referral Loop: Receipt of Specialist Report (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*)(!!) Q384:** Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery (Collection Type: MIPS CQMs Specifications)	**(~) IA_AHE_1:** Enhance Engagement of Medicaid and Other Underserved Populations (High) **(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **(*) IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_25:** Drug Cost Transparency (High) **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans (Medium) **(~) IA_CC_10:** Care transition documentation practice improvements (Medium) **IA_CC_13:** Practice improvements to align with OpenNotes principles (Medium) **(*) IA_ERP_6:** COVID-19 Vaccine Achievement for Practice Staff (Medium) **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_13:** Chronic care and preventative care management for empaneled patients (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium)	**(*) Routine Cataract Removal with Intraocular Lens (IOL) Implantation**

Quality	Improvement Activities	Cost
(!!) Q385: Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery (Collection Type: MIPS CQMs Specifications) **(!!) Q389:** Cataract Surgery: Difference Between Planned and Final Refraction (Collection Type: MIPS CQMs Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **Q499:** Appropriate Screening and Plan of Care for Elevated Intraocular Pressure Following Intravitreal or Periocular Steroid Therapy (Collection Type: MIPS CQMs Specifications) **(*) Q500:** Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up (Collection Type: MIPS CQMs Specifications) **(*) Q501:** Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications) **(!!)(#) IRIS2:** Glaucoma – Intraocular Pressure Reduction (Collection Type: QCDR) **(!!)(#) IRIS13:** Diabetic Macular Edema – Loss of Visual Acuity (Collection Type: QCDR) **(!!)(#) IRIS39:** Intraocular Pressure Reduction Following Trabeculectomy or an Aqueous Shunt Procedure (Collection Type: QCDR) **(!!)(#) IRIS54:** Complications after Cataract Surgery (Collection Type: QCDR) **(!!)(#) IRIS58:** Improved Visual Acuity after Vitrectomy for Complications of Diabetic Retinopathy within 120 Days (Collection Type: QCDR) **(!!)(#) IRIS61:** Visual Acuity Improvement Following Cataract Surgery and Minimally Invasive Glaucoma Surgery (Collection Type: QCDR)		

TABLE A.1b: Complete Ophthalmologic Care MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

A.2 Dermatological Care MVP

The proposed Dermatological Care MVP focuses on the clinical theme of providing treatment and management of dermatologic care. This MVP would be most applicable to clinicians who treat patients within the practice of dermatology, including nonphysician practitioners (NPPs) such as nurse practitioners and physician assistants.

Quality Measures

We are proposing to include 11 MIPS quality measures and 6 QCDR measure within the quality performance category of this MVP, which are specific to the clinical topic of dermatology. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in dermatology:

- Q176: Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy: This MIPS quality measure ensures TB testing is completed prior to the first course of biologic and/or immune response modifier therapy.
- Q397: Melanoma Reporting: This MIPS quality measure assesses that the pathology report for primary malignant cutaneous melanoma includes reporting identifiers needed for microsatellitosis of invasive tumors.
- Q410: Psoriasis: Clinical Response to Systemic Medications: This MIPS quality measure ensures patients with psoriasis vulgaris who are being treated with systemic medications maintain disease control by evaluating documented body surface assessments meet at least one of the specified benchmarks.
- Q440: Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician: This MIPS quality measure ensures pathology reports diagnosing carcinoma or melanoma are communicated from the Pathologist/Dermatopathologist within 7 days from the Pathologist receiving the specimen.
- Q485: Psoriasis – Improvement in Patient-Reported Itch Severity: This MIPS quality measure evaluates patients with a diagnosis of psoriasis for a reduction in itch severity of 3 or more points at follow up visits.
- Q486: Dermatitis – Improvement in Patient-Reported Itch Severity: This MIPS quality measure evaluates patients with a diagnosis of dermatitis for a reduction in itch severity of 3 or more points at follow up visits.

- TBD: Melanoma: Tracking and Evaluation of Recurrence: This proposed MIPS quality measure ensures patients who undergo excisional surgery for melanoma or melanoma in situ within the previous 5 years have documentation that an exam for recurrence of melanoma was performed within the performance period and results captured.
- AAD6: Skin Cancer Biopsy Reporting Time – Clinician to Patient: This QCDR measure ensures timely communication from the clinician to the patient when they have a positive finding for carcinoma, melanoma, or primary cutaneous malignancies.
- AAD8: Chronic Skin Conditions: Patient Reported Quality-of-Life: This QCDR measure ensures a patient- reported quality-of-life assessment is completed and recorded in the medical record with a plan of care at least once in the performance period.
- AAD12: Melanoma: Appropriate Surgical Margins: This QCDR measure ensures the initial biopsy and surgical margins are documented in the medical record and are in compliance with the minimum margin recommended in the current National Comprehensive Cancer Network (NCCN) guideline.
- AAD16: Avoidance of Post-operative Systemic Antibiotics for Office-based Closures and Reconstruction After Skin: This QCDR measure assesses for the appropriate use of post operative antibiotics for patients with skin cancer undergoing an office-based closure or reconstruction procedure.
- AAD17: Continuation of Anticoagulation Therapy in the Office-based Setting for Closure and Reconstruction After Skin Cancer Resection Procedures: This QCDR measure assesses the percentage of patients who had their anticoagulation therapy continued prior to an in-office procedure for intermediate layer and/or complex linear closures OR reconstruction after skin cancer resection performed.
- AAD18: Avoidance of Opioid Prescriptions for Closure and Reconstruction After Skin Cancer Resection: This QCDR measure identifies the number of patients diagnosed with skin cancer who were prescribed an opioid/narcotic therapy as a first line pain management option post-operative by the reconstructing surgeon.

The following broadly applicable MIPS quality measures are relevant to clinicians who specialize in dermatology. The quality measures below assess for age-specific screenings, and follow-up actions for select measures:

- Q130: Documentation of Current Medications in the Medical Record: This MIPS quality measure bases performance on clinicians documenting the list of current medications using all immediate resources for capture of this important clinical topic.
- Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure ensures patients are screened for tobacco use and if screened positive receive tobacco cessation intervention.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
- Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in the clinician's ability to manage their health and be an active partner in the health care journey.

Improvement Activities

We reviewed the Improvement Activities Inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We are proposing to include 11 improvement activities that reflect actions and processes undertaken by clinicians who specialize in dermatology, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_1: Enhance Engagement of Medicaid and Other Underserved Populations
- IA_AHE_6: Provide Education Opportunities for New Clinicians
- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BE_15: Engagement of patients, family and caregivers in developing a plan of care
- IA_EPA_2: Use of telehealth services that expand practice access
- IA_ERP_6: COVID-19 Vaccine Achievement for Practice Staff
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_16: Implementation of medication management practice improvements
- IA_PSPA_8: Use of Patient Safety Tools

We are proposing to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity, which includes a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this proposed rule for all proposed revisions to this activity.

Cost Measures

We are proposing to include one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of dermatology. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measure

provides a meaningful assessment of the clinical care for clinicians who specialize in dermatology, specifically melanoma resection, and aligns with other measures and activities within this MVP:

- Melanoma Resection: This MIPS episode-based cost measure assesses costs associated with excision procedures to remove a cutaneous melanoma. The addition of this measure aligns with Q397: Melanoma Reporting and TBD: Melanoma: Tracking and Evaluation of Recurrence.

Dermatological Care MVP Tables

As stated in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those we determined best fit the clinical concept of the proposed Dermatological Care MVP. We request comment on the measures and activities included in this MVP.

Symbol Key:
Carat symbol (^): new proposed measures and improvement activities
Single asterisk (*): existing measures and improvement activities with proposed revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component
Percent (%): attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category
Pound sign (#): QCDR measures pending testing data

TABLE A.2a: Dermatological Care MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(*)(!) Q130: Documentation of Current Medications in the Medical Record (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*) Q176:** Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy (Collection Type: MIPS CQMs Specifications) **Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications) **(!) Q397:** Melanoma Reporting (Collection Type: Medicare Part B Claims, MIPS CQMs Specifications) **(!!) Q410:** Psoriasis: Clinical Response to Systemic Medications (Collection Type: MIPS CQMs Specifications) **(!) Q440:** Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q485:** Psoriasis – Improvement in Patient-Reported Itch Severity (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q486:** Dermatitis – Improvement in Patient-Reported Itch Severity (Collection Type: MIPS CQMs Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications) **(^)(!) TBD:** Melanoma: Tracking and Evaluation of Recurrence (Collection Type: MIPS CQMs Specifications) **(!)(#) AAD6:** Skin Cancer Biopsy Reporting Time – Clinician to Patient (Collection Type: QCDR) **(!) AAD8:** Chronic Skin Conditions: Patient Reported Quality-of-Life (Collection Type: QCDR) **(!!)(#) AAD12:** Melanoma: Appropriate Surgical Margins (Collection Type: QCDR) **(!)(#) AAD16:** Avoidance of Post-operative Systemic Antibiotics for Office-based Closures and Reconstruction After Skin	**(~) IA_AHE_1:** Enhance Engagement of Medicaid and Other Underserved Populations (High) **(~) IA_AHE_6:** Provide Education Opportunities for New Clinicians (High) **(*) IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **IA_EPA_2:** Use of telehealth services that expand practice access (Medium) **(*) IA_ERP_6:** COVID-19 Vaccine Achievement for Practice Staff (Medium) **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PSPA_8:** Use of Patient Safety Tools (Medium)	**Melanoma Resection**

Quality	Improvement Activities	Cost
Cancer Procedures (Collection Type: QCDR) **(!)(#) AAD17:** Continuation of Anticoagulation Therapy in the Office-based Setting for Closure and Reconstruction After Skin Cancer Resection Procedures (Collection Type: QCDR) **(!)(#) AAD18:** Avoidance of Opioid Prescriptions for Closure and Reconstruction After Skin Cancer Resection (Collection Type: QCDR)		

TABLE A.2b: Dermatological Care MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

A.3 Gastroenterology Care MVP

The proposed Gastroenterology Care MVP focuses on the clinical theme of providing treatment and management of the digestive system and the liver. This MVP would be most applicable to clinicians who treat patients within the practice of gastroenterology, including nonphysician practitioners (NPPs) such as nurse practitioners and physician assistants.

Quality Measures

We are proposing to include 11 MIPS quality measures and 3 QCDR measures within the quality performance category of this MVP, which are specific to the clinical topic of gastroenterology. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in gastroenterology:

- Q113: Colorectal Cancer Screening: This MIPS quality measure ensures appropriate screening of patients for colorectal cancer.
- Q185: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use: This MIPS quality measure ensures appropriate follow-up, an interval of 3 or more years, for patients with a history of prior adenomatous polyp(s) in previous colonoscopy.
- Q275: Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy: This MIPS quality measure requires patients with a diagnosis of inflammatory bowel disease (IBD) have Hepatitis B Virus (HBV) status assessed prior to initiating anti-TNF (tumor necrosis factor) therapy.
- Q320: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients: This MIPS quality measure ensures appropriate follow-up for patients receiving a screening colonoscopy without biopsy or polypectomy.
- Q400: One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation: This MIPS quality measure requires patients have received a one-time screening for hepatitis C virus (HCV) infection as well as treatment initiation or referral if screening is positive.
- Q401: Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis: This MIPS quality measure ensures patients with a diagnosis of chronic Hepatitis C cirrhosis have appropriate surveillance imaging for hepatocellular carcinoma at least once during the performance period.
- GIQIC23: Appropriate follow-up interval based on pathology findings in screening colonoscopy: This QCDR measure ensures appropriate follow-up consistent with US Multi-Society Task Force (USMSTF) recommendations based upon pathology findings from screening colonoscopy with biopsy or polypectomy documented in colonoscopy report.
- GIQIC26: Screening Colonoscopy Adenoma Detection Rate: This QCDR measure evaluates patients who had a screening colonoscopy and at least one conventional adenoma or colorectal cancer was detected.
- NHCR4: Repeat screening or surveillance colonoscopy recommended within one year due to inadequate bowel preparation: This QCDR measure ensures patients with inadequate bowel prep receive a repeat screening or surveillance colonoscopy or an alternate tier 1 or tier 2 colorectal cancer screening modality within one year.

The following broadly applicable MIPS quality measures are relevant to clinicians who specialize in gastroenterology. The quality measures below assess for age-specific screenings, and follow-up actions for select measures:

- Q130: Documentation of Current Medications in the Medical Record: This MIPS quality measure bases performance on clinicians documenting the list of current medications using all immediate resources for capture of this important clinical topic.
- Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure ensures patients are screened for tobacco use and if screened positive receive tobacco cessation intervention.
- Q374: Closing the Referral Loop: Receipt of Specialist Report: This MIPS quality measure is attributable to the clinician referring the patient and ensures report receival from the referred to clinician, closing the communication loop.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
- Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in the clinician's ability to manage their health and be an active partner in the health care journey.

Improvement Activities

We reviewed the Improvement Activities Inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We are proposing to include 11 improvement activities that reflect actions and processes undertaken by clinicians who specialize in gastroenterology, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_AHE_6: Provide Education Opportunities for New Clinicians
- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_CC_7: Regular training in care coordination
- IA_CC_9: Implementation of practices/processes for developing regular individual care plans
- IA_CC_10: Care transition documentation practice improvements
- IA_CC_13: Practice improvements to align with OpenNotes principles
- IA_ERP_6: COVID-19 Vaccine Achievement for Practice Staff
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation

We are proposing to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity. which includes a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this proposed rule for all proposed revisions to this activity.

Cost Measures

We are proposing to include two MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic of gastroenterology. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in gastroenterology, including colonoscopies and broader gastroenterology care, and align with other measures and activities within this MVP:

- Screening/Surveillance Colonoscopy: This MIPS episode-based cost measure assesses costs associated with screening or surveillance colonoscopy procedures. This measure aligns with quality measures such as Q113: Colorectal Cancer Screening or Q320: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.
- Total Per Capita Cost (TPCC): This MIPS cost measure assesses the overall cost of care delivered to a Medicare patient with a focus on the primary care the patient receives from their providers. Gastroenterologists are included in attribution for the TPCC measure as they may provide broad, ongoing care to their patients, which is in line with the intent of the TPCC measure.

Gastroenterology Care MVP Tables

As stated in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those we determined best fit the clinical concept of the proposed Gastroenterology Care MVP. We request comment on the measures and activities included in this MVP.

Symbol Key:
Single asterisk (*): existing measures and improvement activities with proposed revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component
Percent (%): attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category
Pound sign (#): QCDR measures pending testing data

TABLE A.3a: Gastroenterology Care MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(*) Q113: Colorectal Cancer Screening (Collection Type: Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*)(!) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*)(!) Q185:** Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use (Collection Type: MIPS CQMs Specifications) **Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications) **Q275:** Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy (Collection Type: MIPS CQMs Specifications) **(*)(!) Q320:** Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (Collection Type: Medicare Part B Claims Specifications, MIPS CQMs Specifications) **(*)(!) Q374:** Closing the Referral Loop: Receipt of Specialist Report (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **Q400:** One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation (Collection Type: MIPS CQMs Specifications) **Q401:** Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis (Collection Type: MIPS CQMs Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications) **(!) GIQIC23:** Appropriate follow-up interval based on pathology findings in screening colonoscopy (Collection Type: QCDR) **(!!)(#) GIQIC26:** Screening Colonoscopy Adenoma Detection Rate (Collection Type: QCDR)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High) **(~) IA_AHE_6:** Provide Education Opportunities for New Clinicians (High) **(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **(*) IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_CC_7:** Regular training in care coordination (Medium) **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans (Medium) **(~) IA_CC_10:** Care transition documentation practice improvements (Medium) **IA_CC_13:** Practice improvements to align with OpenNotes principles (Medium) **(*) IA_ERP_6:** COVID-19 Vaccine Achievement for Practice Staff (Medium) **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation	**Screening/Surveillance Colonoscopy** **Total Per Capita Cost (TPCC)**

Quality	Improvement Activities	Cost
(!) **NHCR4:** Repeat screening or surveillance colonoscopy recommended within one year due to inadequate bowel preparation (Collection Type: QCDR)		

TABLE A.3b: Gastroenterology Care MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) **Q479:** Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) (!!) **Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

A.4 Optimal Care for Patients with Urologic Conditions MVP

The proposed Optimal Care for Patients with Urologic Conditions MVP focuses on assessing optimal care for patients treated for a broad range of urologic conditions, including kidney stones, urinary incontinence, bladder cancer, and prostate cancer. This MVP would be most applicable to clinicians who treat patients within the practice urology including general urologists, urology oncologists, and sub-specialists focused on urology care for women, including nonphysician practitioners (NPPs) such as nurse practitioners and physician assistants.

Quality Measures

We are proposing to include nine MIPS quality measures and five QCDR measure within the quality performance category of this MVP, which are specific to the clinical topic of urology. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in urology:

- Q050: Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older: This MIPS quality measure ensures patients have a documented plan of care for urinary incontinence at least once within 12 months.
- Q462: Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy: This MIPS quality measure ensures patients with prostate cancer currently on or starting androgen deprivation therapy (ADT), with an intent for treatment greater than or equal to 12 months, have a bone density evaluation prior to starting or within 3 months after the start of ADT.

- Q476: Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia: This MIPS quality measure assesses for improvement in urinary symptoms for patients with a diagnosis of benign prostatic hyperplasia based upon the International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI).
- Q481: Intravesical Bacillus-Calmette Guerin for Non-muscle Invasive Bladder Cancer: This MIPS quality measure ensures patients initially diagnosed with non-muscle invasive bladder cancer have treatment initiated within 6 months of the cancer staging.
- AQUA8: Hospital Admissions or Infectious Complications Within 30 days of Prostate Biopsy: This QCDR measure assesses the number of patients who have urinary retention, infection, or a new antibiotic prescription at least 24 hours after and within 30 days of a prostate biopsy or inpatient consultation or require hospitalization within 30 days of prostate biopsy.
- AQUA14: Stones: Repeat Shock Wave Lithotripsy (SWL) Within 6 Months of Initial Treatment: This QCDR measure assesses the number of patients who had a repeat shock wave lithotripsy procedure within the 6 months of the initial treatment.
- AQUA15: Stones: Urinalysis or Urine Culture Performed Before Surgical Stone Procedures: This QCDR measure ensures patients have a urinalysis or culture within 14 days prior to surgical stone procedures.
- AQUA16: Non-Muscle Invasive Bladder Cancer: Repeat Transurethral Resection of Bladder Tumor (TURBT) for T1 disease: This QCDR measure assesses the number of patients who undergo a second TURBT within 6 weeks of the initial procedure.
- MUSIC4: Prostate Cancer: Active Surveillance/Watchful Waiting for Newly Diagnosed Low-Risk Prostate Cancer Patients: This QCDR measure ensures newly diagnosed low-risk prostate cancer patients are managed via active surveillance or watchful waiting to maintain the patient's quality of life.

The following broadly applicable MIPS quality measures are relevant to clinicians who specialize in urology. The measures assess for age-specific screenings, and follow-up actions for select measures, in addition to recommended vaccinations:

- Q318: Falls: Screening for Future Fall Risk: This MIPS quality measure ensures patients are screened each performance period for future fall risk.
- Q321: CAHPS for MIPS Clinician/Group Survey: This survey provides direct input from patients and their experience regarding timely care, effective communication, shared decision making, care coordination, promotion of health and education, completion of health status/functionality, and courtesy of office staff.
- Q358: Patient-Centered Surgical Risk Assessment and Communication: This MIPS quality measure ensures a personalized surgical risk assessment is completed on each patient using a validated risk calculator or multi-institutional clinical data prior to the surgery along with discussion of the identified risks with the surgeon.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
- Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in the clinician's ability to manage their health and be an active partner in the health care journey.

Improvement Activities

We reviewed the Improvement Activities Inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We are proposing to include 17 improvement activities that reflect actions and processes undertaken by clinicians who specialize in urology, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_AHE_12: Practice Improvements that Engage Community Resources to Address Drivers of Health
- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BE_15: Engagement of patients, family and caregivers in developing a plan of care
- IA_CC_7: Regular training in care coordination
- IA_CC_13: Practice improvements to align with OpenNotes principles
- IA_CC_17: Patient Navigator Program
- IA_EPA_2: Use of telehealth services that expand practice access
- IA_ERP_6: COVID-19 Vaccine Achievement for Practice Staff
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_17: Participation in Population Health Research
- IA_PM_21: Advance Care Planning
- IA_PSPA_7: Use of QCDR data for ongoing practice assessment and improvements
- IA_PSPA_12: Participation in private payer CPIA
- IA_PSPA_19: Implementation of formal quality improvement methods, practice changes or other practice improvement processes
- IA_PSPA_21: Implementation of fall screening and assessment programs

Cost Measures

We are proposing to include three MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic of urology. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in urology and align with other measures and activities within this MVP:

- Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing care in inpatient hospitals, including those who treat patients with urology-related conditions or procedures.
- Renal or Ureteral Stone Surgical Treatment: This MIPS episode-based cost measure assesses costs associated with surgical treatment for renal or ureteral stones. This also aligns with quality measures such as AQUA14: Stones: Repeat Shock Wave Lithotripsy (SWL) Within 6 Months of Initial Treatment or AQUA15: Stones: Urinalysis or Urine Culture Performed Before Surgical Stone Procedures.
- Prostate Cancer: This proposed MIPS episode-based cost measure would assess costs associated with prostate cancer. This also aligns with quality measures such as Q462: Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy or MUSIC4: Prostate Cancer: Active Surveillance/Watchful Waiting for Newly Diagnosed Low-Risk Prostate Cancer Patients. We note that this is a new cost measure we are proposing to adopt as described in section IV.A.4.e.(2)(a)(iii)of this proposed rule.

Optimal Care for Patients with Urologic Conditions MVP Tables

As stated in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those we determined best fit the clinical concept of the proposed Optimal Care for Patients with Urologic Conditions MVP. We request comment on the measures and activities included in this MVP.

Symbol Key:
Carat symbol (^): new proposed measures and improvement activities
Single asterisk (*): existing measures and improvement activities with proposed revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component
Percent (%): attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

TABLE A.4a: Optimal Care for Patients with Urologic Conditions MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(!) Q050: Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older (Collection Type: MIPS CQMs Specifications) **(!) Q318:** Falls: Screening for Future Fall Risk (Collection Type: eCQM Specifications) **(!) Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CSV) **(!) Q358:** Patient-Centered Surgical Risk Assessment and Communication (Collection Type: MIPS CQMs Specifications) **(*) Q462:** Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy (Collection Type: eCQM Specifications) **(!!) Q476:** Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia (Collection Type: eCQM Specifications)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High) **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **IA_CC_7:** Regular training in care coordination (Medium) **IA_CC_13:** Practice improvements to align with OpenNotes principles (Medium) **IA_CC_17:** Patient Navigator Program (High)	**Renal or Ureteral Stone Surgical Treatment** **Medicare Spending Per Beneficiary (MSPB) Clinician** **(^) Prostate Cancer**

Quality	Improvement Activities	Cost
(!) Q481: Intravesical Bacillus-Calmette Guerin for Non-muscle Invasive Bladder Cancer (Collection Type: eCQM Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications) **(!!) AQUA8:** Hospital Admissions or Infectious Complications Within 30 days of Prostate Biopsy (Collection Type: QCDR) **(!!) AQUA14:** Stones: Repeat Shock Wave Lithotripsy (SWL) Within 6 Months of Initial Treatment (Collection Type: QCDR) **(!) AQUA15:** Stones: Urinalysis or Urine Culture Performed Before Surgical Stone Procedures (Collection Type: QCDR) **AQUA16:** Non-Muscle Invasive Bladder Cancer: Repeat Transurethral Resection of Bladder Tumor (TURBT) for T1 disease (Collection Type: QCDR) **(!) MUSIC4:** Prostate Cancer: Active Surveillance/Watchful Waiting for Newly Diagnosed Low-Risk Prostate Cancer Patients (Collection Type: QCDR)	**IA_EPA_2:** Use of telehealth services that expand practice access (Medium) **(*) IA_ERP_6:** COVID-19 Vaccine Achievement for Practice Staff (Medium) **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_17:** Participation in Population Health Research (Medium) **IA_PM_21:** Advance Care Planning (Medium) **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **IA_PSPA_12:** Participation in private payer CPIA (Medium) **IA_PSPA_19:** Implementation of formal quality improvement methods, practice changes or other practice improvement processes (Medium) **IA_PSPA_21:** Implementation of fall screening and assessment programs (Medium)	

TABLE A.4b: Optimal Care for Patients with Urologic Conditions MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

A.5 Pulmonology Care MVP

The proposed Pulmonology Care MVP focuses on assessing optimal care for patients treated for a broad range of pulmonology conditions including COPD, asthma, sleep apnea, and general pulmonology. This MVP would be most applicable to clinicians who treat patients within the practice of pulmonology and sleep medicine, including nonphysician practitioners (NPPs) such as nurse practitioners, and physician assistants.

Quality Measures

We are proposing to include nine MIPS quality measures and one QCDR measure within the quality performance category of this MVP, which are specific to the clinical topic of pulmonology. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in pulmonology:

- Q052: Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation for Long-Acting Inhaled Bronchodilator Therapy: This MIPS quality measure ensures adults 18 and older diagnosed with COPD have spirometry results documented airflow obstruction confirming diagnosis, and have been prescribed a long-acting bronchodilator to provide proper treatment if symptomatic.
- Q277: Sleep Apnea: Severity Assessment at Initial Diagnosis: This MIPS quality measure ensures adults diagnosed with obstructive sleep apnea have an appropriate assessment completed and documented at the time of diagnosis or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.
- Q279: Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy: This MIPS quality measure ensures patients with a diagnosis of obstructive sleep apnea (OSA) who were prescribed an evidence-based therapy with documentation that adherence to the therapy was assessed annually.
- Q398: Optimal Asthma Control: This MIPS quality measure assesses pediatric and adult patients to ensure their asthma is well-controlled as demonstrated by one of three age-appropriate patient reported outcome tools and not at risk for exacerbation.

- ACEP25: Tobacco Use: Screening and Cessation Intervention for Patients with Asthma and COPD: This QCDR measure ensures patients with asthma or COPD seen in the emergency department receive tobacco cessation if screened positive for tobacco use.

The following broadly applicable MIPS quality measures are relevant to clinicians who specialize in pulmonology care. The measures assess for age-specific screenings, and follow-up actions for select measures, in addition to recommended vaccinations:

- Q047: Advance Care Plan: This MIPS quality measure assesses for medical record documentation of an advance care plan or surrogate decisions maker.
- Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: This MIPS quality measure assesses patients for a BMI documented with a follow-up plan documented if their most recent documented BMI was outside of normal parameters.
- Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure ensures patients are screened for tobacco use and if screened positive receive tobacco cessation intervention.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
- Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in the clinician's ability to manage their health and be an active partner in the health care journey.

Improvement Activities

We reviewed the Improvement Activities Inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We are proposing to include 11 improvement activities that reflect actions and processes undertaken by clinicians who specialize in pulmonology care, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_AHE_12: Practice Improvements that Engage Community Resources to Address Drivers of Health
- IA_BE_23: Integration of patient coaching practices between visits
- IA_CC_9: Implementation of practices/processes for developing regular individual care plans
- IA_EPA_2: Use of telehealth services that expand practice access
- IA_ERP_6: COVID-19 Vaccine Achievement for Practice Staff
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_13: Chronic care and preventative care management for empaneled patients
- IA_PM_16: Implementation of medication management practice improvements

Cost Measures

We are proposing to include two MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic of pulmonology care. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in pulmonology and align with other measures and activities within this MVP:

- Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation: This MIPS episode-based cost measure assesses costs associated with inpatient treatment for an acute exacerbation of COPD. This also aligns with quality measures such as Q052: Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation for Long-Acting Inhaled Bronchodilator Therapy.
- Asthma/Chronic Obstructive Pulmonary Disease (COPD): This MIPS episode-based cost measure assesses costs associated with medical care to manage and treat asthma or COPD. This also aligns with quality measures such as Q398: Optimal Asthma Control or ACEP25: Tobacco Use: Screening and Cessation Intervention for Patients with Asthma and COPD.

Pulmonology Care MVP Tables

As stated in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those we determined best fit the clinical concept of the proposed Pulmonology Care MVP. We request comment on the measures and activities included in this MVP.

Symbol Key:
Single asterisk (*): existing measures and improvement activities with proposed revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures

Tilde (~): measures and improvement activities that include a health equity component
Percent (%): attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

TABLE A.5a: Pulmonology Care MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(*)(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQMs Specifications) **Q052:** Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation and Long-Acting Inhaled Bronchodilator Therapy (Collection Type: MIPS CQMs Specifications) **(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications) **Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q277:** Sleep Apnea: Severity Assessment at Initial Diagnosis (Collection Type: MIPS CQMs Specifications) **Q279:** Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy (Collection Type: MIPS CQMs Specifications) **(!!) Q398:** Optimal Asthma Control (Collection Type: MIPS CQMs Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications) **ACEP25:** Tobacco Use: Screening and Cessation Intervention for Patients with Asthma and COPD (Collection Type: QCDR)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High) **(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **IA_BE_23:** Integration of patient coaching practices between visits (Medium) **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans (Medium) **IA_EPA_2:** Use of telehealth services that expand practice access (Medium) **(*) IA_ERP_6:** COVID-19 Vaccine Achievement for Practice Staff (Medium) **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_13:** Chronic care and preventative care management for empaneled patients (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium)	**Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation** **Asthma/Chronic Obstructive Pulmonary Disease (COPD)**

TABLE A.5b: Pulmonology Care MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

A.6 Surgical Care MVP

The proposed Surgical Care MVP focuses on the clinical theme of surgery. This MVP would be most applicable to clinicians who treat patients within the surgical settings of general surgery, neurosurgery, cardiothoracic surgery, anesthesiologists, including nonphysician practitioners (NPPs) such as certified registered nurse anesthetists (CRNAs), nurse practitioners, and physician assistants.

Quality Measures

We are proposing to include 15 MIPS quality measures within the quality performance category of this MVP, which are specific to the clinical theme of surgery. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in surgery:

- Q164: Coronary Artery Bypass Graft (CABG): Prolonged Intubation: This MIPS quality measure identifies patients who undergo an isolated CABG and require intubation > 24 hours following exit from the operating room.
- Q167: Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure: This MIPS quality measure assesses patients for postoperative renal failure or who require dialysis after CABG.
- Q168: Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration: This MIPS quality measure identifies patients who return to the operating room for surgical re-exploration following an isolated CABG surgery during the current hospitalization.
- Q264: Sentinel Lymph Node Biopsy for Invasive Breast Cancer: This MIPS quality measure assesses the percentage of patients with a diagnosis of primary invasive breast cancer who undergo a sentinel lymph node procedure.
- Q354: Anastomotic Leak Intervention: This MIPS quality measure evaluates for anastomotic leak intervention following gastric bypass or colectomy surgery.
- Q355: Unplanned Reoperation within the 30-Day Postoperative Period: This MIPS quality measure evaluates for an unplanned reoperation within 30 days of a denominator eligible procedure.
- Q357: Surgical Site Infection (SSI): This MIPS quality measure evaluates for SSI within 30 days of a denominator eligible procedure.

- Q358: Patient-Centered Surgical Risk Assessment and Communication: This MIPS quality measure ensures a personalized surgical risk assessment is completed on each patient using a validated risk calculator or multi-institutional clinical data prior to the surgery along with discussion of the identified risks with the surgeon.
- Q445: Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG): This MIPS quality measure assesses patients undergoing isolated CABG for quality outcomes by identifying the percentage of patients who die, including all deaths occurring during CABG hospitalization and deaths occurring after discharge up to 30 days post CABG surgery.
- Q459: Back Pain After Lumbar Surgery: This MIPS quality measure evaluates patients for a decrease in back pain post lumbar surgery based upon predetermined benchmarks.
- Q461: Leg Pain After Lumbar Surgery: This MIPS quality measure evaluates patients for a decrease in leg pain post lumbar surgery based upon predetermined benchmarks.
- Q471: Functional Status After Lumbar Surgery: This MIPS quality measure evaluates patients for an increase in functional status post lumbar surgery based upon predetermined benchmarks.

The following broadly applicable MIPS quality measures are relevant to clinicians who treat patients in surgical settings. The measures assess for age-specific screenings, and follow-up actions for select measures, in addition to recommended vaccinations:

- Q047: Advance Care Plan: This MIPS quality measure assesses for medical record documentation of an advance care plan or surrogate decisions maker.
- Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure ensures patients are screened for tobacco use and if screened positive receive tobacco cessation intervention.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

Improvement Activities

We reviewed the Improvement Activities Inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We are proposing to include 12 improvement activities that reflect actions and processes undertaken by surgical care clinicians, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_BE_12: Use evidence-based decision aids to support shared decision-making
- IA_CC_15: PSH Care Coordination
- IA_CC_17: Patient Navigator Program
- IA_CC_18: Relationship-Centered Communication
- IA_ERP_6: COVID-19 Vaccine Achievement for Practice Staff
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_11: Regular review practices in place on targeted patient population needs
- IA_PSPA_7: Use of QCDR data for ongoing practice assessment and improvements
- IA_PSPA_8: Use of Patient Safety Tools

Cost Measures

We are proposing to include six MIPS cost measures within the cost performance category of this MVP, which apply to the clinical theme of surgical care. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in surgical care and align with other measures and activities within this MVP:

- Colon and Rectal Resection: This MIPS episode-based cost measure assesses costs associated with colon or rectal resections for either benign or malignant indications.
- Femoral or Inguinal Hernia Repair: This MIPS episode-based cost measure assesses costs associated with surgical procedures to repair a femoral or inguinal hernia.
- Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels: This MIPS episode-based cost measure assesses costs associated with surgery for lumbar spine fusion. This also aligns with quality measures such as Q471: Functional Status After Lumbar Surgery or Q461: Leg Pain After Lumbar Surgery.
- Lumpectomy, Partial Mastectomy, Simple Mastectomy: This MIPS episode-based cost measure assesses costs associated with partial or total mastectomy for breast cancer.
- Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing care in inpatient hospitals, including those who treat patients within the surgical settings of general surgery, neurosurgery, and cardiothoracic surgery.

- Non-Emergent Coronary Artery Bypass Graft (CABG): This MIPS episode-based cost measure assesses costs associated with CABG. This also aligns with quality measures such as Q164: Coronary Artery Bypass Graft (CABG): Prolonged Intubation or Q168: Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration.

Surgical Care MVP Tables

As stated in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those we determined best fit the clinical concept of the proposed Surgical Care MVP. We request comment on the measures and activities included in this MVP.

Symbol Key:
Single asterisk (*): existing measures and improvement activities with proposed revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component
Percent (%): attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

TABLE A.6a: Surgical Care MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(*)(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Specifications, MIPS CQMs Specifications) **(!!) Q164:** Coronary Artery Bypass Graft (CABG): Prolonged Intubation (Collection Type: MIPS CQMs Specifications) **(!!) Q167:** Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q168:** Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration (Collection Type: MIPS CQMs Specifications) **Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications) **Q264:** Sentinel Lymph Node Biopsy for Invasive Breast Cancer (Collection Type: MIPS CQMs Specifications) **(!!) Q354:** Anastomotic Leak Intervention (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q355:** Unplanned Reoperation within the 30-Day Postoperative Period (Collection Type: MIPS CQMs Specifications) **(!!) Q357:** Surgical Site Infection (SSI) (Collection Type: MIPS CQMs Specifications) **(!) Q358:** Patient-Centered Surgical Risk Assessment and Communication (Collection Type: MIPS CQMs Specifications)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High) **(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **IA_BE_12:** Use evidence-based decision aids to support shared decision-making (Medium) **IA_CC_15:** PSH Care Coordination (High) **IA_CC_17:** Patient Navigator Program (High) **IA_CC_18:** Relationship-Centered Communication (Medium) **(*) IA_ERP_6:** COVID-19 Vaccine Achievement for Practice Staff (Medium) **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **IA_PSPA_8:** Use of Patient Safety Tools (Medium)	**Colon and Rectal Resection** **Femoral or Inguinal Hernia Repair** **Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels** **Lumpectomy, Partial Mastectomy, Simple Mastectomy** **Medicare Spending Per Beneficiary (MSPB) Clinician** **Non-Emergent Coronary Artery Bypass Graft (CABG)**

Quality	Improvement Activities	Cost
(!!) Q445: Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG) (Collection Type: MIPS CQMs Specifications) **(!!) Q459:** Back Pain After Lumbar Surgery (Collection Type: MIPS CQMs Specifications) **(!!) Q461:** Leg Pain After Lumbar Surgery (Collection Type: MIPS CQMs Specifications) **(!!) Q471:** Functional Status After Lumbar Surgery (Collection Type: MIPS CQMs Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications)		

TABLE A.6b: Surgical Care MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

Group B: Modifications to Previously Finalized MVPs for the CY 2025 Performance Period/2027 MIPS Payment Year and Future Years

B.1: Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP

The B.1 tables represent the measures and activities finalized within the Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP (88 FR 88029 through 80032) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. We request comment on the proposed modifications included in this MVP.

Quality Measures

We are proposing to modify the previously finalized Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP to remove one MIPS quality measure as it is a process measure and has become standard of care, based upon MIPS performance data showing continued high performance.

- Q254: Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain

Improvement Activities

For the reasons stated in the introduction of this appendix[1023], we are proposing the following: add the proposed modified IA_ERP_6 to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; remove the weights associated with the improvement activities contained in this MVP; and remove one improvement activity being proposed for removal from MIPS:

- IA_CC_2: Implementation of improvements that contribute to more timely communication of test results

We are proposing to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity, which includes a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this proposed rule for all proposed revisions to this activity.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Single asterisk (*): existing measures and improvement activities with proposed revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component
Percent (%): attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

[1023] See Improvement Activity Policy Update and Global Inclusion of an Improvement Activity

TABLE B.1a: Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(!) Q065: Appropriate Treatment for Upper Respiratory Infection (URI) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(!) Q116:** Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis (Collection Type: MIPS CQMs Specifications) **(!) Q321:** CAHPS for MIPs Clinician/Group Survey (Collection Type: CAHPS Survey Vendor) **(*)(!) Q331:** Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse) (Collection Type: MIPS CQMs Specifications) **(!) Q415:** Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older (Collection Type: MIPS CQMs Specifications) **(!) Q416:** Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years (Collection Type: MIPS CQMs Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(!!) ACEP50:** ED Median Time from ED arrival to ED departure for all Adult Patients (Collection Type: QCDR) **(!) ACEP52:** Appropriate Emergency Department Utilization of Lumbar Spine Imaging for Atraumatic Low Back Pain (Collection Type: QCDR) **(!) ECPR46:** Avoidance of Opiates for Low Back Pain or Migraines (Collection Type: QCDR) **(!) HCPR24:** Appropriate Utilization of Vancomycin for Cellulitis (Collection Type: QCDR)	**(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **(*) IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BMH_12:** Promoting Clinician Well-Being (High) **(+)(*) IA_ERP_6:** COVID-19 Vaccine Achievement for Practice Staff (Medium) **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization (Medium) **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **IA_PSPA_15:** Implementation of an Antimicrobial Stewardship Program (ASP) (Medium)	**Emergency Medicine**

TABLE B.1b: Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

B.2: Advancing Cancer Care MVP

The B.2 tables represent the measures and activities finalized within the Advancing Cancer Care MVP (88 FR 80008 through 80011) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. We request comment on the proposed modifications included in this MVP.

Quality Measures

We are proposing to modify the previously finalized Advancing Cancer Care MVP within the quality performance category of this MVP to include six additional MIPS quality measures and one additional QCDR measure that address appropriate cancer care treatment. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP maintenance period to determine which quality measures to include in this MVP.

The following quality measures proposed within this MVP provide a meaningful and comprehensive assessment of the clinical care for clinicians providing care to patients with cancer:

- Q102: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients: This MIPS quality measure assesses overuse of bone scans for patients with prostate cancer with low incidence of recurrence receiving treatment.
- TBD: Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy: This proposed MIPS quality measure ensures timely biomarker testing for patients with a diagnosis of metastatic non-small cell lung cancer or squamous cell carcinoma of head and neck on first-line immune checkpoint inhibitor (ICI) therapy.
- TBD: Appropriate Germline Testing for Ovarian Cancer Patients: This proposed MIPS quality measure assesses patients with a diagnosed with epithelial ovarian, fallopian tube, or primary peritoneal cancer for completion germline testing within 6 months of diagnosis.
- TBD: Patient-Reported Pain Interference Following Chemotherapy among Adults with Breast Cancer: This proposed MIPS quality measure assesses pain interference following chemotherapy administered with curative intent to adult patients with breast cancer.

- TBD: Patient-Reported Fatigue Following Chemotherapy among Adults with Breast Cancer: This proposed MIPS quality measure assess fatigue following chemotherapy administered with curative intent to adult patients with breast cancer.
- TBD: Utilization of Prophylactic GCSF for Cancer Patients Receiving Low-Risk Chemotherapy (inverse measure): The intent of this QCDR measure is to assess prophylactic use of granulocyte colony stimulating factor (G-CSF) when it is not indicated for low-risk chemotherapy and is not restricted to metastatic colorectal cancer.

In addition, we are proposing the following broadly applicable MIPS quality measure, which is relevant to patients receiving cancer care and their experience of their health care treatment journey:

- Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood: This MIPS quality measure ensures palliative care clinicians and/or teams are actively engaged to ensure patients are understood in a significant and empowering way.

We are proposing to modify the previously finalized Advancing Cancer Care MVP to remove two MIPS quality measures as they are duplicative in concept to current MIPS quality measures and are being proposed for removal from MIPS:

- Q144: Oncology: Medical and Radiation - Plan of Care for Pain
- Q452: Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies

We are also proposing to remove one QCDR measure which will be replaced by TBD: Utilization of Prophylactic GCSF for Cancer Patients Receiving Low-Risk Chemotherapy (inverse measure), which has a broader denominator and is not restricted to metastatic colorectal cancer.

- PIMSH2: Oncology: Utilization of GCSF in Metastatic Colorectal Cancer

Improvement Activities

For the reasons stated in the introduction of this appendix[1024], we are proposing the following: add the proposed modified IA_ERP_6 to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; and add an additional improvement activity that addresses maintenance requests from the public, as well as addresses priority areas including food insecurity and the incorporation of patient voices into health care decision making:

- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols

For the reasons stated in the introduction of this appendix, we are proposing the following: remove the weights associated with the improvement activities contained in this MVP; and remove three improvement activities being proposed for removal from MIPS:

- IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
- IA_ERP_4: Implementation of a Personal Protective Equipment (PPE) Plan

We are proposing to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity, which includes a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this proposed rule for all proposed revisions to this activity.

Cost Measures

We are proposing to add one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of cancer care. We reviewed the MIPS cost measure inventory and considered feedback received from interested parties through the MVP maintenance process to determine the cost measures to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for clinicians who specialize in cancer care and aligns with other measures and activities included within this MVP:

- Prostate Cancer: This proposed MIPS episode-based cost measure would assess costs associated with prostate cancer. This also aligns with quality measures such as Q102: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients. We note that this is a new cost measure we are proposing to adopt as described in section IV.A.4.e.(2)(a)(iii)of this proposed rule.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): new proposed measures and improvement activities
Single asterisk (*): existing measures and improvement activities with proposed revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures

[1024] See MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity

Tilde (~): measures and improvement activities that include a health equity component
Percent (%): attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

TABLE B.2a: Advancing Cancer Care MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(*)(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(+)(!) Q102:** Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*)(!) Q143**: Oncology: Medical and Radiation – Pain Intensity Quantified (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(!) Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CAHPS Survey Vendor) **(*)(!) Q450:** Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer (Collection Type: MIPS CQMs Specifications) **(*) Q451:** RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy (Collection Type: MIPS CQMs Specifications) **(!) Q453:** Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better) (Collection Type: MIPS CQMs Specifications) **(!) Q457:** Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better) (Collection Type: MIPS CQMs Specifications) **(*) Q462:** Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy (Collection Type: eCQM Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(*) Q490:** Appropriate Intervention of Immune-related Diarrhea and/or Colitis in	**(+)(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **(*) IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **IA_BMH_12:** Promoting Clinician Well-Being (High) **IA_CC_13:** Practice Improvements to align with OpenNotes principles (Medium) **IA_CC_17:** Patient Navigator Program (High) **IA_EPA_2:** Use of telehealth services that expand practice access (Medium) **(+)(*) IA_ERP_6:** COVID-19 Vaccine Achievement for Practice Staff (Medium) **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients (Medium) **IA_PM_15:** Implementation of episodic care management practice improvements (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PM_21:** Advance Care Planning (Medium)	**(^)(+) Prostate Cancer** **Total Per Capita Cost (TPCC)**

Quality	Improvement Activities	Cost
Patients Treated with Immune Checkpoint Inhibitors (Collection Type: MIPS CQMs Specifications) **(+)(!!) Q495:** Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications) **(+)(^)(!) TBD:** Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy (Collection Type: MIPS CQMs Specifications) **(+)(^) TBD:** Appropriate Germline Testing for Ovarian Cancer Patients (Collection Type: MIPS CQMs Specifications) **(+)(^)(!!) TBD:** Patient-Reported Pain Interference Following Chemotherapy among Adults with Breast Cancer (Collection Type: MIPS CQMs Specifications) **(+)(^)(!!) TBD:** Patient-Reported Fatigue Following Chemotherapy among Adults with Breast Cancer (Collection Type: MIPS CQMs Specifications) **(!) PIMSH13:** Oncology: Mutation testing for Stage IV Lung Cancer Completed Prior to start of Targeted Therapy (Collection Type: QCDR) **(+)(!) TBD:** Utilization of Prophylactic GCSF for Cancer Patients Receiving Low-Risk Chemotherapy (inverse measure) (Collection Type: QCDR)	**IA_PSPA_13:** Participation in Joint Commission Evaluation Initiative (Medium) **IA_PSPA_16:** Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs (Medium) **IA_PSPA_28**: Completion of an Accredited Safety or Quality Improvement Program (Medium)	

TABLE B.2b: Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

B.3: Advancing Care for Heart Disease MVP

The B.3 tables represent the measures and activities finalized within the Advancing Care for Heart Disease MVP (88 FR 80022 through 80025) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. We request comment on the proposed modifications included in this MVP.

Quality Measures

We are proposing to modify the previously finalized Advancing Care for Heart Disease MVP within the quality performance category of this MVP to include one additional broadly applicable MIPS quality measure relevant to patients receiving care for heart disease. We reviewed the quality measure inventory and considered feedback received during the 2025 MVP maintenance period to determine which quality measures to include in this MVP.

- Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood: This MIPS quality measure ensures palliative care clinicians and/or teams empathize to ensure patients are understood in a significant and empowering way.

Improvement Activities

For the reasons stated in the introduction of this appendix[1025], we are proposing the following: add the proposed modified IA_ERP_6 to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; and remove the weights associated with the improvement activities contained in this MVP.

Cost

We are not proposing to modify the MIPS cost measures included within the cost performance category of this previously finalized Advancing Care for Heart Disease MVP by proposing to add or remove cost measures from the MVP.

[1025] See MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity

However, we are proposing to modify the ST-Elevation Myocardial Infarction (STEMI) with Percutaneous Coronary Intervention (PCI) cost measure, which includes a proposed measure title update. Please see section IV.A.4.e.(2)(a)(vii) of this proposed rule for all proposed revisions to this cost measure.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Single asterisk (*): existing measures and improvement activities with proposed revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component
Percent (%): attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

TABLE B.3a: Advancing Care for Heart Disease MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
Q005: Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **Q006:** Coronary Artery Disease (CAD): Antiplatelet Therapy (Collection Type: MIPS CQMs Specifications) **Q007:** Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **Q008:** Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*)(!) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **Q118:** Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤40%) (Collection Type: MIPS CQMs Specifications) **(**) Q128**: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications)	**(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_12:** Use evidence-based decision aids to support shared decision-making (Medium) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **IA_BE_25:** Drug Cost Transparency (High) **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans (Medium) **(+)(*) IA_ERP_6:** COVID-19 Vaccine Achievement for Practice Staff (Medium) **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_13:** Chronic care and preventative care management for empaneled patients (Medium) **(~) IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high-risk patients	**Elective Outpatient Percutaneous Coronary Intervention (PCI)** **Heart Failure** **(*) ST-Elevation Myocardial Infarction (STEMI) with Percutaneous Coronary Intervention (PCI)** **Medicare Spending Per Beneficiary (MSPB) Clinician** **Total Per Capita Cost (TPCC)**

Quality	Improvement Activities	Cost
(*)(!) **Q238:** Use of High-Risk Medications in Older Adults (Collection Type: eCQM Specifications, MIPS CQMs Specifications) (!) **Q243:** Cardiac Rehabilitation Patient Referral from an Outpatient Setting (Collection Type: MIPS CQMs Specifications) **Q326:** Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy (Collection Type: MIPS CQMs Specifications) (!) **Q377:** Functional Status Assessments for Heart Failure (Collection Type: eCQM Specifications) (!!) **Q392:** Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation (Collection Type: MIPS CQMs Specifications) (*)(!!) **Q393:** Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision (Collection Type: MIPS CQMs Specifications) (!!) **Q441:** Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQMs Specifications) (~)(!) **Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) (*)(!!) **Q492:** Risk-Standardized Acute Cardiovascular-Related Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System (Collection Type: Administrative Claims) (+)(!!) **Q495:** Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQMs Specifications) (*)(!!) **Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications)	(Medium) **IA_PSPA_4:** Administration of the AHRQ Survey of Patient Safety Culture (Medium) (~) **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium)	

TABLE B.3b: Advancing Care for Heart Disease MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

B.4: Advancing Rheumatology Patient Care MVP

The B.4 tables represent the measures and activities finalized within the Advancing Rheumatology Patient Care MVP (88 FR 80026 through 80029) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. We request comment on the proposed modifications included in this MVP.

Quality Measures

We are proposing to modify the previously finalized Advancing Rheumatology Patient Care MVP within the quality performance category of this MVP to include one additional MIPS quality measure and two QCDR measures that are relevant to patients receiving rheumatology care. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP maintenance period to determine which quality measures to include in this MVP.

The following quality measures proposed within this MVP provide address appropriate clinical care for patients with rheumatological conditions:

- Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age: This MIPS quality measure assesses women who have ever received a dual-energy x-ray absorptiometry (DXA) test to evaluate for the disease osteoporosis.
- UREQA2: Ankylosing Spondylitis: Appropriate Pharmacologic Therapy: This QCDR measure assesses patients newly diagnosed with ankylosing spondylitis for appropriate pharmacologic therapy by ensuring a course of NSAIDs is prescribed before initiation of biologics during the first six months of treatment.
- UREQA9: Screening for Osteoporosis for Men Aged 70 Years and Older: This QCDR measure identifies male patients who have ever had a central dual-energy X-ray absorptiometry (DXA) to screen for osteoporosis to identify osteoporotic risk for fracture.

Improvement Activities

For the reasons stated in the introduction of this appendix[1026], we are proposing the following: add the proposed modified IA_ERP_6 to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; remove

[1026] See MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity

the weights associated with the improvement activities contained in this MVP; and remove one improvement activities being proposed for removal from MIPS:

- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record

We are proposing to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity, which includes a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this proposed rule for all proposed revisions to this activity.

Cost Measures

We are proposing to add one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of rheumatology care. We reviewed the MIPS cost measure inventory and considered feedback received from interested parties through the MVP maintenance process to determine the cost measures to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for clinicians who specialize in rheumatology care and aligns with the other measures and activities included within this MVP:

- Rheumatoid Arthritis: This proposed MIPS episode-based cost measure would assess costs associated with medical care to manage and treat rheumatoid arthritis. This also aligns with quality measures such as Q177: Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity or Q178: Rheumatoid Arthritis (RA): Functional Status Assessment. We note that this is a new cost measure we are proposing to adopt as described in section IV.A.4.e.(2)(a)(iii) of this proposed rule.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): new proposed measures and improvement activities
Single asterisk (*): existing measures and improvement activities with proposed revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component
Percent (%): attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

TABLE B.4a: Advancing Rheumatology Patient Care MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(+) Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specification) **(*)(!) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q176:** Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy (Collection Type: MIPS CQMs Specifications) **(*) Q177:** Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity (Collection Type: MIPS CQMs Specifications) **(*) Q178:** Rheumatoid Arthritis (RA): Functional Status Assessment (Collection Type: MIPS CQMs Specifications)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High) **(~) IA_BE_1:** Use of certified EHR to capture patient reported outcomes (Medium) **(*) IA_BE_4**: Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **IA_BE_25**: Drug Cost Transparency (High) **IA_BMH_2:** Tobacco use (Medium) **IA_EPA_2:** Use of telehealth services that expand practice access (Medium)	**(^)(+) Rheumatoid Arthritis** **Total Per Capita Cost (TPCC)**

Quality	Improvement Activities	Cost
(*) Q180: Rheumatoid Arthritis (RA): Glucocorticoid Management (Collection Type: MIPS CQMs Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(*) Q493:** Adult Immunization Status (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications) **ACR12:** Disease Activity Measurements for Patients with PsA (Collection Type: QCDR) **(!!) ACR14:** Gout Serum Urate Target (Collection Type: QCDR) **(!) ACR15:** Safe Hydroxychloroquine Dosing (Collection Type: QCDR) **(+)(!) UREQA2:** Ankylosing Spondylitis: Appropriate Pharmacologic Therapy (Collection Type: QCDR) **(+) UREQA9:** Screening for Osteoporosis for Men Aged 70 Years and Older (Collection Type: QCDR) **(!!) UREQA10:** Ankylosing Spondylitis: Controlled Disease Or Improved Disease Function (Collection Type: QCDR)	**(+)(*) IA_ERP_6:** COVID-19 Vaccine Achievement for Practice Staff (Medium) **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PSPA_28:** Completion of an Accredited Safety or Quality Improvement Program (Medium)	

TABLE B.4b: Advancing Rheumatology Patient Care MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

B.5: Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP

The B.5 tables represent the measures and activities finalized within the Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP (88 FR 80039 through 80041) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. We request comment on the proposed modifications included in this MVP.

Quality Measures

We are proposing to modify the previously finalized Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP to include one additional broadly applicable MIPS quality measure relevant to patients receiving stroke care and their experience of their health care treatment journey. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP maintenance period to determine which quality measures to include in this MVP.

- Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood: This MIPS quality measure ensures palliative care clinicians and/or teams empathize to ensure patients are understood in a significant and empowering way.

We are also proposing to modify the previously finalized Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP to remove one MIPS quality measure as this measure is proposed for removal from MIPS:

- Q409: Clinical Outcome Post Endovascular Stroke Treatment

We are proposing to modify the Q344: Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) quality measure, which includes a proposed measure title update. Please see Appendix 1: MIPS Quality Measures, Table Group D of this proposed rule for all proposed revisions to this measure.

Improvement Activities

For the reasons stated in the introduction of this appendix[1027], we are proposing the following: add the proposed modified IA_ERP_6 to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; remove

[1027] See MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity

the weights associated with the improvement activities contained in this MVP; and remove one improvement activity being proposed for removal from MIPS:

- IA_CC_2: Implementation of improvements that contribute to more timely communication of test results

We are proposing to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity, which includes a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this proposed rule for all proposed revisions to this activity.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Single asterisk (*): existing measures and improvement activities with proposed revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component
Percent (%): attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

TABLE B.5a: Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(*)(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **Q187:** Stroke and Stroke Rehabilitation: Thrombolytic Therapy (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **Q326:** Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q344:** Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q413:** Door to Puncture Time for Endovascular Stroke Treatment (Collection Type: MIPS CQMs Specifications) **Q438**: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(!!) Q441**: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQMs Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(+)(!!) Q495**: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQMs Specifications)	**(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **(~) IA_BE_1:** Use of certified EHR to capture patient reported outcomes (Medium) **(*) IA_BE_4**: Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_24:** Financial Navigation Program (Medium) **(~) IA_BMH_15:** Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults (High) **IA_CC_13:** Practice improvements to align with OpenNotes principles (Medium) **IA_CC_17:** Patient Navigator Program (High) **(+)(*) IA_ERP_6:** COVID-19 Vaccine Achievement for Practice Staff (Medium) **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_13:** Chronic care and preventative care management for empaneled patients (Medium) **IA_PM_15:** Implementation of episodic care management practice improvements (Medium)	**Intracranial Hemorrhage or Cerebral Infarction**

TABLE B.5b: Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

B.6: Focusing on Women's Health MVP

The B.6 tables represent the measures and activities finalized within the Focusing on Women's Health MVP (88 FR 79981 through 79986) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. We request comment on the proposed modifications included in this MVP.

Quality Measures

We are proposing to modify the previously finalized Focusing on Women's Health MVP within the quality performance category of this MVP to include to include one additional MIPS quality measure that is relevant to women's health. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP maintenance period to determine which quality measures to include in this MVP.

The following quality measure proposed within this MVP provides a meaningful and comprehensive assessment of the clinical care for clinicians providing women's health care to patients:

- Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age: This MIPS quality measure assesses women who have ever received a dual-energy x-ray absorptiometry (DXA) test to evaluate for the disease osteoporosis.

We are also proposing to modify the previously finalized Focusing on Women's Health MVP to remove one MIPS quality measure as it is a process measure that has become standard of care, based on MIPS performance data as demonstrated by the measure's high performance in the PY2024 MIPS Historical Quality Benchmarks file, as well as previous year's benchmark data, and is being proposed for removal from MIPS:

- Q472: Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture

We are proposing to modify the Q432: Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair quality measure, which includes a proposed measure title update. Please see Appendix 1: MIPS Quality Measures, Table Group D of this proposed rule for all proposed revisions to this measure.

Improvement Activities

For the reasons stated in the introduction of this appendix[1028], we are proposing the following: add the modified proposed IA_ERP_6 to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; and remove the weights associated with the improvement activities contained in this MVP.

We are proposing to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity, which includes a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this proposed rule for all proposed revisions to this activity.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Single asterisk (*): existing measures and improvement activities with proposed revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component
Percent (%): attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

TABLE B.6a: Focusing on Women's Health MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(+) Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specification) **Q048:** Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older (Collection Type: MIPS CQMs Specifications) **(*)(**) Q112:** Breast Cancer Screening (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specification) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specification) **Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specification) **Q309:** Cervical Cancer Screening (Collection Type: eCQM Specifications) **Q310:** Chlamydia Screening in Women (Collection Type: eCQM Specifications) **(!!) Q335:** Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse) (Collection Type: MIPS CQMs Specifications) **(*)(!) Q336:** Maternity Care: Postpartum Follow-up and Care Coordination (Collection Type: MIPS CQMs Specifications) **Q400:** One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation	**(~) IA_AHE_1:** Enhance Engagement of Medicaid and Other Underserved Populations (High) **(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High) **(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **(*) IA_BE_4**: Engagement of patients through implementation of improvements in patient portal (Medium) **(~) IA_BE_16:** Promote Self-management in Usual Care (Medium) **(~) IA_BMH_11:** Implementation of a Trauma-Informed Care (TIC) Approach to Clinical Practice (Medium) **(~) IA_BMH_14:** Behavioral/Mental Health and Substance Use Screening and Referral for Pregnant and Postpartum Women (High) **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans (Medium) **IA_EPA_2:** Use of telehealth services that expand practice access (Medium)	**Medicare Spending Per Beneficiary (MSPB) Clinician** **Total Per Capita Cost (TPCC)**

[1028] See MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity

Quality	Improvement Activities	Cost
(Collection Type: MIPS CQMs Specifications) **(!) Q422:** Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **Q431:** Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q432:** Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair (Collection Type: MIPS CQMs Specifications) **(*)(!) Q448:** Appropriate Workup Prior to Endometrial Ablation (Collection Type: MIPS CQMs Specifications) **Q475:** HIV Screening (Collection Type: eCQM Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(*) Q493:** Adult Immunization Status (Collection Type: MIPS CQMs Specifications) **Q496:** Cardiovascular Disease (CVD) Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument (Collection Type: MIPS CQMs Specifications) **(!!) UREQA8:** Vitamin D level: Effective Control of Low Bone Mass/Osteopenia and Osteoporosis: Therapeutic Level Of 25 OH Vitamin D Level Achieved (Collection Type: QCDR)	**(+)(*) IA_ERP_6:** COVID-19 Vaccine Achievement for Practice Staff (Medium) **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_6:** Use of toolsets or other resources to close healthcare disparities across communities (Medium) **(~) IA_PM_23:** Use of Computable Guidelines and Clinical Decision Support to Improve Adherence for Cervical Cancer Screening and Management Guidelines (High)	

TABLE B.6b: Focusing on Women's Health MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

B.7: Improving Care for Lower Extremity Joint Repair MVP

The B.7 tables represent the measures and activities finalized within the Improving Care for Lower Extremity Joint Repair MVP (88 FR 80033 through 80035) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. We request comment on the proposed modifications included in this MVP.

Improvement Activities

For the reasons stated in the introduction of this appendix[1029], we are proposing the following: add the proposed modified IA_ERP_6 to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; and add an additional improvement activity that addresses maintenance requests from the public, as well as addresses priority areas including food insecurity and the incorporation of patient voices into health care decision making:

- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols

In addition, we are proposing the following: remove the weights associated with the improvement activities contained in this MVP; and remove one improvement activity being proposed for removal from MIPS:

- IA_PSPA_27: Invasive Procedure or Surgery Anticoagulation Medication Management

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Single asterisk (*): existing measures and improvement activities with proposed revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component
Percent (%): attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

[1029] See MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity

TABLE B.7a: Improving Care for Lower Extremity Joint Repair MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(!) Q024: Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(!) Q350:** Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy (Collection Type: MIPS CQMs Specifications) **(!) Q351:** Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation (Collection Type: MIPS CQMs Specifications) **(*)(!) Q376:** Functional Status Assessment for Total Hip Replacement (Collection Type: eCQM Specifications) **(*)(!!) Q470:** Functional Status After Primary Total Knee Replacement (Collection Type: MIPS CQMs Specifications) **(!!) Q480:** Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS) (Collection Type: Administrative Claims) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High) **(+)(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium Weight) (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_12** Use evidence-based decision aids to support shared decision-making (Medium) **IA_CC_7:** Regular training in care coordination (Medium) **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans (Medium) **IA_CC_13:** Practice improvements to align with OpenNotes principles (Medium) **IA_CC_15:** PSH Care Coordination (High) **(+)(*) IA_ERP_6:** COVID-19 Vaccine Achievement for Practice Staff (Medium) **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **(~) IA_PSPA_18:** Measurement and improvement at the practice and panel level (Medium)	**Elective Primary Hip Arthroplasty** **Knee Arthroplasty**

TABLE B.7b: Improving Care for Lower Extremity Joint Repair MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

B.8: Optimal Care for Kidney Health MVP

The B.8 tables represent the measures and activities finalized within the Optimal Care for Kidney Health MVP (88 FR 80012 through 80015) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. We request comment on the proposed modifications included in this MVP.

Quality Measures

We are proposing to modify the previously finalized Optimal Care for Kidney Health MVP within the quality performance category of this MVP to include three additional broadly applicable MIPS quality measures that are relevant to patients receiving care for kidney health. We reviewed the quality measure inventory and considered feedback received during the 2025 MVP maintenance period to determine which quality measures to include in this MVP.

- Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood: This MIPS quality measure ensures palliative care clinicians and/or teams empathize to ensure patients are understood in a significant and empowering way.
- TBD: First Year Standardized Waitlist Ratio (FYSWR): This MIPS quality measure measures number of incident (newly initiated on dialysis) patients in a practitioner (inclusive of physicians and advanced practice providers) groups who were listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant within the first year of initiating dialysis.
- TBD: Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW): This MIPS quality measure tracks dialysis patients who at a practitioner group practice who were on the kidney or kidney-pancreas transplant waitlist (all patients or patients in active status).

We are proposing to modify the Q001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%) quality measure, which includes a proposed measure title update. Please see Appendix 1: MIPS Quality Measures, Table Group D of this proposed rule for all proposed revisions to this measure.

Improvement Activities

For the reasons stated in the introduction of this appendix[1030], we are proposing the following: add the proposed modified IA_ERP_6 to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; remove the weights associated with the improvement activities contained in this MVP; and remove one improvement activity being proposed for removal from MIPS:

- IA_CC_2: Implementation of improvements that contribute to more timely communication of test results

We are proposing to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity, which includes a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this proposed rule for all proposed revisions to this activity.

Cost Measures

We are proposing to add three MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic of kidney health. We reviewed the MIPS cost measure inventory and considered feedback received from interested parties through the MVP maintenance process to determine the cost measures to include in this MVP. The following proposed new cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in kidney care and align with the other measures and activities included within this MVP and are described in section IV.A.4.e(2)(a)(iii) of this proposed rule:

- Chronic Kidney Disease (CKD): This proposed MIPS episode-based cost measure would assess costs associated with medical care to manage and treat stage 4 or 5 chronic kidney disease.
- End-Stage Renal Disease (ESRD): This proposed MIPS episode-based cost measure would assess costs associated with medical care to manage ESRD.
- Kidney Transplant Management: This proposed MIPS episode-based cost measure would assess costs associated with medical care related to kidney transplant, beginning no sooner than 90 days post-transplant.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): new proposed measures and improvement activities
Single asterisk (*): existing measures and improvement activities with proposed revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component
Percent (%): attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

TABLE B.8a: Optimal Care for Kidney Health MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(*)(!!) Q001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%) (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*)(!) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*)(!) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*)(!!) Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(!!) Q482:** Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate (Collection Type: MIPS CQMs Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High) **(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **(*) IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **(~) IA_BE_14:** Engage Patients and Families to Guide Improvement in the System of Care (High) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium)	**Acute Kidney Injury Requiring New Inpatient Dialysis (AKI)** **(^)(+) Chronic Kidney Disease (CKD)** **(^)(+) End-Stage Renal Disease (ESRD)** **(^)(+) Kidney Transplant Management** **Total Per Capita Cost (TPCC)**

[1030] See MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity

Quality	Improvement Activities	Cost
(Collection Type: MIPS CQMs Specifications) **(*) Q488:** Kidney Health Evaluation (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **Q489:** Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy (Collection Type: MIPS CQMs Specifications) **(*) Q493:** Adult Immunization Status (Collection Type: MIPS CQMs Specifications) **(+)(!!) Q495:** Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications) **(+)(^) TBD:** First Year Standardized Waitlist Ratio (FYSWR) (Collection Type: MIPS CQMs Specifications) **(+)(^) TBD:** Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) (Collection Type: MIPS CQMs Specifications)	**(~) IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_CC_13:** Practice improvements to align with OpenNotes principles (Medium) **(+)(*) IA_ERP_6:** COVID-19 Vaccine Achievement for Practice Staff (Medium) **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **IA_PM_13:** Chronic care and preventative care management for empaneled patients (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PSPA_16:** Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs (Medium)	

TABLE B.8b: Optimal Care for Kidney Health MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

B.9: Patient Safety and Support of Positive Experiences with Anesthesia MVP

The B.9 tables represent the measures and activities finalized within the Patient Safety and Support of Positive Experiences with Anesthesia MVP (88 FR 80036 through 80038) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. We request comment on the proposed modifications included in this MVP.

Improvement Activities

For the reasons stated in the introduction of this appendix[1031], we are proposing the following: add the proposed modified IA_ERP_6 to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; remove the weights associated with the improvement activities contained in this MVP; and remove two improvement activities being proposed for removal from MIPS:

- IA_CC_2: Implementation of improvements that contribute to more timely communication of test results
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Single asterisk (*): existing measures and improvement activities with proposed revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component
Percent (%): attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

TABLE B.9a: Patient Safety and Support of Positive Experiences with Anesthesia MVP Measures and Improvement Activities

[1031] See MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity

Quality	Improvement Activities	Cost
(!!) Q404: Anesthesiology Smoking Abstinence (Collection Type: MIPS CQMs Specifications) **(!!) Q424:** Perioperative Temperature Management (Collection Type: MIPS CQMs Specifications) **(!) Q430:** Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy (Collection Type: MIPS CQMs Specifications) **(!) Q463:** Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics) (Collection Type: MIPS CQMs Specifications) **(!) Q477:** Multimodal Pain Management (Collection Type: MIPS CQMs Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(!) ABG44:** Low Flow Inhalational General Anesthesia (Collection Type: QCDR) **(!!) AQI48:** Patient-Reported Experience with Anesthesia (Collection Type: QCDR) **(!!) EPREOP31:** Intraoperative Hypotension (IOH) among Non-Emergent Noncardiac Surgical Cases (Collection Type: QCDR)	**IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_22:** Improved practices that engage patients pre-visit (Medium) **IA_BMH_2:** Tobacco use (Medium) **IA_CC_15:** PSH Care Coordination (High) **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes (High) **(+)(*) IA_ERP_6:** COVID-19 Vaccine Achievement for Practice Staff (Medium) **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization (Medium) **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **IA_PSPA_16:** Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs (Medium)	**Medicare Spending Per Beneficiary (MSPB) Clinician**

TABLE B.9b: Patient Safety and Support of Positive Experiences with Anesthesia MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

B.10: Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP

The B.10 tables represent the measures and activities finalized within the Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP (88 FR 79991 through 79995) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. We request comment on the proposed modifications included in this MVP.

Quality Measures

We are not proposing to modify the previously finalized Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP within the quality performance category of this MVP by proposing to add or remove quality measures from the MVP. However, we are proposing to modify the Q340: HIV Medical Visit Frequency quality measure, which includes a proposed measure title update. Please see Appendix 1: MIPS Quality Measures, Table Group D of this proposed rule for all proposed revisions to this measure.

Improvement Activities

For the reasons stated in the introduction of this appendix[1032], we are proposing the following: add the proposed modified IA_ERP_6 to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; remove the weights associated with the improvement activities contained in this MVP; and remove one improvement activity being proposed for removal from MIPS:

- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups who Have Real-Time Access to Patient's Medical Record

We are proposing to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity, which includes a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this proposed rule for all proposed revisions to this activity.

[1032] See MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Single asterisk (*): existing measures and improvement activities with proposed revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component
Percent (%): attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

TABLE B.10a: Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(!) Q065: Appropriate Treatment for Upper Respiratory Infection (URI) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*)(!) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM Specifications, MIPS CQMs Specification) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specification) **Q205:** Sexually Transmitted Infection (STI) Testing for People with HIV (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **Q240:** Childhood Immunization Status (Collection Type: eCQM Specifications) **Q310:** Chlamydia Screening in Women (Collection Type: eCQM Specifications) **(!!) Q338:** HIV Viral Suppression (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*)(!) Q340:** HIV Medical Visit Frequency (Collection Type: MIPS CQMs Specifications) **Q387:** Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users (Collection Type: MIPS CQMs Specifications) **Q400:** One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation (Collection Type: MIPS CQMs Specifications) **Q401:** Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis (Collection Type: MIPS CQMs Specifications) **Q475:** HIV Screening (Collection Type: eCQM Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(*) Q493:** Adult Immunization Status (Collection Type: MIPS CQMs Specifications)	**(~) IA_AHE_1:** Enhance Engagement of Medicaid and Other Underserved Populations (High) **(~) IA_AHE_5:** MIPS Eligible Clinician Leadership in Clinical Trials or CBPR (Medium) **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **(*) IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **(+)(*) IA_ERP_6:** COVID-19 Vaccine Achievement for Practice Staff (Medium) **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_6:** Use of toolsets or other resources to close healthcare disparities across communities (Medium) **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **(~) IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients (Medium) **(~) IA_PM_22:** Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services (Medium) **IA_PSPA_23:** Completion of CDC Training on Antibiotic Stewardship (High) **IA_PSPA_32:** Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support (High)	**Total Per Capita Cost (TPCC)**

TABLE B.10b: Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

B.11: Quality Care for Patients with Neurological Conditions MVP

We are proposing to modify the previously finalized Optimal Care for Patients with Episodic Neurological Conditions and the Supportive Care for Neurodegenerative Conditions MVPs into a single consolidated neurological MVP titled Quality Care for Patients with Neurological Conditions. This modification is being proposed because the QCDR measures previously included will no longer be available for use within both of the previously finalized MVPs. As such, due to the removal of these specialty specific QCDR measures we believe the Episodic Neurological Conditions MVP no longer provides a meaningful representation of the care provided by the clinicians identified for reporting this MVP. Therefore, we are proposing to combine the previously finalized MVPs to ensure the availability of a robust and meaningful MVP capturing a broad scope of care provided by neurologists. The B.11 tables represent the measures and activities finalized within the Optimal Care for Patients with Episodic Neurological Conditions MVP (88 FR 80015 through 80018) and the Supportive Care for Neurodegenerative Conditions MVP (88 FR 80019 through 80021) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. We request comment on the proposed modifications included in this MVP.

Quality Measures

We are proposing to modify the previously finalized neurology MVPs within the quality performance category of this MVP to include two additional broadly applicable MIPS quality measures relevant to patients receiving care for neurodegenerative disorders. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

- Q155: Falls: Plan of care: This MIPS quality measure ensures adult patients, with a history of falls, have a plan of care for falls.
- Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood: This MIPS quality measure ensures palliative care clinicians and/or teams empathize to ensure patients are understood in a significant and empowering way.

We are proposing to modify the previously finalized MVPs to remove six QCDR measures no longer being supported by Axon Registry QCDR:

- AAN5: Treatment Prescribed for Acute Migraine Attack
- AAN9: Querying and Follow-Up About Symptoms of Autonomic Dysfunction for Patients with Parkinson's Disease
- AAN22: Quality of Life Outcome for Patients with Neurologic Conditions
- AAN31: Acute Treatment Prescribed for Cluster Headache
- AAN32: Preventive Treatment Prescribed for Cluster Headache

- AAN34: Patient reported falls and plan of care

Improvement Activities

For the reasons stated in the introduction of this appendix[1033], we are proposing the following: add the proposed modified IA_ERP_6 to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; remove the weights associated with the improvement activities contained in this MVP; and remove three improvement activities being proposed for removal from MIPS:

- IA_BMH_8: Electronic Health Record Enhancements for BH data capture
- IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record

We are proposing to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity, which includes a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this proposed rule for all proposed revisions to this activity.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Single asterisk (*): existing measures and improvement activities with proposed revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component
Percent (%): attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

TABLE B.11a: Quality Care for Patients with Neurological Conditions MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(*)(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*)(!) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(+)(*)(!) Q155:** Falls: Plan of Care (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*)(!) Q238:** Use of High-Risk Medications in Older Adults (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **Q268:** Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy (Collection Type: MIPS CQMs Specifications) **(*) Q281:** Dementia: Cognitive Assessment (Collection Type: eCQM Specifications) **(*) Q282:** Dementia: Functional Status Assessment (Collection Type: MIPS CQMs Specifications) **(*)(!) Q286:** Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia (Collection Type: MIPS CQMs Specifications)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High) **(*) IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **(~) IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **IA_BMH_4:** Depression screening (Medium) **IA_EPA_2:** Use of telehealth services that expand practice access (Medium) **(+)(*) IA_ERP_6:** COVID-19 Vaccine Achievement for Practice Staff (Medium) **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High)	**Medicare Spending Per Beneficiary (MSPB) Clinician**

[1033] See MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity

Quality	Improvement Activities	Cost
(*)(!) Q288: Dementia: Education and Support of Caregivers for Patients with Dementia (Collection Type: MIPS CQMs Specifications) **(*) Q290:** Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease (Collection Type: MIPS CQMs Specifications) **(*) Q291:** Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease (Collection Type: MIPS CQMs Specifications) **(*)(!) Q293:** Rehabilitative Therapy Referral for Patients with Parkinson's Disease (Collection Type: MIPS CQMs Specifications) **(*)(!) Q386:** Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences (Collection Type: MIPS CQMs Specifications) **(!) Q419:** Overuse of Imaging for the Evaluation of Primary Headache (Collection Type: MIPS CQMs Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(+)(!!) Q495:** Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications)	**(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PM_21:** Advance Care Planning (Medium) **IA_PSPA_21:** Implementation of fall screening and assessment programs (Medium)	

TABLE B.11b: Quality Care for Patients with Neurological Conditions MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

B.12: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP

The B.12 tables represent the measures and activities finalized within the Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP (88 FR 79986 through 79990) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. We request comment on the proposed modifications included in this MVP.

Quality Measures

We are proposing to modify the previously finalized Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP within the quality performance category of this MVP to remove two QCDR measures whose quality actions reflect a standard of care based upon clinical guidelines recognized as best practices by health care clinicians. Based upon MIPS performance data, AAO16 is high performing and AAO23 has had minimal variation in its historical benchmark. Though allergic rhinitis falls within the spectrum of care otolaryngologists provide, the complexity of caring for the condition is typically low. Many non-surgical clinician specialties, including primary care, treat allergic rhinitis regularly. Further, measure AAO23 requires the use of medications that all are available over the counter. Removal of AAO23 will encourage use of other measures within the MVP that represent the complexity of care otolaryngologists provide.

- AAO16: Age-Related Hearing Loss: Audiometric Evaluation
- AAO23: Allergic Rhinitis: Intranasal Corticosteroids or Oral Antihistamines

Improvement Activities

For the reasons stated in the introduction of this appendix[1034], we are proposing the following: add the proposed modified IA_ERP_6 to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; remove the weights associated with the improvement activities contained in this MVP; and remove two improvement activities being proposed for removal from MIPS:

- IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record

[1034] See MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity

We are proposing to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity, which includes a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this proposed rule for all proposed revisions to this activity.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Single asterisk (*): existing measures and improvement activities with proposed revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component
Percent (%): attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

TABLE B.12a: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(**) Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specification) **Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specification) **(*) Q277:** Sleep Apnea: Severity Assessment at Initial Diagnosis (Collection Type: MIPS CQMs Specifications) **(*)(!) Q331:** Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse) (Collection Type: MIPS CQMs Specifications) **(!) Q332:** Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use) (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q355:** Unplanned Reoperation within the 30 Day Postoperative Period (Collection Type: MIPS CQMs Specifications) **(!!) Q357:** Surgical Site Infection (SSI) (Collection Type: MIPS CQMs Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **AAO20:** Tympanostomy Tubes: Comprehensive Audiometric Evaluation (Collection Type: QCDR) **AAO21:** Otitis Media with Effusion (OME): Comprehensive Audiometric Evaluation for Chronic OME > or = 3 months (Collection Type: QCDR)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High) **(~) IA_AHE_5:** MIPS Eligible Clinician Leadership in Clinical Trials or CBPR (Medium) **(*) IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **IA_CC_13:** Practice improvements to align with OpenNotes principles (Medium) **(+)(*) IA_ERP_6:** COVID-19 Vaccine Achievement for Practice Staff (Medium) **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_16:** Implementation of medication management practice improvements (Medium) **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium)	**Medicare Spending Per Beneficiary (MSPB) Clinician**

TABLE B.12b: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

B.13: Quality Care in Mental Health and Substance Use Disorders MVP

The B.13 tables represent the measures and activities finalized within the Quality Care in Mental Health and Substance Use Disorders MVP (88 FR 79986 through 80001) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. We request comment on the proposed modifications included in this MVP.

Improvement Activities

For the reasons stated in the introduction of this appendix[1035], we are proposing the following: add the proposed modified IA_ERP_6 to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; and remove the weights associated with the improvement activities contained in this MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Single asterisk (*): existing measures and improvement activities with proposed revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component
Percent (%): attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

[1035] See MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity

TABLE B.13a: Quality Care in Mental Health and Substance Use Disorders MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(*) Q009: Antidepressant Medication Management (Collection Type: eCQM Specifications) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specification) **(!) Q305:** Initiation and Engagement of Substance Use Disorder Treatment (Collection Type: eCQM Specifications) **Q366:** Follow-Up Care for Children Prescribed ADHD Medication (ADD) (Collection Type: eCQM Specifications) **(!!) Q370:** Depression Remission at Twelve Months (Collection Type: eCQM Specifications, MIPS CQMs Specification) **(!) Q382:** Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment (Collection Type: eCQM Specifications) **(*)(!!) Q383:** Adherence to Antipsychotic Medications For Individuals with Schizophrenia (Collection Type: MIPS CQMs Specifications) **(!) Q468:** Continuity of Pharmacotherapy for Opioid Use Disorder (OUD) (Collection Type: MIPS CQMs Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(!!) Q502:** Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder (Collection Type: MIPS CQMs Specifications) **(!) Q504:** Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q505:** Reduction in Suicidal Ideation or Behavior Symptoms (Collection Type: MIPS CQMs Specifications) **(!!) MBHR2:** Anxiety Response at 6-months (Collection Type: QCDR) **(!!) MBHR7:** Posttraumatic Stress Disorder (PTSD) Outcome Assessment for Adults and Children (Collection Type: QCDR)	**(~) IA_AHE_1:** Enhance Engagement of Medicaid and Other Underserved Populations (High) **(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High) **(~) IA_AHE_5:** MIPS Eligible Clinician Leadership in Clinical Trials or CBPR (Medium) **(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **IA_BE_12:** Use evidence-based decision aids to support shared decision-making. (Medium) **(~) IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_BE_23:** Integration of patient coaching practices between visits (Medium) **IA_BMH_2:** Tobacco use (Medium) **IA_BMH_5:** MDD prevention and treatment interventions (Medium) **(~) IA_BMH_7:** Implementation of Integrated Patient Centered Behavioral Health Model (High) **(~) IA_BMH_14:** Behavioral/Mental Health and Substance Use Screening and Referral for Pregnant and Postpartum Women **(~) IA_BMH_15:** Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults (High) **IA_EPA_2:** Use of telehealth services that expand practice access (Medium) **(+)(*) IA_ERP_6:** COVID-19 Vaccine Achievement for Practice Staff (Medium) **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation	**Medicare Spending Per Beneficiary (MSPB) Clinician** **Depression** **Psychoses and Related Conditions**

Quality	Improvement Activities	Cost
	(~) **IA_PM_6:** Use of toolsets or other resources to close healthcare disparities across communities (Medium) **IA_PSPA_32:** Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support (High)	

TABLE B.13b: Quality Care in Mental Health and Substance Use Disorders MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) **Q479:** Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) (!!) **Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

B.14: Rehabilitative Support for Musculoskeletal Care MVP

The B.14 tables represent the measures and activities finalized within the Rehabilitative Support for Musculoskeletal Care MVP (88 FR 80002 through 80007) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. We request comment on the proposed modifications included in this MVP.

Quality Measures

We are proposing to modify the previously finalized Rehabilitative Support for Musculoskeletal Care MVP within the quality performance category of this MVP to include one additional MIPS quality measure and four QCDR measures that are relevant to patients receiving rehabilitative support for Musculoskeletal Care. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

- Q050: Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older: This MIPS quality measure ensures that female patients with a diagnosis of urinary incontinence have a documented plan of care regarding rehabilitative treatment for urinary incontinence at least once within 12 months. A rehabilitation plan of care for these patients would address the musculoskeletal impairments of the pelvic floor related to urinary incontinence in women.
- MSK6: Patients Suffering From a Neck Injury who Improve Pain: This QCDR measure evaluates patients with a neck

injury for achieving the minimal clinically important difference (MCID) improvement in pain by the end of treatment.
- MSK7: Patients Suffering From an Upper Extremity Injury who Improve Pain: This QCDR measure evaluates patients with an upper extremity injury for achieving the minimal clinically important difference (MCID) improvement in pain by the end of treatment.
- MSK8: Patients Suffering From a Back Injury who Improve Pain: This QCDR measure evaluates patients with a back injury for achieving the minimal clinically important difference (MCID) improvement in pain by the end of treatment.
- MSK9: Patients Suffering From a Lower Extremity Injury who Improve Pain: This QCDR measure evaluates patients with a lower extremity injury for achieving the minimal clinically important difference (MCID) improvement in pain by the end of treatment.

Improvement Activities

For the reasons stated in the introduction of this appendix[1036], we are proposing the following: add the proposed modified IA_ERP_6 to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; remove the weights associated with the improvement activities contained in this MVP; and remove two improvement activities being proposed for removal from MIPS:
- IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Single asterisk (*): existing measures and improvement activities with proposed revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component
Percent (%): attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category
Pound sign (#): QCDR measures pending testing data

TABLE B.14a: Rehabilitative Support for Musculoskeletal Care MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(+)(!) Q050: Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older (Collection Type: MIPS CQMs Specifications) **(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specification) **(*)(!) Q155:** Falls: Plan of Care (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specification) **(!!) Q217:** Functional Status Change for Patients with Knee Impairments (Collection Type: MIPS CQMs Specifications) **(!!) Q218:** Functional Status Change for Patients with Hip Impairments (Collection Type: MIPS CQMs Specifications) **(!!) Q219:** Functional Status Change with Lower Leg, Foot or Ankle Impairments (Collection Type: MIPS CQMs Specifications) **(!!) Q220:** Functional Status Change for Patients with Low Back Impairments (Collection Type: MIPS CQMs Specifications)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High) **(~) IA_AHE_6:** Provide Education Opportunities for New Clinicians (High) **(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BMH_12:** Promoting Clinician Well-Being (High) **(~) IA_BMH_15:** Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults (High) **IA_CC_8:** Implementation of documentation	**Low Back Pain**

[1036] See MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity

Quality	Improvement Activities	Cost
(!!) Q221: Functional Status Change for Patients with Shoulder Impairments (Collection Type: MIPS CQMs Specifications) **(!!) Q222:** Functional Status Change for Patients with Elbow, Wrist or Hand Impairments (Collection Type: MIPS CQMs Specifications) **(!!) Q478:** Functional Status Change for Patients with Neck Impairments (Collection Type: MIPS CQMs Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(+)(!!)(#) MSK6:** Patients Suffering From a Neck Injury who Improve Pain (Collection Type: QCDR) **(+)(!!)(#) MSK7:** Patients Suffering From an Upper Extremity Injury who Improve Pain (Collection Type: QCDR) **(+)(!!)(#) MSK8:** Patients Suffering From a Back Injury who Improve Pain (Collection Type: QCDR) **(+)(!!)(#) MSK9:** Patients Suffering From a Lower Extremity Injury who Improve Pain (Collection Type: QCDR)	improvements for practice/process improvements (Medium) **IA_CC_12:** Care coordination agreements that promote improvements in patient tracking across settings (Medium) **IA_EPA_2:** Use of telehealth services that expand practice access (Medium) **(~) IA_EPA_3:** Collection and use of patient experience and satisfaction data on access (Medium) **(+)(*) IA_ERP_6:** COVID-19 Vaccine Achievement for Practice Staff (Medium) **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PSPA_16:** Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs (Medium) **IA_PSPA_21:** Implementation of fall screening and assessment programs (Medium)	

TABLE B.14b: Rehabilitative Support for Musculoskeletal Care MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

B.15: Value in Primary Care MVP

The B.15 tables represent the measures and activities finalized within the Value in Primary Care MVP (88 FR 80042 through 80047) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. We request comment on the proposed modifications included in this MVP.

Quality Measures

We are not proposing to modify the previously finalized Value in Primary Care MVP within the quality performance category of this MVP by proposing to add or remove quality measures from the MVP. However, we are proposing to modify the Q001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%) quality measure, which includes a proposed measure title update. Please see Appendix 1: MIPS Quality Measures, Table Group D of this proposed rule for all proposed revisions to this measure.

Improvement Activities

For the reasons stated in the introduction of this appendix[1037], we are proposing the following: add the proposed modified IA_ERP_6 to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; and add a proposed improvement activity that addresses risk for heart disease, the leading cause of death in the United States, as well as risk for stroke, which is the fifth most common cause of death. Promoting the implementation of standardized, evidence-based cardiovascular disease risk assessment and care management in the primary care setting has the potential to impact patient outcomes sizably and positively. This new activity, IA_PM_XX, is based on the results of the CMS Innovation Center Million Hearts Model:

- IA_PM_XX: Save a Million Hearts: Standardization of Approach to Screening and Treatment for Cardiovascular Disease Risk

In addition, we are proposing the following: remove the weights associated with the improvement activities contained in this MVP; and remove two improvement activities being proposed for removal from MIPS:

- IA_CC_2: Implementation of improvements that contribute to more timely communication of test results

[1037] See MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity

- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record

We are proposing to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity, which includes a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this proposed rule for all proposed revisions to this activity.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): new proposed measures and improvement activities
Single asterisk (*): existing measures and improvement activities with proposed revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component
Percent (%): attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

TABLE B.15a: Value in Primary Care MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(*)(!!) Q001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%) (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*)(!) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*)(!!) Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(!) Q305:** Initiation and Engagement of Substance Use Disorder Treatment (Collection Type: eCQM Specifications) **(!) Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CAHPS Survey Vendor) **Q438:** Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **Q475:** HIV Screening (Collection Type: eCQM Specifications) **(!!) Q483:** Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) (Collection Type: MIPS CQMs Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High) **(~) IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **(*) IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_12:** Use evidence-based decision aids to support shared decision-making (Medium) **IA_CC_13:** Practice improvements to align with OpenNotes principles (Medium) **(+)(*) IA_ERP_6:** COVID-19 Vaccine Achievement for Practice Staff (Medium) **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **IA_PM_13:** Chronic care and preventative care management for empaneled patient (Medium)	**Asthma/Chronic Obstructive Pulmonary Disease (COPD)** **Diabetes** **Depression** **Heart Failure** **Total Per Capita Cost (TPCC)**

Quality	Improvement Activities	Cost
(*) Q493: Adult Immunization Status (Collection Type: MIPS CQMs Specifications) **(*) Q497:** Preventive Care and Wellness (composite) (Collection Type: MIPS CQMs Specifications) **(!) Q504:** Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk (Collection Type: MIPS CQMs Specifications)	**IA_PM_16:** Implementation of medication management practice improvements (Medium) **(~) IA_PM_22:** Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services (Medium) **(~) IA_PM_23:** Use of Computable Guidelines and Clinical Decision Support to Improve Adherence for Cervical Cancer Screening and Management Guidelines (High) **(^)(+) IA_PM_XX:** Save a Million Hearts: Standardization of Approach to Screening and Treatment for Cardiovascular Disease Risk (High)	

TABLE B.15b: Value in Primary Care MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

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Part III

The President

Notice of July 29, 2024—Continuation of the National Emergency With Respect to Lebanon

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The President

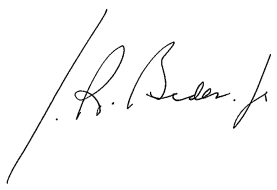
Notice of July 29, 2024

Continuation of the National Emergency With Respect to Lebanon

On August 1, 2007, by Executive Order 13441, the President declared a national emergency with respect to Lebanon pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States constituted by the actions of certain persons to undermine Lebanon's legitimate and democratically elected government or democratic institutions; to contribute to the deliberate breakdown in the rule of law in Lebanon, including through politically motivated violence and intimidation; to reassert Syrian control or contribute to Syrian interference in Lebanon; or to infringe upon or undermine Lebanese sovereignty. Such actions contribute to political and economic instability in that country and the region.

Certain ongoing activities, such as Iran's continuing arms transfers to Hizballah—which include increasingly sophisticated weapons systems—serve to undermine Lebanese sovereignty, contribute to political and economic instability in the region, and continue to constitute an unusual and extraordinary threat to the national security and foreign policy of the United States. For this reason, the national emergency declared on August 1, 2007, must continue in effect beyond August 1, 2024. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency with respect to Lebanon declared in Executive Order 13441.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
July 29, 2024.

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